Scientific Committee

Minutes of the 87th Plenary meeting

Held on 14-15 February 2018, EFSA

(Agreed on 21 March 2018)

Participants

- Scientific Committee Members:

  Tony Hardy (Chair), Diane Benford, Thorhallur Halldorsson, Mike Jeger, Helle Katrine Knutsen, Simon More, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford, Antonia Ricci, Josef Schlatter, Vittorio Silano, Roland Solecki, Dominique Turck and Maged Younes.

- European Commission: Marina Marini (DG SANTE DDG2.D.1)

- EFSA:
  - **EXECUTIVE Directorate**: Bernhard Url, Marta Hugas, Juliane Kleiner
  - **COMCO Department**: Barbara Gallani (agenda item 5.3b), Anthony Smith (agenda item 4.a)
  - **RASA Department:** Hans Verhagen
  - **REPRO Department:** Jose Tarazona (agenda item 5.3 c)
  - **SCER Unit**: Tobin Robinson, Ana Afonso, Bernard Bottex, Jean-Lou Dorne, Georges Kass, Angelo Maggiore, Daniela Maurici, Caroline Merten, Alexandre Nougadere (for agenda item 5.3 d).

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Guido Rychen (FEEDAP Panel).

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Committee Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[1] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[2], 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.

No additional interests were declared at the meeting.

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

4.a Draft EFSA Guidance on Communicating Uncertainty in Scientific Assessment (EFSA-Q-2017-00466): for information and discussion

The Scientific Committee discussed a very preliminary draft of the Guidance on Communicating Uncertainty in Scientific Assessment which is still work in progress. The main aim of the guidance is to develop practical guidance for communicators on how to communicate the outcome of the uncertainty analyses (e.g. qualitative, quantitative) described in EFSA's Uncertainty guidance and its supporting opinion (EFSA 2018a; 2018b).

The SC provided comments for revisions. It was suggested to improve clarity in relation to the scope, the target audience and the level of obligation to follow the guidance. A brief description of the target audiences and of uncertainty communication both within the context of the EFSA communication strategy and within major communication guidance documents of international organisations, should provide a better context upfront.

The aim is to present the SC with a revised draft by May 2018 to be endorsed for public and targeted consultation.

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

4.b Update on the guidance on risk assessment of chemical mixtures: for information (EFSA-Q-2017-00595)

The Scientific Committee was presented with an update on the further revisions on the guidance on risk assessment of chemical mixtures. The progress made on the draft guidance document dealing with harmonised methods for human health, animal health and ecological risk assessment of chemical mixtures was briefly presented.

The SC acknowledged the progress made on the draft guidance and provided further suggestions for additional revisions. Further explanations on the proposed tier approach are needed, in particular, on the one applied to hazard characterisation and how this relates to the step wise approach. It was highlighted that the approach proposed in the guidance needs to be practical for the panels. The component-based approach is the most applicable for mixture risk assessment. However, the whole-mixture approach will also be addressed. It was suggested to add an explanation on the complexity of the mixtures to the introduction/background part. This should include aspects on the stability of mixtures and the advice to start with a simple mixture (where all the components are characterised) since uncertainty increases with more complex mixtures. It was agreed to include aspects in the recommendation section related to aggregate non-dietary exposure and occupational health related exposure since the focus of this guidance is on dietary exposure.

A revised document will be tabled at the next SC plenary (11-12 April).

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

5.1 Feedback from the Scientific Committee and its Working Groups

5.1a Working Group on Compendium of Botanicals (version 3.0) (EFSA-Q-2012-00486

The Working Group is screening the articles retrieved for 2600 plant species and is validating the composition and toxicity/adverse effect information to be transferred to the EFSA data warehouse.

The SCER Unit received a request from the head of the NUTRI unit to provide support in relation to the implementation of the new novel food regulation (Regulation (EC) 2015/2283). A member of the SCER Unit will participate in the NUTRI Working Group on Traditional Novel Foods and help with the taxonomic identification and retrieval of information on composition and toxicity for the traditional plant-based novel foods notified to the European Commission and to be assessed for possible

safety issues by the EFSA NUTRI Unit. The Compendium of botanicals and the expertise in the SC WG on Botanicals will be used for that purpose.

5.1b Working Group on Nanotechnologies (EFSA-Q-2016-00281)

The guidance document is currently under public consultation until the first week of March. In light of the future implementation phase, it is planned to organise a technical hearing with the stakeholders. It is possible that piloting of the proposed approach will be done to make sure that the guidance developed is applicable to the extent requested.

5.1c Working Group on the Threshold of Toxicological Concern (TTC) (EFSA-Q-2017-00468)

The WG will have their next meeting on 15 February. A more extensive summary on the ongoing work will be given at the next SC plenary.

5.1d Standing WG Genotoxicity

The WG has embarked on a new self task activity (EFSA-Q-2018-00126) to develop a statement on the risk assessment of chemical mixtures. The kick off meeting was held in January.

The different areas within EFSA's remit, with different data requirements in relation to the assessment of mixtures, were presented. These include plant protection products and feed and food additives.

The SC discussed the proposed terms of reference. Starting from the basic definition of chemical mixtures as presented in the draft "Guidance on harmonised risk assessment methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals", the SC should develop a statement that:

- Clarifies the peculiarities related to the genotoxicity assessment of mixtures, i.e. identification of specific additional considerations and their triggers (cross reference to previous guidance).
- Addresses both component-based and whole mixture approaches.

5.1e Working Group MUST-B: EU Bee Partnership Discussion group & EFSA Research project on a field data collection for the calibration and evaluation of the landscape agent based simulation model APIS-RAM (EFSA-Q-2016-00358)

The EU Bee Partnership Discussion group has been set-up to establish the terms of reference for the EU Bee Partnership, aiming at collecting and sharing data on bee health in Europe. The discussion group is composed of 11 members from NGOs, food industry, practitioners, farmers associations and academia. It is coordinated by the EFSA External Relations Unit with scientific support of the EFSA Scientific Committee and Emerging Risks Unit (and chaired by EFSA) and Animal

Health Unit. It is one of the targeted platforms of EFSA's Stakeholder Engagement Approach. The first meeting was held in Brussels on 4th December 2017.

EFSA is also involved in the development of a mechanistic model (ApisRAM) to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors (Beekeeping management practices, biological agents, environmental conditions) changing in space and time. It is an individual-based model and considers different landscapes built on GIS data.

An outsourced procurement project (OC/EFSA/SCER/2017/02) has just started aimed at the collection of field data for the evaluation of the model. This activity is aligned with the specifications provided by the MUST-B working group

(http://onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2017.EN1234/pdf).

5.1f Standing Working Group on Emerging Risks (EFSA-Q-2017-00385)

The chair of the Standing WG, with the support of the EFSA Emerging risks team, gave the Committee an update of the various activities over the period November 2017 to February 2018. The Emerging Risks Exchange Network (composed of MS representatives) met on 22-23 November 2017. Seven different issues were presented and discussed at the meeting of which four were considered emerging issues according to the EFSA definition. The Stakeholders' Discussion group met on 13-14 December 2017. The renewed framework for interaction was approved in accordance with the new EFSA stakeholder's engagement approach and a call for the group membership is ongoing.

An update was given on the progress made in the outsourced procurement projects: AQUARIUS (food supply chain analysis for emerging risks identification), REACH 2 (Applying a tested procedure for identification of potential emerging chemical risks in the food chain to substances registered under REACH) and the grant agreement DEMETER (Development of methodologies and collaborative approaches in emerging risk identification process-ERI). The progress of the working group CLEFSA (Climate Change and Emerging Risks for food safety, including plant and animal health) were also summarised.

The standing working group on emerging risk (SWG – ER) is drafting an EFSA report to assist in the review of the emerging risk identification process (ERI). The WG proposal focuses on 3 areas for future development of the ERI process:

1. A food system based approach that applies resilience thinking in emerging risks identification to understand the complex interactions and dynamics that exist between actors and the drivers operating in the food system environment.

2. "Big data" and creates opportunities for emerging issues identification. The issues arising from "big data" sources are not very different from any other data source with the capacity to go from weak signals to data, from data to information and to obtain intelligence from information and knowledge.
3. Revision of the EFSA procedure for emerging risk identification to distinguish different objectives and increase transparency and accountability.

The WG proposes a series of actions to support identified future developments.

The chair of the plant health (PLH) panel informed the SC about an ongoing PLH project in which a media monitoring tool (Medisys) developed by the Joint Research Centre (JRC) is used to screen media sources to identify known and emerging plant pests. A monthly newsletter with one section on emerging issues is generated under that project. ANSES is organising a workshop on 23-24 April 2018 on plant health diseases in relation to global changes.

5.2 Feedback from the chairs of the Scientific Panels: Exchange on cross cutting activities in the panels

AHAW Panel

SIGMA data collection project: In recent years, AHAW has had a series of mandates that involve affected MS (and third countries in the case of Lumpy Skin Disease -LSD). EFSA has played a central role in data collection and analysis. This work is now being supplemented by discussions with the EC and Member States (MS) to improve data collection more broadly, particularly with respect to harmonised collection of denominator data and data from non-affected farms. Specifically, an EFSA WG and the Panel will generate an overarching EFSA Animal Disease data Model (EFSA-ADM), which will be discussed with MS during a Network meeting in Spring 2018. The EFSA-ADM will be a starting point for new data collections, in particular regarding populations of domestic animals. The project will also work together with MS to improve and automate animal health data flows.

Avian Influenza (AI) surveillance: The European reference laboratory (EURL) for AI is currently located in London. As a consequence of Brexit, some key tasks of the EURL are being transferred to EFSA, including the annual reporting on avian influenza surveillance from 2019 onwards. In the coming months, a scientific report will be developed, critically evaluating current approaches and opportunities for improvement.

ANS Panel

Re-evaluation of the safety of phosphates and polyphosphates as food additives: The new WG has started its work and the work of the NDA panel in this area is considered.

The opinion on "Evaluation of the safety of hydroxyanthracenes under article 8" was published at the end of January 2018. The news story attracted some attention particularly from the industry that is challenging the uncertainties raised in the risk assessment.

The ANS panel is dealing with many compounds that are showing effects on the microbiome, but the interpretation of such effects remains difficult, given that the microbial gut composition changes between individuals and within the same individual all the time. There seems to be a need to reflect on a possible opinion or guidance presenting the state of the art in this area and on how to deal with effects of food chemicals on the microbiome.

The chair of the PPR panel informed the SC that a discussion has also started in the PPR panel on potential effects of certain compounds on the microbiome and that the Panel is interested in being kept updated regarding any new developments in this area undertaken by the ANS panel. It was suggested by the SC to put this subject on the list for possible priority topics for discussion by the new SC that will take up duties in September 2018.

BIOHAZ Panel

The chair of the BIOHAZ Panel mentioned a proposal for a mandate for an opinion on the application and use of whole genome sequencing and metagenomics for risk assessment of foodborne pathogens. The aim is to start this activity within the first semester of this year as the panel is still awaiting the results of an outsourced project.

A scientific opinion on Listeria *monocytogenes* contamination of ready-to-eat (RTE) foods and the risk for human health in the EU was published in January 2018. Starting from the data of EU monitoring and three EFSA outsourcing activities under "Closing gaps for performing a risk assessment on L. *monocytogenes* in RTE foods" a quantitative model was employed to assess the risk posed by L. *monocytogenes* in ready to eat foods, and to evaluate underlying risk factors. The opinion underwent public consultation and was adopted in December 2017.

CEF Panel

CEF/BIOHAZ collaboration - Development multi-sectorial opinion:

The CEF Panel has recently established a joint Standing WG (SWG) with the BIOHAZ panel. The SWG has the mandate to evaluate substances used to reduce microbial contamination from products of animal origin. Paul Fowler (CEF Panel member) and Panagiotis Skandamis (BIOHAZ Panel member) have been appointed as chair and as vice chair respectively.

Two new mandates have been received from the Commission on the use of organic acids (lactic and acetic acids) to reduce microbial surface contamination from pork carcasses and cuts (EFSA-Q-2017-00666) and on the use of lactic acid to reduce microbiological surface contamination on carcasses from wild game and small stock (EFSA-Q-2017-00667).

Bisphenol A (BPA) risk assessment

The mandate for the "Re-evaluation of the risks to public health related to the presence of Bisphenol A (BPA) in foodstuffs and protocol for the risk assessment strategy" (EFSA-Q-2016-00635) involves two subsequent steps, namely the development of a scientific protocol for BPA hazard assessment, and its implementation in the re-evaluation of the safety of BPA.

The first part of the mandate has been finalised. The new protocol for BPA re-evaluation was endorsed by the CEF Panel on 30 November 2017 and published on the EFSA website on 14 December 2017.

The second part of the mandate refers to the re-evaluation of the tolerable daily intake (TDI) for BPA in foodstuffs, taking into account the results of the US NIEHS/FDA CLARITY–BPA project (Consortium Linking Academic and Regulatory Insights on BPA Toxicity) along with other new evidence not previously evaluated by EFSA (published from 2013 onwards). As yet, the results of the CLARITY–BPA Project (Core Study and Grantee studies) are not publicly available. Until then (possibly in the late summer), EFSA cannot anticipate a feasible timeline for the finalisation of the new BPA review.

In preparation for the BPA re-evaluation, as soon as all the scientific data become available, the Food Ingredients and Packaging Unit (FIP) has either planned or undertaken the following activities:

- January 2018: launch of a procurement for outsourcing part of the work foreseen by the BPA protocol, i.e. screening for relevance of all the literature on BPA published from 2013 to 2018, and extraction of data from the relevant studies;

- February 2018: launch of a public call for data in order to gather study reports and other information on BPA which are not available in the bibliographic databases or are unpublished;
- Spring 2018: set up an ad hoc CEF Panel working group (WG) of independent experts in charge of the re-evaluation of BPA's safety.

CONTAM Panel

The CONTAM Panel is using Benchmark dose (BMDL) modelling on human epidemiological data in the opinion on perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). Since there is no SC guidance on such modelling, the proposal is to use a similar approach as in previous opinions (e.g risk assessment of lead) where human epidemiological data have been applied. Of note, only aggregated data are available for the modelling approach for the on-going risk assessment.

GMO Panel

Landscape data for environmental risk assessment and monitoring: A new procurement for updating the current model is in preparation. The model will take into account landscape data and the timeline for completion of the procurement is approximately 3 years. It was clarified that links have been established with the PPR unit.

NDA Panel

The following outputs were adopted in December 2017:

- Guidance for the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health (update of the 2011 guidance);
- Three scientific opinions on heath claims: L-carnitine and normal lipid metabolism; tea flavanols and improvement of endothelium-dependent vasodilatation; NWT-02 and reduction of loss of vision; beta pyrroloquinoline quinone disodium salt, taxifolin, and L-ergo-thioneine;

Work is ongoing in the WG to prepare an opinion on the daily intake of added sugar in food. The aim is to establish a science-based cut-off value for daily exposure to added sugars from all sources which is not associated with adverse health effects. The work will be carried out following a request from Denmark, Finland, Iceland, Norway and Sweden. A technical meeting was held with stakeholders in Brussels on 13 February 2018 to discuss the methodology that will be used in the assessment of the most recent scientific evidence. The meeting had focused on the methods for i) collecting data (i.e. which data to use for the assessment and how to identify and select them), ii) appraising the relevant evidence, and iii) analysing and integrating the evidence to draw conclusions that will form the basis of the EFSA Scientific opinion

on free sugars. The scientific opinion will be developed using the final version of the protocol and will be the subject of a dedicated public consultation and technical meeting (expected last quarter 2019).

PLH Panel

The draft guidance on quantitative pest risk assessment is currently undergoing public consultation until the end of March. The aim is to have the draft guidance endorsed by the last plenary before the panel renewal in summer.

A new mandate is expected to be received by the PLH panel on risk assessment of high risk commodities. This is a cross cutting issue because generic issues are expected to arise from this mandate as it relates to risk assessment on imports. The challenge will be to develop a systems-based approach for food group commodities rather than risk assessment for individual pest species.

PPR Panel

The PPR panel discussed a first version of a draft roadmap related to the use of landscape scale risk assessment in Europe. This document reviews the current modelling capabilities and the extensions under development, and proposes an implementation strategy following short and long term timelines. The panel exchanged views on elements to develop or further consider, such as the integration of terrestrial, aquatic and residential risk mapping, the model validation, the development of regulatory scenarios and protection goals and the identification of representative focal species. The feasibility and benefits of the approach should be discussed with Member States and Risk Managers.

5.3 Feedback from EFSA

5.3a General matters arising

The Scientific Committee was provided with a document summarising relevant activities that had taken place since the last plenary meeting with focus on the activities of the EFSA Management Board, Advisory Forum (AF), interagency and international scientific cooperation and EFSA Stakeholders.

Clarifications were provided regarding the Terms of reference of the Emerging Risk Exchange Network (EREN) which were adopted at the last AF meeting in Parma.

5.3b Activities of the Communications Department

The EFSA Communication department (Communication Engagement and Cooperation - COMCO) has recently been restructured and it is now

composed of two units: the Communication unit and the Engagement and Cooperation Unit. The SC was provided with a summary overview of the department's ongoing and new activities on risk communications, stakeholder engagement and crisis communications.

5.3c Update on EFSA-ECHA guidance for the identification of endocrine disrupting properties in chemical substances proposed as pesticides and biocides in the EU

The SC was consulted on the ongoing and planned developments on the draft guidance for identifying endocrine disruptors under EU legislation for pesticides and biocides. This draft guidance, which was requested by the European Commission, has been developed by the two agencies with the support of the Commission's Joint Research Centre (JRC).

Interested parties were invited during a public consultation to comment on the draft guidance by 31 January. About 2000 comments were received. A first screening is expected to be finalised by end of February. EFSA, in collaboration with ECHA and JRC, will evaluate the comments and propose how to address them.

A workshop was held in Brussels on 1-2 February 2018 with MS experts in evaluating endocrine disruption in the regulatory context and with stakeholders. The workshop was organised by the European Commission in collaboration with EFSA and ECHA to assess the applicability of the Guidance. The outcome of the workshop will be published in the form of a summary report.

The final steps will include a consultation with risk assessment bodies such as the biocidal committee from ECHA, and the SC, the PPR panel and the pesticide network from EFSA. The targeted consultation will start on 16 April and should be closed by the end of April.

5.3d Risk Assessment Methodologies Programme (RAM-Pro)

The SC was presented with an overview of the EFSA Risk Assessment Methodologies Programme (RAM-Pro). The programme co-coordinates, steers and monitors science development projects aimed at ensuring that EFSA is prepared for present and future challenges in a dynamic food safety system, by innovating and harmonising its risk assessment methodologies. The programme currently includes 42 projects falling in three thematic areas:

- Harmonisation of risk assessment methodologies;
- New methodologies in risk assessment of chemicals for human health;
- New methodologies in environmental risk assessment of chemicals.

The programme is aimed at a better prioritisation for follow up projects, a maximisation of the benefits by a systematic analysis and management of risks of the individual projects and to increase the

opportunities to identify synergies among projects.

The SC welcomed the presentation and highlighted that the aim of the program is to be prepared for future risk assessment challenges. In addition, it was clarified that the programme will also include projects in the area of microbiological risk assessment.

5.4 Public Consultation on the transparency and sustainability of the EU risk assessment in the food chain

The SC was presented with the background of the current EC initiative on the transparency and sustainability of the EU risk assessment model in the food chain and related ongoing public consultation (PC) managed by DG SANTE.

The following objectives were targeted by the initiative:

- Improve and clarify the rules on transparency (scientific studies supporting risk assessment);
- Increased reliability, objectivity and independence of studies used by EFSA in its risk assessment (mainly authorisation dossiers);
- Improve governance and strengthen the scientific cooperation and more involvement of Member States in EFSA;
- Address the limitations affecting the long term scientific capacity of EFSA and its ability to maintain a high level of scientific expertise;
- Develop a more effective and transparent risk communication with the public, in collaboration with Member States;

DG SANTE therefore launched a public consultation on the transparency and sustainability of the EU risk assessment in the food chain on 23 January. The consultation is aimed at all stakeholders and at EU and non-EU citizens and will end on 20 March 2018.

The public consultation contains fifty questions. DG SANTE aimed to inform the SC about this consultation and invited the experts to answer as individuals or as representatives of their national institutions. It was clarified that no common view will be gathered from the SC. Furthermore, it was clarified that MS will also be consulted and individual meetings with various stakeholders will be held.

6. Any other business

– Update on the 3rd EFSA Scientific Conference (September 2018)

The EFSA Conference on Science, Food & Society will be organised in Parma from 18-21 September 2018. The conference is constructed

around the motto "contextualising risk assessment". This means reflecting on the future of risk assessment in food safety while acknowledging the social and political context within which it operates. Researchers, risk assessors, social scientists, risk managers and stakeholders from all over the world will gather to discuss issues around the complex interplay between science, food and society. The conference will be web streamed and is targeting to attract around 700 participants. Registration is open and will be accepted until the maximum venue capacity is reached, and in any case no later than 30 June 2018.

- SC Open Plenary, 11-12 April

The SC was reminded that the next plenary will be a meeting open to observers and will therefore be web streamed.

- Colloquium on "OMICS in risk assessment", 24-25 April 2018

EFSA's 24th Scientific Colloquium on "OMICS in risk assessment: state-of-the-art and next steps" will take place in Berlin, Germany. It will explore the opportunities for integration of datasets produced via specific "OMICS" tools within the remit of EFSA's risk assessment approaches. It is co-organised by the EFSA SCER and GMO units.

Discussions will focus on genomics in microbial strain characterisation, metabolomics for the comparative assessment of GM plants and the use of OMICS for toxicological and environmental risk assessment.

The SC was reminded that the registration deadline for the colloquium is 12 March.

END OF MEETING