

Scientific Committee Minutes of the 86th Plenary meeting

Held on 15-16 November 2017

Grand Hotel de la Ville, Parma, Italy

(Agreed on 12 December 2017)

Participants

■ Scientific Committee Members:

Tony Hardy (Chair), Diane Benford, Susanne Hougaard Bennekou, Thorhallur Halldorsson, Mike Jeger (day 2 only), Huw Jones, Helle Katrine Knutsen, Simon More, Hubert Noteborn, Antonia Ricci (day 1 only), Guido Rychen, Josef Schlatter, Vittorio Silano, Dominique Turck (day 1 only) and Maged Younes.

■ Hearing experts¹:

Alijca Mortensen (agenda item 4a only), Andy Hart (agenda items 4d and 4e only)

■ European Commission: Marina Marini

■ EFSA:

- **EXECUTIVE Directorate:** Bernhard Url (day 2 only), Marta Hugas (day 1 only), Juliane Kleiner
- **RASA Department:** Hans Verhagen
- **REPRO Department:** Guilhem de Seze, Jose Tarazona (agenda item 6 only)
- **BuS Department:** Simone Gabbi (agenda item 5.3b)
- **SCER Unit:** Tobin Robinson, Bernard Bottex, Jean-Lou Dorne, Nikolaos Georgiadis, Tilemachos Goumperis, Melpo Karamitrou, Georges Kass, Angelo Maggiore, Daniela Maurici, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans.

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hanspeter Naegeli (GMO Panel) and from Colin Ockleford (PPR Panel). They were substituted by Huw Jones and Susanne Hougaard Bennekou, respectively. Apologies were also received from Roland Solecki.

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 Processes² and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests³, 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4.a Draft guidance on risk assessment of nanomaterial ([EFSA-Q-2016-00281](#)): for discussion and endorsement for public consultation

The Scientific Committee was informed about the changes made in the draft text after the first reading during the September plenary meeting. More comments were tabled and addressed during this meeting. Some comments were scheduled for further follow up with specific members of the SC and will be addressed in the coming weeks. The document was endorsed for public consultation. It will be launched in January 2018 until the end of February 2018.

4.b Draft opinion on genotoxicity assessment: for discussion and possible adoption ([EFSA-Q-2017-00112](#))

The Scientific Committee was presented with the draft opinion on "Clarification of some aspects related to genotoxicity assessment". The chair of the WG, Josef Schlatter, presented the last version of the document following the public consultation which lasted from 24 July to

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

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

6 September 2017. He highlighted the main comments received, the way they were addressed and the consequent amendments that were made to the opinion.

The SC welcomed the efforts of the WG and adopted the scientific opinion. The opinion will be published at the beginning of December and the report summarising the comments received during the public consultation will then be published by the end of the year.

4.c Preliminary draft opinion on risk assessment of chemical mixtures ([EFSA-Q-2017-00595](#))

The draft opinion on “Harmonisation of methods for human and ecological risk assessment of combined exposure to multiple chemicals” was presented to the SC by the secretariat with particular attention to the current structure, step wise approaches and the associated schematics for each step of the risk assessment process. A discussion followed where members of the SC commented on the current draft and requests for a clear definition of mixtures upfront as well as for simplifications of the document to avoid duplications and harmonise terminology. The members also commented that detailed descriptions of tools used for single chemicals were not necessary and that annexes could also be shortened. A revised version of the guidance document will be presented at the next plenary in 2018.

4.d Draft opinion on Principles and methods behind EFSA’s Guidance on Uncertainty Analysis in Scientific Assessment (supporting document of the guidance document): for discussion and possible adoption ([EFSA-Q-2017-00695](#))

The draft opinion had been revised by addressing the feedback received at the EFSA workshop (22-23 June 2017) on the trial phase on uncertainty. The former guidance document, which was used for the trial phase, had been revised into a supporting opinion on the principles and methods behind EFSA’s Guidance on Uncertainty Analysis in Scientific Assessment. It will serve as a textbook for reference. The main revisions in the document were briefly introduced.

The SC adopted the draft opinion that will be published at the beginning of January.

4.e Draft EFSA Guidance on Uncertainty Analysis in Scientific Assessment (new concise guidance): for discussion ([EFSA-Q-2013-00738](#))

Another need identified at the EFSA workshop on the trial phase on uncertainty on 22-23 June 2017 was to have a concise and practical Guidance on Uncertainty Analysis. Hence, a short and more user-friendly guidance was developed by the WG uncertainty which contains flow charts with clear step by step guidance with separate sections for the main types of assessment, regulated products/standardised procedures, case-specific quantitative assessments, case-specific qualitative assessments, emergency assessments and development/revision of guidance documents.

The SC adopted the draft opinion after having provided some suggestions for final revisions. The guidance will be published at the beginning of January.

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 busy validating the data retrieved by the Contractor to further develop the EFSA Compendium of botanicals containing naturally occurring substances of possible concern for human health. Around 2,000 plant species and 1,500 substances / chemical groups of possible concern will be added to the database. The work should be finalised by the end of 2018.

5.1b Standing Working Group on BMD

The Standing Working Group on Benchmark Dose was established to provide support for the application of the BMD approach to the different panels. The first request was from the CONTAM Panel to review whether the BMD analysis performed for the update of the risk assessment on 3-monochloropropane diol and its fatty acid esters has been done according to the revised SC guidance published in 2017 on the use of the benchmark dose approach in risk assessment. A number of suggestions for clarification were sent for the consideration of the CONTAM Panel on 14 November 2017.

5.1c Working Group MUST-B ([EFSA-Q-2016-00358](#))

The mechanistic model to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors is under development. An automated procedure for generating model landscapes, the methodology to perform the search and screening of the scientific literature and a list of variables, parameters and processes relevant for modelling were received by the contractor.

The open call for a procurement procedure on the field data collection to calibrate and evaluate the model was closed on 30 October 2017. The evaluation of the offers is now in progress. The project will have a duration of 3 years (2018-2020).

Following up on the Scientific Symposium organised by EFSA and EPBA (European Professional Beekeepers Association), ECPA (European Crop Protection Association), COPA-COGECA (European farmers and agri-cooperatives) and BeeLife (European Beekeeping association) in June 2017 at EP Bee Week Event, EFSA set up a "Bee Stakeholder Discussion Group". The call for expressions of interest was published on the EFSA website in September and the composition of the group was finalised in October.

The objective is to draft the Terms of Reference of an EU Bee Partnership to strengthen collaboration among stakeholders and promote harmonised data collection and sharing on bee health in the EU. The Terms of Reference will be presented to the European Parliament at the Bee Week event in June 2018.

5.1d Standing Working Group on Emerging Risks ([EFSA-Q-2017-00385](#))

The Standing Working Group on Emerging risks, chaired by Hub Noteborn, provides scientific and methodological support, from the preparation of grants and procurement calls to following up projects and evaluation of reports. Among these projects, the chair mentioned AQUARIUS (use of food supply chain analysis for identification of emerging risks), REACH 2 (prioritization of possible chemical emerging risks) and DEMETER (metrics and methods for emerging risks identification).

The group is also developing a technical report reviewing EFSA activities and formulating recommendations for future work on emerging risks.

It is also involved in the preparation of an EU wide web survey on emerging risks communication. The survey explores consumer views about a range of food topics like new consumer trends, new technologies and food fraud.

An effort to integrate data and methodologies from social sciences into the emerging risk identification process on a farm-to-fork approach is being conducted.

A paper has been submitted for the proceedings of the European Safety, Reliability and Data Association (ESReDA) conference "Enhancing Safety: the Challenge of Foresight", held on 14 and 15 November at the Joint Research Centre (DG JRC) in Ispra. The paper was entitled "Emerging Risks in food and feed, the importance of foresight". It will also be presented at the next Emerging Risks Exchange Network Meeting which will be held on 23rd November in Lisbon.

The 2016 report on EFSA's Activities on Emerging Risks is now publicly available in the EFSA website (<http://www.efsa.europa.eu/en/supporting/pub/1336e>). The report summarizes the activities of all groups involved in the Emerging Risks Identification process, the issues identified in the course of 2016, a description of the methodologies being developed and collaboration activities carried out.

5.1e Working Group on the Threshold of Toxicological Concern (TTC) ([EFSA-Q-2017-00468](#))

The first meeting of the Working Group on TTC took place on 7-8 November. The mandate and terms of reference for a Guidance on the TTC approach were discussed. It was proposed to produce a single document containing a guidance backed up by an update of the 2012 SC opinion on "Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern" (<https://www.efsa.europa.eu/en/efsajournal/pub/2750>). The update of the latter will consider the recommendations of the EFSA-WHO workshop published in 2016 and reported in the "Review of the TTC approach and development of new TTC decision tree" (<https://www.efsa.europa.eu/en/supporting/pub/1006e>) and scientific papers published since. The next WG meeting will take place on 15 and 16 February 2018.

5.1f Working Group on RASFF on chemical contaminants ([EFSA-Q-2017-00664](#))

EFSA was mandated by the European Commission to provide technical assistance for the development of guidance on risk evaluation for chemical contaminants to classify RASFF (Rapid Alert System for Food and Feed) notifications. The EFSA Working Group that was established to work on this mandate consisted of external experts and EFSA staff and delivered the first work package on hazard characterisation based on toxicological information available for chemical contaminants in food.

Associated data sources of toxicological information were also provided. The working group is now working on the second work package on estimating exposure. A report summarising the outcomes of the second work package will be delivered by April 2018 and will include information on an IT tool expected to be available by March 2019.

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

AHAW Panel

In recent years, the panel has had a series of mandates on animal diseases threatening the European Union, like African Swine Fever, Lumpy Skin Disease and Avian Influenza, that involve affected Member States (and third countries in the case of Lumpy Skin Disease). EFSA has played a central role in data collection and analysis. This work is now being supplemented by discussions with the European Commission and Member States to improve data collection, particularly with respect to harmonising it across Member States and including additional data (about non-affected herds and about the overall population).

BIOHAZ

A joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals was published on 26 October 2017 (<http://www.efsa.europa.eu/en/efsajournal/pub/5017>). The opinion will give tools to monitor the progress of the EU and national action plans in reducing antimicrobial resistance.

A self-task will start next year for developing an opinion on the application and use of whole genome sequencing and metagenomics for risk assessment of foodborne pathogens. This activity is relevant also for the GMO and FEEDAP Panels.

CEF Panel

The development of a BPA risk assessment protocol is ongoing. The aim is to develop, together with Member States' experts, a harmonised evaluation procedure. A stakeholders meeting took place on 14 September. The meeting was very successful and a large consensus was achieved and concluded in two weeks' time. The protocol will be further discussed at the next open plenary of the CEF Panel (29-30 November 2017), together with the report on the public consultation.

An *ad hoc* working group on the review of three opinions on phthalates for use in food contact materials, which were published in 2005, has been established. This follows a request from the EC to update the risk assessment of three phthalates for use in food contact materials based on an opinion of the Risk Assessment Committee of ECHA proposing an amendment to Annex XVII to REACH.

Another *ad hoc* working group has been established to evaluate the chemical substances used to remove microbial surface contamination from products of animal origin. Issues related to the environmental risk due to the use of such substances will be considered. The BIOHAZ Panel will be involved for the evaluation of the efficacy and resistance to therapeutic antimicrobials.

CONTAM Panel

EFSA has received a request to assess health effects of aflatoxins and potential change of maximum levels in peanuts. The assessment will focus on exposure and the use of different cut-off levels. It will be discussed at the next plenary on 23-25 January 2018 and finalised by February 2018.

The opinion on the health risks related to the presence of Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) in food will be presented for possible adoption at the next 87th plenary meeting (21-23 November 2017).

FEEDAP Panel

The public consultation on the draft guidance document on the characterisation of microorganisms used as feed additives or as production organisms was closed on 15 September 2017 and the panel is working on the final version of the document considering the comments received.

The opinion on the use of saccharin sodium as a flavouring is scheduled for re-evaluation in 2020.

The guidance on the assessment of the safety of feed additives for the environment will be presented to the FEEDAP Panel in the Plenary meeting of 28-30 November 2017 for a first discussion. There are no cross cutting issues with other units/panels. The draft guidance is planned to be endorsed by the FEEDAP Panel in February 2018. An open consultation will follow and the new guidance is planned to be adopted at the FEEDAP Plenary of June 2018.

GMO Panel

A new working group has been established to address an EC mandate on the assessment of Next Generation Sequencing (NGS) data and their potential use in the risk assessment of GMOs, in cooperation with the JRC. A Guidance for applicants on the use of NGS data will be developed and completed in the summer of next year.

NDA Panel

The summary report on Dietary Reference Values (DRVs) for nutrients has been published on the EFSA website at the end of September (https://www.efsa.europa.eu/sites/default/files/2017_09_DRVs_summary_report.pdf). It summarises the opinions published by EFSA over 7 years (covering water, fats, carbohydrates and dietary fibre, protein, vitamins and minerals).

The NDA Panel and the Nutrition Unit have participated in a workshop organised by the US National Academies of Sciences, Engineering, and Medicine. It was held on 21-22 September 2017 in Rome. The aim of the workshop was to explore issues related to harmonisation of methodological approaches to nutrient intake recommendations.

On 8-9 November, the first meeting of the EFSA Scientific Network on Novel Foods was held. The safety assessment of Novel Foods' applications and Traditional Foods' notifications was discussed in the light of the new Regulation 2015/2283 on novel foods, amending Regulation (EU) No 1169/2011.

PPR Panel

The Scientific Opinion on the follow-up of the findings of the External Scientific Report 'Literature review of epidemiological studies linking exposure to pesticides and health effects' was published on 31 October 2017.

Most relevant associations were found between pesticide exposure and liver cancer, breast cancer, stomach cancer, amyotrophic lateral sclerosis, asthma, type II diabetes, childhood leukaemia and Parkinson's disease.

The opinion includes a discussion on how to use epidemiological data in risk assessment and how to integrate this information with data from adverse outcome pathways and mechanisms of action.

A scientific conference on the use of epidemiological findings in regulatory pesticide risk assessment is scheduled to take place at EFSA on 21 November 2017.

In the previous plenary (20-21 September 2017), the panel discussed the Scientific Opinion addressing the state of the science on risk assessment for amphibians and reptiles. It is scheduled for possible adoption at the next plenary meeting.

The Scientific Opinion on the state of Toxicokinetic/Toxicodynamic (TK/TD) models for regulatory risk assessment of pesticides for aquatic organisms is under development. The Working group on TK-TD and simple food chain models for aquatic organisms meet on 13-15 November 2017. The draft opinion will undergo consultation of the Pesticide Steering Network, most probably in February 2018. The finalisation and adoption is foreseen by July 2018.

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, interagency and international scientific cooperation and EFSA Stakeholder Meetings.

5.3b New rules on independence

In June 2017, the EFSA Management Board adopted a new Policy on Independence. The changes to the previous policy are based on EFSA's experience on managing interests as well as input received from stakeholders, including the European Parliament and the general public.

The changes are primarily in the areas of:

- Definition of conflict of interest;
- Risk based approach for competing interest management;
- Cooperation with EFSA's partners;
- Cooling-off periods;
- Transparency;
- Enforcement for breaches of the independence rules.

In particular, EFSA identifies earnings from entities with an interest in EFSA's activities to be a main driver for conflict of interest. The new screening approach introduces therefore different restrictions depending on the expert's proportion of the annual earnings originating from such entities. Employment with food industry is considered incompatible with

any involvement at EFSA for two years after it ended. Furthermore, two years cooling off criteria leading to more straightforward conclusions are applied to professional engagements with private entities that overlap with the mandate of the scientific group.

Among the transparency measures, a register of activities of Management Board members after they fulfil their mandate with EFSA and the list of EFSA's partner organisations will be published on the EFSA's website.

The rules applicable to (hearing) experts and observers (including staff of Union institutions, bodies or agencies), Network Members, members of EFSA's Governance bodies, tenderers and participants in EFSA's procurement and grant awarding procedures are detailed and publicly available (https://www.efsa.europa.eu/en/corporate/pub/independence_policy17).

The new policy shall be applicable as of 1 December 2017 for experts applying for the EFSA's panels. For all other concerned individuals, it shall apply as of 1 July 2018.

5.3c Draft implementation plan for the Uncertainty Guidance

The Draft implementation plan was shared for information with the Scientific Committee but no further comments were received.

6 Any other business

- Update on the EFSA-ECHA endocrine guidance

The SC was provided with an overview on the guidance document for the Implementation of the Hazard-based Criteria to Identify Endocrine Disruptors. This guidance is being jointly developed by EFSA and ECHA (European Chemicals Agency). Because of the common scientific principles, it will be applicable to pesticides and biocides and can be relevant for other chemicals as well.

A scoping paper was published on the EFSA website last December 2016.

The public consultation of the draft document will start in December 2017.

- Guidance lifecycle: review of current guidance documents before panel renewal

The panel chairs were reminded to table, in one of the upcoming plenary meetings, a review of the sectoral guidance document in use in their respective panels. This will allow planning of possible revisions of guidance documents before the new panels enter into force. The planned revisions will then be carefully discussed with the new panels

and work scheduled during the next mandate of the respective panel. This is part of the guidance lifecycle implemented in EFSA to make sure that every panel is aware of the key cross-cutting and sectoral guidance documents in use in EFSA and that the documents are kept up to date.

- SC Open plenaries 2018

The SC discussed possible dates for open plenary meetings in 2018. As for the SC, the open plenaries will be held on 11-12 April and on 21-22 November 2018. The full list will be shortly published on the EFSA website (please click [here](#)).

END OF MEETING