# Scientific Committee

## Minutes of the 91st Plenary meeting

**Held on 21 November 2018, 9.00 – 18.45h**
**22 November 2018, 9.00 – 13.00h**

**(Meeting open to Observers)**

**(Agreed on 11 December 2018)**

**Participants**

- Scientific Committee Members:

  Simon More (Chair), Vasileios Bampidis, Diane Benford, Claude Bragard, Tamas Dalmay, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Susanne Hougaard Bennekou, Kostas Koutsoumanis, Søren Saxmose Nielsen, Josef Schlatter, Vittorio Silano, Dominique Turck and Maged Younes.

- Hearing experts[1]: Christer Hogstrand (agenda item 6.1), Laura Maxim (agenda item 6.4)
- European Commission: Marina Marini (DG SANTE DDG2.D.1)
- EFSA:
  - **EXECUTIVE Directorate**: Bernhard Url[§], Marta Hugas, Hans Verhagen*
  - **RASA Department:** Juliane Kleiner°
  - **REPRO Department:** Guilhem de Seze°
  - **COMCO Departement:** Barbara Gallani, Domagoj Vrbos Anthony Smith (agenda item 6.4 and 8.2b)
  - **SCER Unit**: Tobin Robinson°, Ana Afonso*, Bernard Bottex, Jean-Lou Dorne, Andrea Gervelmeyer, Georges Kass, Djien Liem, Angelo Maggiore, Daniela Maurici, Caroline Merten, Alexandre Nougadère, Reinhilde Schoonjans.
  - **BIOCONTAM Unit**: Marco Binaglia

§ Only for the opening and agenda item 6.1

*Only day 2

°only for some agenda items

[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. Opening and apologies for absence

Simon More welcomed the participants. Apologies were received from Hanspeter Naegeli, chair of the GMO panel (replaced by Tamas Dalmay); Dieter Schrenk, chair of the CONTAM panel; Claude Bragard, chair of the Plant Health panel; Jos Boesten

## 2. Adoption of the draft agenda

The agenda was adopted without changes.

## 3. Brief introduction Scientific Committee members and observers present in the room

All participants were briefly introduced. The chair explained the primary areas of activity and composition of the Scientific Committee.

## 4. Declarations of Interest of Scientific Committee Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[3], 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.

## 5. Presentation of Guidelines for observers

The observers were reminded about the code of conduct before, during and after the meeting.

The chair suggested opening the floor for discussion with the observers at the end of each substantive item during the course of the meeting.

## 6. Scientific outputs submitted for discussion and/or possible adoption

### 6.1 Draft guidance on chemical mixtures: outcome of the public consultation and possible next steps (EFSA-Q-2017-00595)

The Scientific Committee provided feedback and comments on the guidance document on "Harmonised framework for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals", which has been subject to public consultation (29 June - 15 September) and amended after consideration of comments from relevant stakeholders. The draft was welcomed as a useful document providing a review of methods for risk assessment of combined exposure to multiple chemicals.

The Scientific Committee suggested clarifications in relation to the terminology used in the guidance, on the characterisation of composition of mixtures, on the grouping criteria. The inclusion of more examples to illustrate the applicability of the guidance document was also suggested.

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

Plans for future work, including a short guidance for each area (human, animal and ecological) were also discussed. The finalised document will be presented for adoption at the next plenary 19-20-21 February 2019, when the finalised report of the public consultation will also be presented.

### 6.2 Draft statement on genotoxicity assessment of chemical mixtures (EFSA-Q-2018-00126)

The Scientific Committee was presented with the final draft of the statement on genotoxicity assessment of chemical mixtures. The document was adopted without changes. The Scientific Committee congratulated the chair and the WG for the excellent work done. The statement will be published together with the report of the public consultation by the end of 2018.

### 6.4 Draft guidance on communication of uncertainty in scientific assessments (EFSA-Q-2017-00466)

The Scientific Committee was presented with a revised draft of the EFSA guidance on communication of uncertainty in scientific assessment. The document provides guidance for communicators on how to communicate the various expressions of uncertainty described in EFSA's document: "Guidance on uncertainty analysis in scientific assessments" published in 2018 (link here). It also contains specific guidance for assessors on how best to report the various expressions of uncertainty. A previous draft went through a public consultation between 4 May and 24 June 2018. 212 comments from 24 participants were submitted during that process. The WG screened the comments and addressed all the relevant ones by revising the guidance document. All comments received during the public consultation and how they have been addressed are presented in the EFSA technical report that will be published together with the guidance early in 2019. It was noted that the document benefitted from advice of social science experts.
The SC endorsed the EFSA guidance for publication.

## 7 New Mandates

### 7.1 EC mandate on Synthetic Biology

The EC requests EFSA to determine whether the existing guidelines for risk assessment are adequate and sufficient for current and near future Synthetic Biology (SynBio) developments for agri-food uses, meaning agri/food/feed products falling within the remit of EFSA. The deadline set by the Commission for EFSA scientific opinions is March 2020. The following two opinions will be delivered:

(1) An opinion on the adequacy of the guidance for Category 4 genetically modified micro-organisms (GMMs) for molecular characterisation and environmental aspects, and

(2) An opinion on the adequacy of the guidance for environmental risk assessment of GM plants, including molecular characterisation.

The first opinion is of overarching nature and will be prepared by a working group under the Scientific Committee. The SC agreed with the proposed chair, Pier Sandro Cocconcelli, member of the CEP panel. The expertise required to deliver the mandate has also been briefly presented and discussed: molecular characterisation, SynBio techniques and environmental risk assessment.

### 7.2 Self task mandate on interpretation of epidemiological studies

This new self-task activity intends to address the needs expressed by the Scientific Committee in its reports of 2013[4] and 2016[5]. A presentation of the self-task was given with the aim to define the scope of the guidance document. In the ensuing plenary discussions, the Scientific Committee members expressed the view that the document should focus on the appraisal and integration of epidemiological studies and their application in risk assessment. It should cover all types of epidemiological studies, i.e. descriptive and analytical epidemiological studies and studies targeting animals, plants and the environment, as well as humans. Equally, the field of nutrition and both chemical hazard and biological hazard studies should be included in the guidance.

The importance of the guidance being applicable by all panels was underlined, and that it should facilitate a harmonised appraisal of epidemiological evidence, taking into considerations methodological differences between human, animal and plant epidemiology. The guidance should therefore include specific sections illustrating how to appraise epidemiological evidence for the different scientific areas of activities of EFSA's panels.

The proposed structure of the opinion with a short introductory section with definitions of the principles of evidence appraisal, followed by a section explaining the appraisal of different epidemiological evidence in EFSA scientific assessments, and finally a section with considerations of appraisal and use of epidemiological evidence for specific scientific assessment questions of the different EFSA Panels, was welcomed. It was agreed that the Terms of Reference and a table of content of the guidance document should be presented at the next Scientific Committee Plenary meeting for final agreement.

This activity is expected to last two years. The need to establish a new WG for this task was identified, and it was agreed that Thor Halldorsson, member of the SC, will chair the WG.

### 7.3 Self task on non-monotonic dose response

This activity, already presented and discussed with the former Scientific Committee, is intended to follow up on the statistical analysis made in 2016[6] on studies claiming non-monotonic dose responses. A WG will be established to consider the biological plausibility for such response for the endpoints considered.

The Scientific Committee underlined the importance of this exercise for apical endpoints in *in-vivo* studies. The report of this review exercise will then be considered by the Scientific Committee to determine whether there is a need to adapt methodological guidance documents used by EFSA for its assessments to better take into account this type of dose-response.

This activity is expected to last 9 months. Maged Younes, chair of the FAF Panel, will chair the WG.

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

[5] EFSA Scientific Committee, 2016. Scientific opinion on priority topics for the development of risk assessment guidance by EFSA's Scientific Committee in 2016–2018. EFSA Journal 2016;14(6):4502, 9 pp. doi:10.2903/j.efsa.2016.4502

[6] See https://www.efsa.europa.eu/en/press/news/160503

## 8 Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

### 8.1 Confirmation of existing Scientific Committee Working groups (WGs)

**Cross-cutting WG Genotoxicity**

The Scientific Committee was invited to re-establish the cross-cutting WG on Genotoxicity. The WG assists EFSA Units and Panels upon request when there are diverging views on genotoxicity data interpretation by different panels. It also provides views for the implementation of the guidance on genotoxicity testing strategies.
In addition, at the last plenary meeting, the Scientific Committee was presented with a request from the Unit on Food Ingredients and Packaging (FIP Unit) in relation to the cross-cutting issue of assessment of aneugenicity.
As the evaluation of possible aneugenicity of substances is a cross-cutting issue relevant to several Panels, the Scientific Committee agreed to prepare a statement clarifying the issue of aneugenicity assessment.
Preparatory work should be done by the cross-cutting WG genotoxicity. This activity will start in December 2018 and be concluded hopefully by end of 2019.

The WG is established for the whole duration of the mandate of this Scientific Committee, 2018-2021. Diane Benford, member of the SC, was nominated as chair of the WG genotoxicity.

**Cross-cutting WG Benchmark dose**

The Scientific Committee was invited to re-establish the cross-cutting Working Group on Benchmark Dose. The WG assists EFSA Units and Panels upon request, when encountering a difficulty for applying the benchmark dose approach for their assessments. A second task of the working group is to monitor methodological developments outside EFSA (e.g. Bayesian Benchmark Dose modelling), and eventually update the EFSA guidance document and BMD Platform so that the approach is used consistently within EFSA but also in a harmonised way between EFSA and its Partners (e.g. other agencies, Member States Competent Authorities, US EPA, WHO JECFA).

The WG is established for the whole duration of the mandate of this Scientific Committee. Josef Schlatter was re-confirmed as Chair of the WG.

**WG Botanicals**

The Scientific Committee was invited to confirm this ongoing work. The WG is currently expanding the information of the EFSA Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health. 1000 plants are ready to be transferred to the EFSA data warehouse and added to the 900 already existing ones. 800 plants are still to be validated by the end of 2019.

A second task of the WG is to assist the EFSA NDA Panel and NUTRI Unit with the assessment of the plant-based novel or traditional foods. The WG is retrieving the information in the compendium to do the hazard identification (identification of problematic substances, toxicity/genotoxicity/allergenicity information, case reports of adverse effects) for the product considered. This information is then forwarded to the

NDA WG on Novel Foods or the NUTRI WG on Traditional Foods to finalise the assessment.

This WG has a mandate until end of 2019. Vittorio Silano, chair of the CEP panel, was confirmed as Chair of the WG.

**WG Threshold of Toxicological Concern (TTC)**

The Scientific Committee was invited to confirm this ongoing working group whose task is to develop guidance for the use of the Threshold of Toxicological Concern (TTC) approach in food safety assessment. The draft guidance is currently under public consultation following endorsement at the 90th Plenary of the Scientific Committee. The consultation will close on 8th January 2019. Heather Wallace, vice chair of the CONTAM panel, was confirmed as Chair of the WG.

**WG Multiple Stressors in Bees (MUST-B)**

The MUST-B project (EFSA-Q-2016-00358) aims to evaluate the impact of multiple biological, chemical and environmental stressors on honeybees colonies by developing a holistic approach for the assessment of the risk. The WG is involved in the activities related to the development of the ApisRAM mechanistic model, honeybee data collection project and EU Bee Partnership. In July 2018, EFSA has received a mandate from the European Parliament for a scientific opinion on the science behind the development of an integrated holistic approach for the risk assessment of multiple stressors in managed honeybees (*Apis Mellifera*). The MUST-B WG will therefore be involved also in the development of this opinion, scheduled to be delivered by December 2020. Simon More, chair of the SC, was confirmed as chair of the WG.

**WG Chemical mixtures**

The Scientific Committee was invited to confirm this ongoing working group with the current chair Christer Hogstrand, member of the CONTAM panel. The WG is currently finalising the guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals which will be presented for adoption at the February plenary 2019.

## 8.2 Feedback from EFSA, including its Working Groups

### General matters arising

**a.** Work programme of the SC 2018-2021

The work-programme of the Scientific Committee was presented. The ongoing WGs were confirmed. For new mandates, the need for new WGs was discussed and agreed (see also agenda item 7 and 8).

The existing network activities were also illustrated (Network for Risk Assessment of the use of Nanotechnologies in food and feed – NANO Network, Emerging Risks Network- EREN, Stakeholder Discussion group on Emerging Risks - StaDG-ER, CLimate change and Emerging risks for Food Safety - CLEFSA, International Liaison Group on MEthods for Risk Assessment of Chemicals in food - ILMERAC).

**b.** Communication, Engagement and Cooperation: overview of the activities and social science roadmap

The Scientific Committee was presented with an overview of the communication, engagement and cooperation activities of the EFSA department of communication. The guiding principles to communicate to the various EFSA target audiences are defined in a number of outputs: including: handbook on "When food is cooking up a storm" (link here), "How to communicate during a food crisis" (link here), "Social media guidelines" and "Guidance document on how to communicate on uncertainty", the latter presented today at this meeting. Further the road-map on social science related work was presented to the SC.

The Scientific Committee discussed the challenges arising from different risk perceptions and post truth concepts on EFSA communication. The aim will be to be more systematic about understanding the needs of different target audience and the impact that EFSA's communication is aiming at. Also a better coordination of communication with other national and international players needs to be ensured. Citizens want to better understand the context around the risk assessment and how it is done. EFSA need to better contextualise its risk assessment work and become more trustworthy. Training on risk communication for risk assessors would also be welcomed. The new guidance on how to communicate on uncertainty contains also some guidance for risk assessors. Discrepancy between national and EFSA's risk assessment conclusions are dealt with by Art. 30 of the general food law (Regulation 178/2002).

The Scientific Committee was reminded about EFSA's role to communicate on crisis situations and on emerging issues. In both situations the need to communicate on related uncertainties is heightened. The Scientific Committee appreciated the presentation on EFSA's social science work and expressed interest in future updates as the roadmap evolves.

**c.** Crisis response and preparedness

The Scientific Committee was provided with an overview of EFSA legal obligation[7] to provide scientific and technical assistance support management of crisis or incidents in the areas of food safety or other areas under EFSA remit. Such requests are particularly challenging due to short timelines and high levels of uncertainty due to scarceness of data and knowledge. EFSA has established procedures for urgent response[8] and training that aims at improving crisis preparedness and focus on the various aspects of providing scientific advice such as data collection and collaboration between stakeholders. EFSA procedures, training strategy[9] and reports of previous trainings including training material[10] are available on line.

**d.** New EFSA Working Groups (WGs) on cross-cutting guidance implementation

[7] https://ec.europa.eu/food/safety/biosafety/crisis_preparedness_en
[8] https://www.efsa.europa.eu/en/supporting/pub/en-1228
[9] https://www.efsa.europa.eu/en/supporting/pub/en-1279
[10] https://zenodo.org/record/1419169#.XAE8mFVKiJA

**WG Uncertainty**

EFSA has established a cross-cutting WG on uncertainty in scientific assessment (cross-cutting WG uncertainty) to support the implementation of the Scientific Committee (SC) guidance on Uncertainty in EFSA's scientific assessments (published in early 2018, link here).

The objective of this WG is to support EFSA panels and units and, in particular, those from the Risk Assessment and Scientific Assistance (RASA) department in implementing the EFSA guidance on uncertainty by:

(i) Providing scientific advice and support to ad hoc requests on how to apply the uncertainty guidance document across the various EFSA opinions, guidance documents, technical and scientific reports;
(ii) Providing scientific advice and support to the development of panel tailor made training materials;
(iii) Ensuring a sustainable capacity building across the panels on uncertainty analysis;

In order to fulfil its objective, the cross-cutting WG uncertainty consists of members with experience in the uncertainty analysis within the remit of EFSA and of members from each panel with a minimum experience in uncertainty analysis and/or with a statistical background. The chairmanship of the EFSA cross-cutting WG uncertainty is Caroline Merten from the SCER unit.
The newly appointed WG will hold its first meeting on 23 November 2018.

**WG Nanotechnology**

The Scientific Committee agreed to establish an EFSA cross-cutting WG on nanotechnology, chaired by Reinhilde Schoonjans from the SCER Unit. The WG will support the testing phase of the guidance on "Risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health" (link here) published in July 2018. In particular, the WG will advise on cases from EFSA Panels/Units to implement the guidance and assist Member States' representatives as part of the EFSA network on Risk assessment of nanotechnologies in food and feed (Nano network, link here) that will test the guidance on the cases/activities they have in the respective competent authorities. This supporting work may involve the inspection of some (part of) the applications received by EFSA for market authorisation of novel food, food contact materials, feed additives, food additives, or pesticides.
The WG will also provide advice for the development of a guidance on environmental risk assessment of nanomaterials.

In the end of the testing phase, a technical hearing/workshop with the stakeholders on lesson learnt with the testing of the guidance will be organised and the guidance revised, if needed.

**Guidance Consistency Group (GCG)**

This WG is meant to ensure consistency between horizontal cross cutting guidance documents and sectoral guidance documents. It will probably be established in the

second part of 2019 and detailed terms of reference will be tabled for possible agreement in one of the next SC plenary meetings.

### e. Network activities

**Risk assessment of nanotechnologies in food and feed** (Nano network, link here)

The EFSA Nano Network met for its 8th meeting on 15-16 November 2018. The meeting was kindly hosted by the Italian representative in the Istituto Superiore di Sanità, Rome. The meeting was dedicated to the implementation by national risk assessors of the EFSA Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health. No full assessments have been conducted so far. Member States participants presented and discussed ongoing research with particular substances, as well as for further test development. The minutes of the meeting will be published on EFSA's website soon.

**Emerging Risks Exchange Network (EREN)**

The EFSA Scientific Emerging Risk Exchange network (EREN) held its 20th meeting in Brussels, Belgium on 8th and 9th November 2018. EREN meets twice a year to discuss and exchange information between EFSA, the MSs and international organisations on new emerging issues within the remit of EFSA. It shares new evidence on emerging issues identified in the past and shares expertise and experience on methodological developments on how to identify emerging issues.

**Stakeholders Discussion Group on Emerging Risks (StaGER)**

The Stakeholder Discussion Group on Emerging Risks (StaDG-ER) will hold its 20th meeting in Parma on the 26-27 November 2018. This will be the second meeting of the new composition of the group recently renewed in 2018. The members belong to EFSA registered stakeholders organisations representing industry, consumers associations, primary producers, NGOs, practitioners and academia.

**CLimate change and Emerging risks for Food SAfety (CLEFSA)**

The group aims to further develop and improve the emerging risk identification methodologies and approaches as well as the prioritisation process.

In particular, the objectives of the group are:

(a) to develop a methodological approach for identifying, ranking and prioritising emerging issues related to effects of climate change on food/feed safety, plant, animal health and nutritional quality, in the EU and

(b) to produce a prioritised list of emerging issues potentially affected by climate change.

The CLEFSA project will improve the horizon scanning capacity through crowdsourcing and collaboration with wider audiences than the EFSA Emerging Risks Networks and explore the feasibility of Multi Criteria Decision Analysis procedures for prioritisation of emerging issues. It will bring together existing EFSA initiatives in the area of climate

change, increasing transparency on how EFSA is contributing to addressing this global problem. The project timeline conclusion is March 2020.

**International Liaison Group on MEthods for Risk Assessment of Chemicals in food (ILMERAC)**

EFSA has taken an initiative to create ILMERAC, a network of governmental and intergovernmental food safety agencies. Its activities are focused on the development and implementation of methods for risk assessment of chemicals in food.

The group is currently mapping the guidance documents which already exist for the different aspects to be evaluated for exposure, hazard and risk assessment. The aim is to achieve a better understanding worldwide of best practices in chemical risk assessment and to give recommendations to WHO, FAO and OECD on priorities and action plans for international harmonisation and innovation of methods for chemical risk assessment in the coming years. In addition, the targets are to reduce divergence, to increase risk assessment capacity and, ultimately, to improve consumer trust and stakeholder confidence.

### 8.3 Feedback on panel work programme 2018-2021, particularly in relation to cross-cutting issues

Animal Health and Welfare (AHAW) Panel

The Chair of the Panel mentioned that the Panel is testing the Guidance on Uncertainty in EFSA scientific assessments, applying it to the assessments related to the development of the opinion on Salmonella control in poultry flock and its public health impact. This opinion is related to an EC Mandate to the BIOHAZ Panel. However some parts have been discussed by the AHAW Panel as they concern the occurrence of Salmonella in laying hens and broilers in relation to housing conditions and other welfare indicators.

Biological Hazards (BIOHAZ) Panel

The Chair of the Panel indicated that the scientific opinion on Salmonella control in poultry flocks and its public health impact has been submitted for discussion at the next Panel's plenary.

The Scientific opinion on the evaluation of the safety and efficacy of lactic acid to reduce microbiological surface contamination on carcasses from wild game and small stock, drafted in conjunction with the CEP Panel, has been endorsed and will be published soon.

Food Additives and Flavourings (FAF) Panel

The chair of the FAF Panel consulted the Scientific Committee on a methodological question, arising from the ongoing re-evaluation of phosphoric acid, phosphates and polyphosphates as food additives (E 338-341, E 343, E 450-452) when deriving an HBGV for a nutrient. The different possible options to address this issue were discussed. The SC agreed to further discuss the issue with members of the FAF panel and of the WG on food additives.

Food Contact Materials, Enzymes and Processing Aids (CEP) Panel

The panel has adopted the scientific opinion on the evaluation of the safety and efficacy of lactic and acetic acids for reduction of pathogens on pork carcasses and cuts. This opinion is the outcome of a joint effort with the BIOHAZ Panel. The Chair of the Panel illustrated the toxicological safety of the two organic acids and the risk related to their release into the environment, together with the outcome of the efficacy assessment, the potential emergence of reduced susceptibility to biocides and/or resistance to therapeutic antimicrobials linked to the use of these organic acids.

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

The Chair of the Panel indicated the scientific outputs scheduled for discussion and/or possible adoption at the next Panel plenary, focusing on chemically defined flavourings used in feed and on the assessment of microorganisms including those intended for production of aminoacids or enzymes. The Chair also reminded the existing synergies among EFSA Panels (FEEDAP, CONTAM, GMO and BIOHAZ Panels), to assess risks concerning animal feed, as in the areas of animal feed chemical contaminants (like gossypol and mercury), the genetic modifications of microorganisms used as feed additives or as production organisms (as in aminoacids, enzymes, probiotics), or the transmission of pathogens via animal feed (like transmissible encephalophathies).

Genetically Modified Organisms (GMO) Panel

The chair of the panel informed about two recent generic mandates from the European Commission. The first is an opinion on GMOs engineered with gene drives and their implications for risk assessment methodologies. EFSA is requested to identify potential risks in terms of impact on human, animal health and the environment, to identify potential novel hazards and to determine whether there is a need for updated guidance. The second is an EC mandate on Synthetic Biology, already presented at this meeting (see point 7.1 of these minutes). The main objective of the mandate is to determine whether the existing guidance are adequate or whether there is a need for updating the guidance documents. More information on the mandate are available in the EFSA register of questions (link here).

Contaminants in the Food Chain (CONTAM) Panel

The CONTAM Panel endorsed for public consultation an opinion on the presence of cyanogenic glycosides in food other than raw apricot kernels. A minor cross-cutting issue was identified with a 2004 opinion on the presence of hydrocyanic acid in flavourings and other food ingredients with flavouring properties. The opinion was shared with the CEP panel and no critical conflicts were identified. Additional comments can be received during the consultation period.

Regarding the application of cross-cutting guidance documents, the CONTAM Panel is planning to implement the guidance on uncertainty after the specific panel training that will be organised in July 2019.

Nutrition, Novel Foods and Food Allergens (NDA) Panel

The Chair informed on the progress made in the systematic reviews conducted in relation to the development of the scientific opinion on the Tolerable Upper Intake Level of dietary sugars (EFSA-Q-2016-00414). The Panel has discussed the principles and tools that will be used for the critical appraisal of the individual studies.

The Panel is also involved in the implementation of the systematic review on sodium intake and health outcomes (EFSA-Q-2011-01224).

Plant Protection Products and their Residues (PPR) Panel

The Chair of the Panel described the mandates in which the Panel will be involved in the period 2018-2021, among which the preparation of a statement on the coverage of bats by the current pesticide risk assessment for birds and mammals and two scientific opinions on health-based reference values for metabolites of the active substance terbuthylazine and on the genotoxic potential of triazine amine (metabolite common to several sulfonylurea active substances).

The PPR Panel proposes to support the conceptual developments regarding the integration of landscape paradigms in the environmental guidance documents for pesticides. This would imply the inclusion of spatially and temporally varying agricultural landscape characteristics (like landscape structure, management, climate and environment) in pesticide risk assessments.

## 9. Other scientific topics for information and/or discussion

### 9.2 Ongoing grants and procurement in SCER Unit

EFSA cooperates in a number of scientific activities with organisations in the EU, by outsourcing part of its scientific work, giving access to high level expertise and independent knowledge. EFSA outsources scientific activities through grants and procurement. As regards to grants, EFSA provides financial contribution to carry out specific projects within the areas of EFSA's work. EFSA also purchases scientific services through public procurement procedures.
Tobin Robinson, head of the Scientific Committee and Emerging Risks Unit, gave an overview about the ongoing grants and procurements in the SCER Unit.

### 9.3 Overview of guidance lifecycle. Planning 2019 trainings on cross-cutting guidance document

EFSA has recently published a technical report explaining the "EFSA cross cutting guidance lifecycle" (link here) describing the different steps involved in this process i.e. development, implementation, review and revision of horizontal guidance documents.

Within the implementation activities, the Scientific Committee and Emerging Risks Unit coordinates several training courses on cross cutting guidance documents. The Scientific Committee has been consulted for advice on the scientific training topics to be prioritised for 2019 as well as the best training modality (e.g. physical training, webinar, e-learning modules).

## 10. Questions from and answers to Observers (in application of the guidelines for Observers)

Observers can attend EFSA's Scientific Committee open plenary meetings to see first-hand how EFSA's Scientific Committee discuss and adopt its scientific assessments. Attendees, following the plenary via EFSA's dedicated web stream or attending the meeting in person, were encouraged to pose questions. The questions received were addressed by the EFSA's scientific experts.

## 11. Any other business

- **Report back on issues relevant for the Scientific Committee**

  The Scientific Committee was provided with a document summarising the 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.

- **Update on the document on "Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products"**

  The SCER Unit is preparing an update of EFSA's Scientific Report from 2014 on "Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products" in close cooperation with the relevant units in EFSA. It is planned to publish the update on the EFSA Website in cooperation with the Application Desk early 2019.

- **Possible additional SC plenary meeting date in 2019**

  The SC was informed about a possible additional SC plenary meeting to be held as teleconference of physical meeting in Brussels, in 2019. The extra SC plenary will probably take place in April 2019.

**END OF MEETING**

## ANNEX 1

## List of observers attending in person

| Name | Title | Country | Organisation/Affiliation |
|---|---|---|---|
| Stefanie Geiser | Ms | Belgium | EAS Strategies/Private sector |
| Maurizio Ferri | Mr | Italy | Italian Veterinary Service. Local Health Unit of Pescara, Italy |
| Maodo Malick Diop | Mr | Slovakia | MANE |

| List of observers attending via web-streaming | | | |
|---|---|---|---|
| **Title** | **Name** | **Country** | **Organisation / Affiliation** |
| Mr | Nicolas Farion | France | ANSES |
| Ms | Eliana Spilioti | Greece | Benaki Phytopathological Institute |
| Ms | Silvia Toia | Italy | GB Foods |
| Mr | Eric Jhon Cruz | Philippines | National Crop Protection Center - University of the Philippines Los Baños |
| Mr | Kevin Jorgensen | Denmark | Senior Adviser |
| Ms | Giovanna Semino | France | Bayer SAS |
| Ms | Adanela Musaraj | Italy | EUI.EU |
| Ms | Océane Albert | Belgium | Cefic |
| Ms | Krista Meurer | Germany | BASF SE |
| Ms | Kate Trollope | United Kingdom | EU Food Policy |
| Ms | Anna van der Zalm | United Kingdom | PETA International Science Consortium Ltd. |
| Mr | Chad Thompson | United States | ToxStrategies |
| Mr | Nico van Belzen | Netherlands | ScienceConsult BV |
| Ms | Candace Doepker | United States | CANDACE doepker |
| Ms | Stefanie Geiser | Belgium | EAS Strategies |
| Ms | CARLOTTA FERRONI | Italy | MINISTRY OF HEALTH |

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| Ms | Marta Felez | Spain | Tolsa |
| Ms | Claire Koenig | United States | Claire Koenig |
| Ms | Agathi Charistou | Greece | Benaki Phytopathological Institute |
| Ms | Milena Busova | Czech Republic | Charles University, First Faculty of Medicine in Prague, Institute of Hygiene and Epidemiology |
| Ms | Effrosyni Katsanou | Greece | Benaki Phytopathological Institute |
| Ms | Sylvie Braibant | Belgium | Cefic |
| Mr | Unai Baigorri Ibarrola | Spain | Kerry Ingredients & Flavours |
| Ms | Cristina Martin Jimenez | Spain | Pen & Tec |

**Questions from observers submitted before the meeting and answers from EFSA**

**Q1**: Will EFSA re-evaluate TiO2 (E171) due to new data on potential association with T2D? (Heller et al. 2018 Chem Res Tox 31:506, Yuan et al. 2018 Env Pol 237:917) (**From:** Mr Nico van Belzen, **Affiliation:** ScienceConsult BV)

**A1**: Please be informed that according to the provisions of the Regulation 257/2010, "*EFSA may at any moment start the re-evaluation of a food additive or a group of food additives with priority, on a request from the Commission or on its own initiative, if new scientific evidence emerges that: (a) indicates a possible risk for human health or (b) may in any way affect the safety assessment of that food additive or group of food additives*."

For example, earlier this year the European Commission requested EFSA to assess four studies (Bettini et al. 2017, Heringa et al., 2016, Proquin et al. 2017 and Guo et al., 2017) published after the completion of the re-evaluation of titanium dioxide (E171) as a food additive by the former ANS Panel in 2016. In this latest opinion published in July 2018 (ANS Panel 2018), the Panel concluded that the outcome of these four studies did not merit re-opening the existing EFSA 2016 opinion related to the safety of titanium dioxide (E 171) as a food additive.
In general, the approach described in the 'Scientific opinion on scientific motivations and criteria to consider updating EFSA scientific assessments' adopted by the EFSA Scientific Committee in 2017 is followed when deciding if new scientific evidence merit to re-open a previously adopted EFSA opinion. The following criteria should be considered in order to take this kind of decision for the specific case of titanium dioxide as a food additive:

- Are the new data relevant to the safety of $TiO_2$ used as a food additive?
- Does the new scientific evidence address important data gaps previously identified?
- Are the new data likely to change the overall conclusions of the scientific opinion (EFSA ANS Panel, 2016), in a weight of evidence approach?

Whenever new data fulfilling any of the above criteria become available, EFSA can discuss the need to re-open the re-evaluation.

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**Q2:** What are the mechanism you propose for suspending, restarting or extending an assessment? (**From:** Ms Adanela Musaraj, **Affiliation:** EUI.EU)
**A2:** During the risk assessment of regulated products, additional or supplementary information may be needed to be gathered and analysed by EFSA, either through "calls for data" as

prescribed through some sectoral legislation or through a mechanism of suspended timelines for the risk assessment.

Through the former mechanism interested parties and applicants may submit supportive data prior to the final assessment of the product by EFSA. Through the latter mechanism, EFSA requests a specific applicant to answer questions or submit additional or supplementary information directly linked to the assessment of a specific market access application. A document is published (here) and it is a present under revision. The revised document will be published in the beginning of 2019, probably as an annex of the "Administrative guidance for the processing of applications for regulated products (link here). This administrative guidance for the processing of applications for regulated products describes in a harmonised way: the general workflow of applications, the key steps of the scientific risk assessment process, the mechanism of suspension / extension of the scientific assessment, its restart, the conclusion of the scientific risk assessment process and the publication of the scientific output.

In general, information on "Scientific motivation and criteria to consider updating EFSA scientific assessment" is presented in an opinion published in 2017 (link here).

Abstract: EFSA is obliged to re-assess past assessments in specific regulatory contexts such as those on food and feed additives, active substances in plant protection products and genetically modified food and feed. In other sectors, the consideration for updating past EFSA scientific assessments is taken on an ad hoc basis mainly depending on specific requests by risk managers or on EFSA self-tasking. If safety is potentially at stake in any area within EFSA's remit, the readiness to update past scientific assessments is important to keep EFSA at the forefront of science and to promote an effective risk assessment. Although this task might be very complex and resource demanding, it is fundamental to EFSA's mission. The present EFSA Scientific Committee opinion deals with scientific motivations and criteria to contribute to the timely updating of EFSA scientific assessments. It is recognised that the decision for updating should be agreed following careful consideration of all the relevant elements by the EFSA management, in collaboration with risk managers and stakeholders. The present opinion addresses the scientific approaches through which it would be possible for EFSA to increase the speed and effectiveness of the acquisition of new data, as well as, to improve the consequent evaluations to assess the relevance and reliability of new data in the context of contributing to the better definition of whether to update past scientific assessments.

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**Q3:** We would like to know if EFSA will be published an scientific opinion on wild life pressure other than boars. ( **From:** Mr Luigi Tozzi, **Affiliation:** Confagricoltura)

**A3:** The question is not clear. If it relates to African Swine Fever (ASF) only, the answer is that EFSA has not published a scientific opinion on other wild life pressure.
On the other hand, if it is not limited to ASF, then EFSA has for example very much published on the importance of wild birds for the transmission of avian influenza and I am sure there are other examples such as Echinococcus multilocularis etc where the role of wildlife was examined.

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**Q4**: Are botanicals considered chemical mixtures? **From**: Cristina Martin Jimenez, **Affiliation**: Pen & Tec, consultancy, Spain)
**A4:** Yes. The approach for the risk assessment is to be decided on a case by case basis depending on the level of characterisation of the constituents of the mixtures.

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**Questions submitted during the meeting and answers from EFSA**

**Q1.** Mr Nico van Belzen, affiliation ScienceConsult BV
In relation to the information provided by the EFSA Executive Director in the opening of the meeting that concern the Commission's proposal for the revision of the General Food Law (more info available here), the question is: how EFSA thinks to increase the coherence of risk communication between the different bodies in practise?

**A1 :**
One of the key proposal of the revision of the General Food Law is strengthen risk communication to citizens, with common actions to enhance consumer confidence by promoting public awareness and understanding and better explaining scientific opinions expressed by the European Food Safety Authority, as well as the basis of risk management decisions.. There will be probably a strategic communication plan between EFSA, EC and Member States but the procedure is still under discussion. The separation is between risk assessment (EFSA) and risk management (Commission) but risk communication is a joint paradigm, where we need to make sure to communicate in a coherent way and respecting each other's roles.

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**Q2**. Eric John Cruz, affiliation National Crop Protection Center - University of the Philippines Los Baños
The question relates to the draft guidance on chemical mixtures (agenda point 6.1): how do we account for the inherent variability in the sensitivity of different species (bees, aquatic organisms, etc.) to different components of a mixture when developing a harmonised risk assessment?
**A2:** Consideration should be given on species sensitivities distribution and then to the whole ecosystem. The risk assessment should be based on the most sensitive species.

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**Q3.** Krista Meurer, affiliation BASF SE
The question is related to the statement on genotoxicity assessment of mixtures (agenda item 6.2): when will the adopted statement be published?
**A3:** The statement will be published by the end of 2018.

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**Q4.** Giovanna Semino, affiliation Bayer SAS
The question is related to the statement on genotoxicity assessment of mixtures (agenda item 6.2): could you better explain "*the possible limitations of in vivo test should be weighed*"?
**A4:** Any test has a limit of sensitivity. The assessor should well consider and weigh the characterisation of the mixture. It is very important to consider how much is known about the mixture and consequently, to the design of the testing strategy.

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**Q5.** Giovanna Semino, affiliation Bayer SAS
Again on agenda item 6.2 (genotoxicity assessment of mixtures): Did you include more guidance regarding the uncertainty analysis to be conducted?
**A5:** Not in details, as the concepts/principles are described in the guidance documents on uncertainty in scientific assessment and the guidance on the weight of evidence approach published in 2018 and 2017, respectively.

**List of abbreviations**

**SC:** Scientific Committee

**TTC:** Threshold of Toxicological Concern

**WG:** Working Group

**RASA Department:** Risk Assessment and Scientific Assistance

**REPRO Department:** Scientific Evaluation of Regulated Products

**COMCO Department:** Communication Engagement and Cooperation

**SCER Unit:** Scientific Committee and Emerging Risks Unit

**FIP Unit:** Food Ingredients and Packaging Unit

**NUTRI Unit:** Nutrition Unit

**BIOCONTAM Unit:** Biological Hazards and contaminants Unit