
SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

Scientific Committee

Minutes of the 103rd Plenary meeting

**Held on 14-15 April 2021, TELE-conference,
(Agreed on 06 May 2021)**

Participants

- Panel Members
Simon More (chair), Diane Benford (vice chair), Susanne Hougaard Bennekou (vice chair), Vasileios Bampidis, Claude Bragard, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Hanspeter Naegeli, Søren Saxmose Nielsen, Josef Schlatter, Dieter Schrenk, Dominique Turck, Maged Younes.
- Hearing Experts¹:
Christer Hogstrand (for item 4.4)
Jean-Charles Leblanc (for agenda item 4.2)
- European Commission and/or Member States representatives:
Athanasios Raikos (DG SANTE Unit D1, Farm to Fork Strategy)
- EFSA:
Executive Directorate: Marta Hugas
Risk Assessment and Scientific Assistance Department (RASA):
Juliane Kleiner
Scientific Evaluation of Regulated Products Department (REPRO):
Guilhem De Seze
Scientific Committee and Emerging Risks Unit (SCER): Tobin Robinson, Daniela Maurici, Maria Chiara Astuto, Maria Bastaki, Bernard Bottex, Yann Devos, Jean-Lou Dorne, Raquel Garcia Matas, Milen Georgiev, Georges Kass, Christina Kyrkou, Djien Liem, Angelo Maggiore, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans, Rositsa Serafimova, Justyna Slodek-Wahlström, José Tarazona.

¹ As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

Update on Science Studies and Project Identification and Development (SPIDO): Claudia Heppner (for item 6.1)

Animal and Plant Health (ALPHA) Unit: Andras Szoradi (for item 6.3)

Communication Unit (COM): Anthony Smith (for item 6.2)

1 Welcome and apologies for absence

The Chair welcomed the participants

2 Adoption of agenda

The agenda was adopted without changes

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

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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

4.1 A systems-based approach to the environmental risk assessment of multiple stressors in honey bees (EFSA-Q-2018-00645)

This agenda item was chaired by Diane Benford since the chair of the Scientific Committee (SC), Simon More, is also the chair of the WG (MUST-B) assigned to this mandate from the European Parliament ENVI Committee. The draft scientific opinion on a systems-based approach to the environmental risk assessment of multiple stressors in honey bees has been in public consultation until 4 March 2021. Agnes Rortais provided details on the contributors and the type of comments received and an overview on amendments made in the various sections of the opinion. The draft opinion concludes that more discussions are needed to implement the approach proposed, taking into account concerns from all stakeholders. The SC had no further questions and adopted the opinion. The chair of the WG thanked

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³

http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

the WG for the excellent preparatory work and contributions to the draft opinion.

4.2 Draft review of the existing health-based guidance values for copper and its exposure assessment from all sources (EFSA-Q-2020-00399)

The Scientific Committee was presented with the first draft of the opinion in response to an EC mandate to revisit by end 2021, the derivation of the health-based guidance values (HBGV) for copper, to resolve the different HBGVs proposed for copper, and to perform a total exposure assessment from all sources.

Copper is an essential nutrient, is naturally present in the environment and is also used in regulated products. The current status of the data available for copper, and the critical values (NOAEL, Uncertainty Factors) and approaches that were used to establish the HBGVs (i.e. Upper Levels - ULs, ADI) under different regulatory frameworks were reviewed. The WG applied the principles and recommendations laid out in the EFSA Statement on the derivation of HGBV for regulated products that are also nutrients, published in March 2021 (link [here](#)), to address the divergence between HBGVs for copper reported previously by the Scientific Committee on Foods in 2003 and EFSA in 2008 and 2018. Accordingly, the draft opinion reviews updated information on copper homeostasis, transport mechanisms and the range of potential copper-related toxicity; and examines the role of hepatic retention in copper toxicity from chronic intake and the impact of genetic susceptibility.

For the second Term of Reference of the mandate, the WG performed a preliminary refined exposure assessment. The total copper levels in food from all relevant sources have led to the identification of the major contributing food categories. A sector-based refined exposure assessment is now being performed for these main food categories, based on data of nutritional concentrations and reported copper occurrence levels in commodities/crops, or food products. The latter includes all sources of copper in agricultural products. In addition to oral exposure, the WG assessed other sources of copper exposure, from reported uses of copper in consumer products, cosmetics and medical devices.

The sections on uncertainty and weight of evidence still need to be developed by the WG. A more detailed section on previous assessments has also been suggested. The draft opinion will be tabled at the next plenary for possible endorsement for public consultation.

4.3 Scientific guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health (EFSA-Q-2020-00269) and EFSA scientific opinion on the guidance on technical requirements of regulated food and feed product applications to establish the presence of particles in the nanoscale (EFSA-Q-2019-00692)

Both draft Guidance documents have been presented to the SC in November 2020 and have been reviewed by the Panels afterwards: Consultation with EFSA Panels (PPR, NDA), Units (FEED, FIP) and WGs (food contact materials and Genotox). The updated guidances are now presented and will be scheduled for possible adoption at the June plenary. All the Panel chairs are asked to confirm, with the head of units and the respective teams, the usability of these guidances. Also, the EC and the JRC have provided thorough feedback on both guidances and the documents were updated accordingly.

A presentation given by Jose Tarazona provided information on where the experiences with dossiers/cases have influenced updates of both guidances. Both guidances will be made available for possible final comments by the Panels in May. Panels' feedback are welcomed before the next SC plenary.

4.4 Update on draft guidance on scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals (EFSA-Q-2019-00517)

The Chair of the WG, Christer Hogstrand, presented the latest modifications of the draft guidance document. Previous comments from the SC members, at the previous plenary, were taken into account and the document was modified accordingly. In addition, comments from EFSA Units, EFSA Panels and the Pesticide Steering Network were also provided and taken into account during the consultation exercise and presentations in their respective Plenary meetings.

The SC members provided further suggestions to amend the text particularly in chapter 3 and 4 as well as in the Annexes. The SC endorsed the draft guidance for public consultation to be launched in May for the period May-June 2021. Finalisation of the guidance is expected by the end of 2021.

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

5.1 Scientific Panel(s) including their Working Groups

5.1.1 Overview of the work programme of AHAW and FAF panels. Last minute issues relevant for the Scientific Committee

Maged Younes, chair of the FAF panel, presented an overview of the mandates in the remit of the Panel: Food Additives (new applications under Regulation (EC) No 1331/2008 and re-evaluation of already permitted food additives under Regulation (EU) No 257/2010 and follow-up of re-evaluation opinion); Flavourings (new applications under Regulation (EC) No 1331/2008); new smoke flavourings; evaluation of flavouring substances reported with a footnote in Commission Implementing Regulation (EU) 872/2012; Guidance development for smoke flavourings (new and renewals), flavourings and food additives. More details were presented on the work experiences that relied on overarching guidances from the SC, that had complexity and challenges and required specific modalities of cooperation. Future work and challenges were also presented with a prospectus on the increasing workload for the FAF panel and the modalities for co-operations.

Søren Saxmose Nielsen, chair of the AHAW panel, presented the various mandates under Art. 29 and Art. 31 on Animal Health. These primarily include work on African Swine Fever (ASF), which has been spreading in Europe since 2007. The focus is on exit strategies in (previously) affected countries, movement of ASF-virus in matrices used for feed and the like on farms, the contribution of outdoor farming in the transmission of ASF-virus and focus on knowledge gaps. Furthermore, control efforts specific for each of the 13 Category A diseases according to the 2016-Animal Health Law are being reviewed and suggested. The EU Animal Welfare legislation is to be reviewed; this requires development of 6 scientific opinions from EFSA over the time period until 2023. Being prepared for rapid risk assessments is of increasing importance (only Animal Health and Welfare related or Animal Health and Public Health related (One Health)). Recently 2 rapid risk assessments were requested for SARS-CoV-2 in mink and risk of cross-border spread (Nov 2020) and for Avian Influenza (Nov 2020): risk of further incursions and spread; public health risk. The SC discussed how the capacity and interactions needed for such rapid assessment can be reinforced (e.g., processes within EFSA and liaison with ECDC and EURL).

In relation to general issues of relevance for the SC, Dieter Schrenk, chair of the CONTAM panel, raised the point that some cross-cutting guidance documents might need revision and a survey was launched within the

CONTAM Panel to collect feedback. The use of default uncertainty factors continues to cause discussion and the SC Guidance on default values might need to be revised. For genotoxic carcinogens, the Margin of Exposure approach is often followed and the respective EFSA guidance documents (2005/2012) might need to be updated. It was agreed to have further discussion on these 2 guidance documents in one of the next plenary meetings.

5.2 Draft mandate for an opinion on fluoride in food and drinking water

Dieter Schrenk, chair of the CONTAM panel, presented a new EC mandate for a scientific opinion on an updated consumer risk assessment for fluoride in food and drinking water, taking into account: available information on the occurrence of fluoride in food and drinking water, and an exposure assessment considering the levels of fluoride in food and drinking water and the contribution from other known sources of exposure. In addition, all available scientific information on the hazards of fluoride needs to be considered. The proposed deadline to deliver the opinion is September 2023.

The NDA Panel assessed the beneficial effect of fluoride in 2013. The Panel concluded that fluoride is not an essential element but set an Adequate Intake (AI) of 0.05 mg/bw per day in view of the beneficial effects of dietary fluoride on prevention of dental caries. Excessive intake of fluoride may cause dental and skeletal fluorosis. The NDA Panel in 2005 established Upper Levels (ULs) for children and adults. No ULs were established for infants. Both ULs and AI are relevant to the overall oral exposure to fluoride, including non-dietary exposure (e.g., fluorinated tap water and dental hygiene products).

The SC discussed the set-up of and modality of the group of experts that would be working on this mandate. A cross cutting WG under the umbrella of the SC will be considered, composed of members of the concerned panels (NDA and CONTAM), as well as external experts to cover the multiple disciplines needed. The chair of this working group will be selected as soon as possible and a protocol for the work will be done.

5.3 End of project report “Risk characterisation of Ciguatera fish poisoning in Europe”

Angelo Maggiore presented the EuroCigua project for Risk characterisation of Ciguatera fish poisoning in Europe (Grant GP/EFSA/AFSCO/03).

In 2004, *Gambierdiscus spp.* were detected for the first time in the waters of the Canary Islands and Madeira, with the first autochthonous Ciguatera outbreak in Canary Islands. In 2008-2015 16 outbreaks were reported: Canary Islands (14) and Madeira (2). As a signal of emerging risk, the issue

was brought to the attention of the EFSA's Emerging Risks Exchange Network in 2015, where it became clear that a large data collection was necessary to collect useful information for the characterization of the risk of Ciguatera fish poisoning in Europe. The Eurocigua project was therefore launched in 2016 (see [here](#) and [here](#)), consisting of three parts: epidemiological, environmental and analytical. The project relies on the partnership with 14 partners from six Member States. Ciguatera fish poisoning has been confirmed as an emerging risk for Europe and a new endemic food-borne disease in Canary Islands and Madeira. A follow up project was proposed aiming at further environmental data collection for Ciguatera risk characterisation and for development of predictive modelling, production of reference materials, strengthening the reporting and investigation of Ciguatera outbreaks, awareness raising and investigating the contribution of imported fish. An explanatory note will be distributed to the Scientific Committee for possible comments.

5.4 Update on relevant WGs activities:

5.4.1 WG Non-Monotonic Dose Response

The draft SC opinion on the biological plausibility of NMDR and its impact on risk assessment in the remit of EFSA was published from 4 December 2020 to 4 February 2021 for public consultation.

Jose Tarazona presented an update on the activities since February. A dedicated discussion at the last ILMERAC (International Liaison Group on Methods for Risk Assessment of Chemicals in Food) web-conference confirmed that no parallel activities by other organisations are ongoing.

It was suggested to explore the possibility of an international effort under OECD auspices for the preparation of a guidance document for addressing NMDR in the risk assessment. The WG will continue to discuss the comments received and suggested a modification in the title of the Opinion that reads now "Impact of non-monotonic dose responses on EFSA's human health risk assessments" and should be considered as a contribution from EFSA to the international developments in this area. The draft opinion will be finalised and proposed for adoption in September along with the finalised technical report of the public consultation.

5.4.2 Cross-cutting WG Genotoxicity

The ccWG has finalised the genotoxicity evaluation of titanium dioxide (E 171) in the context of the request for advice from the FAF Panel. Further requests for advices were received from FIP, FEED, Pesticides and Nutri Units: some of them have been already addressed during the last WG meeting; others are planned for the upcoming meetings. The work on the

Guidance on Aneugenicity assessment has resumed; two rapporteurs were nominated and the WG aims at presenting the guidance for adoption in the June SC plenary meeting.

The call for expression of interest for external experts with an expertise in genotoxicity was closed in April. The list will be used by the EFSA Units for selection of experts when a need is identified.

6 Other scientific topics for information and/or discussion

6.1 Update on Science Studies and Project Identification and Development Office (SPIDO)

Claudia Heppner presented feedback from the broad survey on SPIDO, the roadmap generating themes of 2020 and the themes for 2021 and beyond. The process for scientific theme selection entails six concrete selection criteria. For 2021, the selected themes are 1) Application of OMICS & bioinformatic approaches: next generation risk assessment and 2) Insect pollinators: advancing the environmental risk assessment of chemicals for insect pollinator. The theme papers are being developed and will be presented to the SC for consultation in June. The roadmaps for implementation will be outsourced.

The SC was presented with the details for each theme and provided inputs with ideas and complementary suggestions. The SC endorsed the proposals and encouraged strongly that the theme OMICS needs to be further developed. The theme of pollinators is also supported, but further details are needed on the concrete elements of the theme and the related activities.

6.2 Technical assistance in the field of risk communication

Tony Smith provided an update on the activities of the EFSA WG on Social Research Methods and Advice, that is working on an EC request from early 2020 for technical assistance on risk communication in the context of the new transparency regulation and its new provisions. The transparency regulation foresees a General Plan for Risk Communication framework and the EC requested for EFSA support in implementation. The outputs already delivered are a Scientific Report on technical assistance in the field of risk communication, a Communication Product Catalogue & Dissemination Guidelines (best practice), mapping communication capacities, processes and linkages through fora and networks (risk assessments and risk managements) and an Engagement Toolkit - Methods, tips and best practices to design effective participatory processes. Details of the report were presented, and follow-up actions will now be determined by the EC with support of EFSA and the MS partners in the communications expert network.

6.3 Scientific Conference 2022: ONE (Health, Environment, Society), 21-24 June 2022, Brussels & online

Marta Hugas introduced the item on the ONE Conference 2022 that EFSA is co-creating with the other ENVI Agencies and the JRC. As part of this introduction Marta presented the EFSA Project Team behind the Conference, the rational for having the Conference, as well as the dates and venue of the Conference in Brussels (and online) in June 2022. The Conference should be seen as a step towards the gradual implementation of the One Health approach by fostering engagement and collaboration among experts from different sectors and expertise (including natural and social sciences). In addition, the intention of the Conference is to prepare for the future by identifying forward-looking actions for risk assessors and risk managers within the framework of sustainability and the EU Green Deal.

Yann Devos, the Chair of the Scientific Programme Committee, presented the draft scientific program outline of the Conference (including the overarching goals, the structure and the draft list of thematic sessions).

Andras Szoradi concluded the joint presentation by presenting the role and composition of the Scientific Programme Committee and the two advisory boards, the ONE Conference logo and communication activities, as well as the overall timelines of the Conference Project. As part of the discussion, it was agreed that members of the Scientific Committee would be consulted in writing on some aspects of the scientific program and that the Conference Project Team would update the Scientific Committee on progress made with the Conference at regular intervals.

7 Any other business

7.1 Draft agenda next SC Plenary

The SC was presented with an overview of the topics that will be on the agenda of the next meeting scheduled for the 30 June-1 July 2021 which will be open to Observers.

7.2 Proposal for SC Plenary dates in 2022 and 2023

The SC was presented with a proposal for plenary meeting dates in 2022 and 2023. The dates have been agreed to avoid to the extent possible overlapping the dates of the Management Board, Advisory Forum, Focal Points and Panel plenaries.

7.3 Thematic workshop November 2021

Tobin Robinson announced the next edition in the series of SC Thematic workshops on scientific topics to be explored. Availability will be requested for around the plenary in November. The theme is yet to be selected and will be presented in the June plenary.

7.4 General matters arising

The Scientific Committee was provided with a document summarising relevant activities that took 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 Meetings.

End of the meeting

List of acronyms

AF: Advisory Forum

AHAW: Panel on Animal Health and Welfare

AI: Adequate Intake

AMU: Assessment and Methodological Support Unit

APDESC: Applications Desk Unit

ASF: African Swine Fever

BIOCONTAM: Biological Hazards and Contaminants Unit

ccWG: cross-cutting Working Group

COM: Communication Unit

COMCO: Communication, Engagement and Cooperation Department

CONTAM: Panel on Contaminants in the Food Chain

DATA: Evidence Management Unit

DG SANTE: Directorate General for Health and Food Safety

EC: European Commission

ECDC: European Centre for Disease Prevention and Control

ENCO: Engagement and Cooperation Unit

ENVI: European Parliament Committee on Environment, Public Health and Food Safety

EURL: European Union Reference Laboratory

FAF: Panel on Food Additives and Flavourings

FCM: Food Contact Materials

FIP: Food Ingredients and Packaging Unit

GMO: Panel on Genetically Modified Organisms

HBGV: health-based guidance values

ILMERAC: International Liaison Group on Methods for Risk Assessment of Chemicals in Food

JRC: Joint Research Centre

MS: Member States

NDA: Panel on Nutrition, Novel Foods and Food Allergens

NMDR: Non-Monotonic Dose Response

NUTRI: Nutrition Unit

OECD: Organisation for Economic Co-operation and Development

PPR: Panel on Plant Protection Products and their Residues

PRES: Pesticide Residues Unit

PREV: Pesticide Peer Review Unit

RASA: Risk Assessment & Scientific Assistance Department

REPRO: Scientific Evaluation of Regulated Products Department

SC: Scientific Committee

SCER: Scientific Committee and Emerging Risks Unit

SPIDO: Science Studies and Project Identification and Development

ULs: Upper Levels

WG: Working Group