



## Scientific Committee

### Minutes of the 107th Plenary meeting

**Held on 9-10 February 2022, web meeting,  
(Agreed on 2 March 2022)**

#### **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, Ewen Mullins, Søren Saxmose Nielsen, Josef Schlatter (absent in the morning of the 1<sup>st</sup> day), Dieter Schrenk, Dominique Turck, Maged Younes.
- Hearing Experts<sup>1</sup>:  
Jean-Charles Leblanc (for item 4.3)
- European Commission and/or Member States representatives:  
Luis Vivas Alegre (DG SANTE Unit D1, Farm to Fork Strategy),  
Athanasios Raikos (DG SANTE Unit D1, Farm to Fork Strategy),
- EFSA:  
Bernhard Url, EFSA Executive Director (for agenda item 3)  
Executive Director Office: Marta Hugas, Georges Kass  
Risk Assessment Services Department (ENABLE): Nicolaus Kriz  
Risk Assessment Production Department (ASSESS): Guilhem De Seze  
Methodology and Scientific support Unit (MESE): Claudia Roncancio-Peña, Daniela Maurici, Elisa Aiassa, Maria Bastaki, Jose Cortiñas

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<sup>1</sup> As defined in Article 15 of the Decision of the Executive Director Fconcerning 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](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)



Abrahantes, Djien Liem, Laura Martino, Alexis Nathanail, Agnes Rortais, Justyna Slodek-Wahlström, José Tarazona.

Knowledge Innovation and Partnership Unit (KNOW): Bernard Bottex, Angelo Maggiore

Biological Hazards & Animal Health and Welfare (BIOHAW): Andras Szoradi

## **1 Welcome and apologies for absence**

The Chair welcomed all 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 Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, 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 Draft updated guidance on benchmark dose approach ([EFSA-Q-2020-00137](#))**

The Scientific Committee was presented with an update of the draft guidance document on benchmark dose approach, as a result of the revision of the existing guidance published in 2017 ([EFSA 2017](#)).

The Scientific Committee underlined the quality of the document in terms of readability and clarity of the concepts presented, as well as the step forward it represents for benchmark dose analysis methodology, with Bayesian model averaging becoming the recommended approach for EFSA assessments.

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<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



The Scientific Committee endorsed the guidance for public consultation pending minor editorial revisions. A targeted consultation of relevant EFSA Panels, EU Agencies, Member States Competent Authorities and international organisations will be organised in parallel to ensure that the guidance addresses the various needs of EFSA and that the proposed approach is agreeable by EFSA Partners dealing with benchmark dose analysis. The comments received will be considered for finalising the updated guidance that will be probably submitted for possible adoption at the July plenary meeting.

#### **4.2 Draft protocol for opinion on fluoride in food and drinking water ([EFSA-Q-2021-00358](#))**

The draft protocol for the risk assessment of fluoride was presented to the Scientific Committee for discussion. The Scientific Committee was reminded of the terms of reference and deadline for the mandate as the context within which the protocol was prepared. The proposed scope of the hazard assessment was discussed. As a result of this discussion, it was broadened to include all hazard information for fluoride without specific emphasis on any particular endpoint. A tiered approach to screening, retrieving, and assessing the relevant evidence was agreed.

A systematic review approach will be followed as a second tier for the most pertinent outcome(s), following the screening of all hazard information. Existing risk assessments conducted on fluoride from other agencies will be screened and considered to the extent possible. Additionally, it was recognised that the purpose of the protocol is to communicate the intended plan of the WG. The Scientific Committee agreed that the protocol should remain flexible to accommodate possible further amendments.

The general consensus was that public consultation of the protocol will be useful in obtaining input that can be taken into consideration early in the process.

The Scientific Committee endorsed the draft protocol for public consultation, pending incorporation of minor amendments as discussed during the meeting. A recommendation to include clear explanations on the reason to consult the public on the protocol was noted as this is not a requirement or a practice applicable to all sectors. The consultation will be probably launched in March and will last about 4 weeks.

#### **4.3 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 a revised draft opinion on copper, tabled for possible endorsement for public consultation. The draft was completed with all sections of the exposure assessment, including the results on contributions from each dietary source of copper. Additions and revisions were also made in the hazard assessment sections, specific to the role of zinc in copper homeostasis as well as additional evidence from farm animals. Revisions were made in the uncertainty analysis section, in response to previous SC feedback, to indicate the impact of each identified uncertainty on the assessment, although the analysis of uncertainties remained qualitative.

In the draft, the Chair of the Panel on Nutrition, Novel Foods and Food Allergens (NDA) proposed to also include tolerable upper levels (ULs) for copper for all age groups in addition to the establishment of the Acceptable Daily Intake (ADI) value, in line with the provisions of the EFSA Statement (2021) for establishing Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients.

The Scientific Committee agreed that this revision is appropriate in the context of this Scientific Opinion. The WG will incorporate the relevant narrative in a revised version of the Opinion. Furthermore, the Scientific Committee commented on the qualitative approach taken for the uncertainty analysis and advised the WG to review this chapter. Concerns were raised that such additional work would require considerable time that may impact on the already extended deadline for delivering the Scientific Opinion. Endorsement for public consultation was postponed to the April plenary meeting to allow incorporation of the suggestions agreed during the present meeting.

## **5 Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission Scientific Panel(s) including their Working Groups**

### **5.1.1 Overview of the work programme of BIOHAZ and CONTAM panels. Last minute issues relevant for the Scientific Committee**

#### **BIOHAZ Panel**

The Panel on Biological Hazards (BIOHAZ) of EFSA provides scientific advice on biological hazards in relation to food safety and food-borne diseases. The BIOHAZ Panel's Chair, Kostas Koutsoumanis, presented an overview of the recently completed activities and on-going tasks of the Panel. Several Scientific Opinions and Guidance Documents were published in 2021, concerning antimicrobial resistance (AMR), quality presumption of safety (QPS), the so-called 'superchilling' technique, date marking and related



food information and inactivation of indicator microorganisms and biological hazards by standard and/or alternative methods.

Currently, several new opinions are under development by the Panel in the topics of high-pressure processing, ageing of meat, use and reuse of water in processing of fruits and vegetables and evaluation of the safety and efficacy of lactic acid to reduce microbial contamination. Additional on-going work in food hygiene is underway for QPS assessments, persistence of microbiological hazards in food-processing environments and transmission of antimicrobial resistance during animal transport.

The Chair of the Panel also informed the Committee about successful collaborations with other EFSA Panels, Units and other EU agencies.

## **CONTAM Panel**

The work of the Contaminants in the Food Chain (CONTAM) Panel revolves around contaminants and undesirable substances in the food chain such as natural toxins, mycotoxins, processing contaminants, metals and inorganic substances, among others. The Chair of the Panel, Dieter Schrenk, provided an overview of the Panel's 2022 work programme and informed the Committee about the on-going mandates for a wide variety of substances, including acrylamide, nitrosamines, mycotoxins, brominated flame retardants, and mineral oil hydrocarbons.

## **5.2 Feedback from EFSA**

### **5.2.1 Presentation of the Methodology and Scientific Support (MESE) Unit and new Head of ENABLE Department**

An introduction of the newly established Risk Assessment Services (ENABLE) Department of EFSA was given by the recently appointed Head of Department, Nikolaus Kriz. After introducing himself to the participants, he described the structure of the ENABLE Department and the foreseen interactions with the other departments of EFSA. ENABLE consists of four Units, namely, Methodology and Scientific Support (MESE), Front Desk and Workforce Planning (FDP), Integrated Data (iDATA) and Risk Assessment Logistics (RAL), with approximately 110 staff members. The key functions of the Department are to assist, support and streamline risk assessments, primarily performed by the Risk Assessment Production (ASSESS) Department. In addition, the Department aims to lead activities of data collection and data analysis and provide the necessary statistical and methodological support.

Following Nikolaus Kriz's introduction, the Head of the MESE Unit, Claudia Roncancio-Peña, presented the new MESE Unit, which is subdivided into four teams. The first team (Scientific Committee coordination and cross-



cutting activities) is dealing with matters relevant to the Scientific Committee, Working Groups and cross-cutting issues (e.g. methodologies development). The second team (Methods development and support: Analysis) is dealing with data analysis and modelling management (e.g. exposure, dose-response modelling, etc.). The third team (Methods development and support: End-to-end Evidence) is tasked with evidence collection, synthesis and integration of data, as well as information retrieval, problem formulation and uncertainties. The fourth team (Methods development and support: Preparedness) is leading and contributing to EFSA's strategic objectives and preparedness activities.

The new EFSA organigramme was shared with the participants (link [here](#)).

### **5.2.2 Draft work-programme Scientific Committee 2022 – 2024: topics already identified and preparation of brainstorming session for SC April plenary meeting**

The Scientific Committee was presented with an overview of the ongoing WG activities and the timelines for the finalisation of the different outputs. A summary of the new activities already discussed and agreed at the November 2021 plenary was also presented. Panels and Units will be consulted in time before the next SC plenary on possible topics to be included in the SC work programme 2022-2024. A prioritisation exercise will be also done at the next plenary in order to decide which activities could be initiated in 2022 and which ones will be initiated in 2023 and 2024.

### **5.2.3 Guidance lifecycle overview and possible review of the 2012 “Guidance on selected default values to be used by the EFSA in the absence of actual measured data”**

The life cycle of EFSA's Guidance Documents foresees a regular review of their validity. The Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data ([EFSA 2012](#)) has now reached this milestone. A presentation of the content of the guidance was provided to the Scientific Committee, with the request for the next Plenary meeting to review with the EFSA Panels and Units if some of the default values have become obsolete or are missing; the results will be presented at the April meeting in order to decide if a revision of the Guidance is needed.

### **5.2.4 Update on WGs activities:**



- Cross-cutting (cc) WG Nano

Following the publication of the two Guidance Documents in 2021 (link [here](#) and [here](#)), the activity of the ccWG Nano is focused on providing advice to the different Panels and Units dealing with assessments of nanoparticles. Regarding the Technical guidance ([here](#)), a recurrent request from stakeholders is to provide clarifications on the interpretation of the results of the dissolution protocol for substances that only dissolve rapidly under acidic conditions.

A proposal addressing this issue will be presented to the SC at the next Plenary meeting.

In addition, the ccWG is preparing the upcoming Stakeholders Workshop on small particles and nanoparticles in food, 31 March-1 April, 2022. SC members interested in attending this event were invited to register through the EFSA web page (link [here](#)).

- Cross-cutting (cc) WG on Genotoxicity

In the last meeting of the ccWG on Genotoxicity (February 2022), the request for advice from the Pesticides Peer-Review (PREV) Unit regarding the genotoxic potential of two common pyrethroid metabolites, the 3-phenoxybenzoic acid and its hydroxylated derivative was finalised.

The ccWG also provided scientific advice on a request from the Food Ingredients & Packaging (FIP) Unit on an agreed way to report the results of the genotoxicity studies for the opinions on sweeteners. The agreed template will be included as an Appendix document to the Opinion including considerations on the reliability and relevance of the genotoxicity assays.

- WG Compendium of Botanicals

Work is ongoing for the characterisation of the toxicity of substances already identified of possible concern for human health. The endpoints addressed are mutagenicity, carcinogenicity, reproductive toxicity and systemic toxicity. QSAR and read-across prediction of the endpoints of interest for the 1100 plant-based substances of possible concern for human health will be collected for the next meeting of the WG at the end of February 2022.

Recent WG activities were focused on validation of the composition/toxicity information retrieved for around 891 plant species and coding of the relevant information. The aim is to make the data ready to be transferred to the EFSA database.



- WG Read Across ([EFSA-Q-2020-00413](#))

The first Read Across meeting of the year took place on the 12-13 of January, 2022. Experts provided contributions for the initial four steps of the read across framework. More specifically, progress was made on the steps of problem formulation, data gap analysis, analogue identification and analogue evaluation. The WG also formulated the remaining steps comprising the workflow and populated each step with the key elements to be considered.

- WG Risk Benefit Assessment (RBA)

The new WG had its first three (virtual) meetings on 20 December (2021), 12 January and 3 February (2022). The WG discussed the scope of the self-task mandate and possible directions to take for the update of the 2010 EFSA Guidance on the risk benefit assessment of foods. In order to further define the work of the WG, a scientific colloquium has been organised on 15-17 February, 2022 (link [here](#)), to collect stakeholder input on the needs for risk-benefit assessments of foods.

The discussions and key outcomes of the colloquium will help to inform an update of the EFSA Scientific Committee's Guidance on RBA, published in 2010. The Guidance will be used in a wide range of assessments related to the health risks and health benefits of fish consumption.

- WG Protocol Development

In the last meeting, the SC agreed to finalise work on protocol development, after the positive outcome of the pilot phase following the publication in 2020 of the "Draft framework for protocol development for EFSA's scientific assessment" (link [here](#)). The SC identified the need to include examples to make its use more user-friendly. The decision was to finalise the document as SC Guidance, incorporating the part on problem formulation, currently addressed by a contractor, and to publish the document for public consultation before finalisation. The activity of the WG has already re-started. Two meetings were held in December 2021 and January 2022. Considering the new tasks of the WG, it was felt useful to include new experts covering knowledge on evidence-based methods, protocol development including problem formulation, possibly coming from international organisations with remit similar to EFSA. The plan is to submit the draft guidance to the SC plenary meeting in July for a first reading.





## **5.2.5 Food and feed safety vulnerabilities in a circular economy: preliminary results of an outsourced project**

In the context of the Emerging Risks Identification process, EFSA has outsourced an extensive literature review to gather and evaluate the evidence for vulnerabilities of the circular economy (CE) for food and feed safety, plant, animal health and the environment.

Four CE macro areas were identified, corresponding to twenty-six CE practices. Following a stakeholders' survey based on a set of criteria, it was decided to focus the identification and characterisation of emerging risks on the analysis of novel sources of food and feed in a CE context.

Primary research about risks in this area is focused on insects and worms as food or feed and the substrate that they are reared on. Specific hazards identified in primary research in this review include the presence of: (i) Antimicrobial Resistant Genes; (ii) high levels of the heavy metals; (iii) uptake of allergens from the substrate e.g. gluten.

Other relevant examples of novel food and feed sources include aquatic food/feed sources (e.g. by-catch, micro/macro algae), fermentation of food waste, recycling of plant waste into flavouring, colouring and other additives/ingredients, biofuel waste into animal feed. Primary research about the risks of these sources is limited.

A large stakeholder's network is under construction. The extensive literature search conducted in the first part of the project will be complemented with other consultation processes aiming at refining the emerging risks identification and characterisation.

The Scientific Committee welcomed the presentation and congratulated EFSA for the interesting project. The external technical report will be soon published.

## **6 Other scientific topics for information and/or discussion**

### **6.1 Update on the EFSA ONE Conference 2022**

EFSA's Chief Scientist, Marta Hugas, informed the Committee about the forthcoming ONE conference (Brussels/Hybrid conference, 21-24 June 2022). The event will be co-organised with EFSA's sister agencies (ECHA, EMA, ECDC, EEA) and JRC. As the EU is pioneering the change towards a more sustainable future with the Green Deal, the Farm-to-Fork Strategy, as well as the Chemicals Strategy for Sustainability, the ONE conference aims to put food safety in the context of sustainable food systems.



The conference aspires also to bring together experts, scientists and policy makers from different backgrounds and discuss advances in food safety and identify forward looking actions. In addition, transitioning into a ONE Health approach requires use of integrated safety assessments and collaborations with Member States and international partners.

The structure of the conference will include the opening plenary session on Day 1, followed by two days of thematic (break-out sessions) and concluding with the closing plenary session on Day 4. The thematic sessions are grouped into four tracks: ONE Society (Food safety ecosystem, social sciences, EU research and policy), ONE Life (sustainable diets, safety of food innovations and infectious diseases), One Planet (sustainability and environmental safety assessments) and Many Ways (AI, NAMs, exposure to multiple chemicals, etc.). The year 2022 marks also the 20th anniversary of EFSA and the ONE conference will provide an opportunity to celebrate this important milestone. The draft programme is currently being finalised and will soon become available in ONE conference's website (<https://www.one2022.eu/>). The registrations have already opened.

## **7 Any other business**

### **7.1 Draft Scientific Opinion on Bisphenol A**

The Chair of the Panel on Food Contact Materials, Enzymes and Processing Aids (CEP panel) informed the SC on the ongoing work for the re-evaluation of the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA's conclusions on BPA are explained in a draft Scientific Opinion that is open for public consultation until 22<sup>nd</sup> of February 2022. EFSA organised a virtual meeting with stakeholders on 24 January 2022 ([link](#)).

The objectives of the meeting were to give a detailed overview of the approach taken in the safety assessment, to share the main conclusions of the draft Opinion and to address questions raised by stakeholders during the meeting. Stakeholders were encouraged to submit comments to the public consultation for consideration by the CEP Panel as they finalise the Opinion. The final Opinion is expected to be adopted by December 2022. A more detailed presentation will take place at the next Scientific Committee plenary meeting.

### **7.2 Update on Science Studies and Project Identification and Development (SPIDO) office**



An update was provided on the Science Studies and Project Identification and Development (SPIDO) office. Prior information has been published in the EU Official Journal in relation to the upcoming call for the roadmap for action on Evidence-based Risk Communication in the EU Food Safety System and the call for the roadmap for action for new risk assessment methodologies and harmonised animal welfare data. The two open calls will be launched in April 2022.

### **7.3 Highlights of draft agenda April 2022**

The SC was provided with a highlight of the topics to be presented to the next Plenary (108th meeting) scheduled on 27-28 April 2022. The dates for the 2023 Scientific Committee proposed meeting dates have also been circulated.

### **7.4 Useful info as new way of working**

As of the 1st of January 2022, the Risk Assessment Logistics (RAL) Unit is providing support for the organisation of the plenary and working group meetings within the new EFSA organigramme (link [here](#)). The use of functional mailboxes will be implemented, and this information was shared with the members of the SC.

### **7.5 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, interagency and international scientific cooperation and EFSA Stakeholders Meetings.

**End of the meeting**