SCIENTIFIC COMMITTEE
112th Plenary meeting

15 - 16 February 2023
9:00-18:00 / 9:30-13:00
MINUTES - Agreed on 14 March 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Webconference

Attendees:

- **Scientific Committee Members:**
Simon More (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, Dieter Schrenk, Dominique Turck, Maged Younes.

- **Hearing Experts[1]:**
Greg Paoli (for agenda item 4.3)

- **European Commission and/or Member States representatives:**
EC: Athanasios Raikos, Alexandra Tuijtelaars (DG SANTE Unit E1- for agenda item 4.3)

Carolin BENDADANI (DG SANTE Unit A1 – for agenda item 4.1)

- **EFSA:**
EFSA Executive Director: Bernhard Url (on day 1 until coffee break, for agenda item 4.3)

Risk Assessment Production Department (ASSESS): Guilhem De Seze

Risk Assessment Services Department (ENABLE): Nick Kriz

Chief Scientist Office: Carlos Gonçalo das Neves

Methodology and Scientific support Unit (MESE): Claudia Roncancio-Peña, Elisa Aiassa, Maria Chiara Astuto, Maria Bastaki, Fulvio Barizzone, Irene Cattaneo, Petra Gergelova, Djien Liem, Daniela Maurici, Alexis Nathanail.

Biological Hazards & Animal Health and Welfare Unit (BIOHAW): Frank Boelaert, Giusi Amore

Nutrition & Food Innovation Unit (NIF): Ana Afonso (for agenda item 6.1)

1. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Diane Benford (vice chair of the Scientific Committee). Claude Bragard, chair of the PLH panel, did not participate during the second day of the meeting. Josef Schlatter participated only on the first day until coffee break.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest

[1] As defined in Article 17 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/en/keydocs/docs/expertselection.pdf

[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

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 topics for discussion

4.1. Draft opinion on fluoride. (EFSA-Q-2021-00358)

The Scientific Committee was presented with draft sections of the Opinion and was updated on the status of the activities of the EFSA WG on Fluoride. An overview of the screening of literature on health effects was presented, which includes a systematic literature review for the effects considered to potentially impact the existing upper level of fluoride and a narrative review methodology for all other endpoints. The WG has completed the Risk of Bias (RoB) analysis for endpoints related to the central nervous system and on neurodevelopment and will proceed with the RoB analysis for the endpoint bone health. The data extraction for these endpoints has also been completed. Data extraction from literature on other health effects is ongoing. The assessment of the available evidence is in progress. The draft Opinion section on preliminary exposure assessment from food and drinking water was presented, while exposure from dental care products will follow. The draft section on the ADME properties of the ion fluoride and an update on the status of the physiologically based kinetic model to predict fluoride concentration in tissues and target organs were provided. The draft section on analytical methods used for fluoride detection and measurement in different matrices relevant to the sources of exposure in biological samples was also presented.

EFSA has engaged with the European Medicines Agency (EMA) for information on the current use of oral fluoride tablets in Europe and is examining public databases maintained by Member States for data on the use of oral tablets. EFSA will seek to engage with the U.S. National Toxicology Program (NTP) with the purpose of exchanging views on the literature review related to neurodevelopment.

4.2. Survey on the Guidance on Uncertainty in scientific assessment

The preliminary results of an internal survey on the implementation of the Guidance on Uncertainty Analysis (UA) in Scientific Assessments targeted to EFSA Scientific Committee (SC) and Panel Experts and to EFSA Scientific staff were presented.

Overall, 173 replies were collected, the participation rate was higher for Experts than for EFSA staff (about 60% and 25% respectively).

The results of the survey showed that, as expected, UA is implemented more frequently when performing risk assessment of mandates not linked to application dossiers. According to the survey, the user-friendliness and the time needed to apply the guidance seem to be the most critical aspect of the document. No critical issues were raised when considering the guidance from a scientific point of view. A discussion was held on the interpretation of the results and on the best way to enhance the usefulness of UA for the risk managers.

The SC Members were informed about the next steps on the activities related to UA.

4.3. Guidance on protocol development (EFSA-Q-2022-00289)

The draft guidance on protocol development was presented and the major revisions since the last plenary meeting outlined. These were based on feedback and input from the Scientific Committee, DG SANTE, and the EFSA scientific units and teams. In the revised guidance, further emphasis is given on the need for flexibility in EFSA protocols to produce timely and fit for purpose scientific assessments. The APRIO paradigm (Agent, Pathway, Receptor, Intervention, and Output) for

problem formulation is also further clarified and put into the context of each panel/unit/team. Further examples of the application of APRIO in a series of hypothetical mandates are included. The revised guidance also contains draft conclusions and recommendations. The draft template for protocols (Annex A to the guidance) was not discussed as only minor changes (mainly editorial) had been made.

The Scientific Committee expressed very positive feedback on the overall project and unanimously endorsed the draft guidance and template for public consultation (13 March – 15 May 2023). Public comments will be collected on the draft guidance only, while the template will be shared with the public for information, as it is a more practical tool for EFSA staff and experts.

An open, web-based information session on the draft guidance will be held on 28 March. Registration is open on the EFSA website. SC members were invited to register and inform their panels.

5. Feedback from the Scientific Committee

5.1. Overview of the BIOHAZ panel work programme

The BIOHAZ Panel and the EFSA BIOHAZ Team provide scientific advice on food-borne diseases due to biological agents, antimicrobial resistance, food hygiene, food microbiology, transmissible spongiform encephalopathies (TSE), methods for processing animal-by products, decontamination of products of animal origin.

Ongoing activities of the BIOHAZ Panel comprises, among others, the requests for scientific opinions on the use of water in processing of fruits and vegetables, on the persistence of microbiological hazards in food-processing environments, on the public health aspects of *Vibrio* related to consumption of seafood, on parasites in fishery products, on Chronic Wasting Disease in cervids, and on the efficacy of methods for producing pig processed animal proteins. Collaborations are ongoing on different matters with several EFSA units and with the other panels as for example on the use of artificial intelligence for literature screening, on the Qualified Presumption of Safety (QPS) for assessing safety of biological agents in applications for market authorisation of feed additives, food additives, food enzymes, food flavourings, novel foods, and plant protection products, etc.

Possible mandates in the pipeline include: for the area of food hygiene an update of previous scientific opinion on the use of tubs for the transport of fishery products, for the area of BSE (Bovine Spongiform Encephalopathy, mad cow disease) a mandate related to the BSE risk from ruminant collagen and gelatine, for the area of animal by-products (ABP) a mandate related to the use of category 1 ask as fertilizer, and possible applications in the framework of ABP and fertilizers legislation.

The panel has welcomed a new member, Romolo Nonno, starting his membership in January 2023.

5.2. Overview of CONTAM panel work programme

The CONTAM Panel and the EFSA CONTAM Team provide scientific advice on contaminants in the food chain and undesirable substances. An overview of the mandates dealt within 2022 and 2023 was presented. The mandates cover the areas of:

- Process contaminants: three opinions adopted in 2022-2023 (i.e. hydroxymethyl furfural (HMF) in feed for bees, nitrosamine (*N*-NAs) in food and acrylamide in food (genotoxicity),
- Natural toxins: four opinions adopted in 2022-2023 (i.e. Fumonisins, Deoxynivalenol, T2-HT2, Grayanotoxins) and three ongoing opinions (i.e. ergot alkaloids in feed, Ochratoxin A in feed and Ambrosia seeds),

- Environmental contaminants: one opinion endorsed for public consultation (mineral oil hydrocarbons) and three ongoing opinions (i.e. inorganic Arsenic, Polybrominated diphenyl ethers (PBDEs) in food, Polychlorinated naphthalenes (PCNs) in food and feed).

The Panel Chair also highlighted the areas where more guidance would be needed, for example on biomarkers of effects, BMD modelling of epidemiological data, margins of exposure and dose-response characteristics of genotoxic carcinogens, and scientific requirements to establish relative potencies among congeners. Some of these topics have been already included in the Scientific Committee Workplan for 2023-2024 and will be initiated as soon as resources become available.

The CONTAM Panel is also contributing to cross-cutting activities, as for example involvement of CONTAM Panel members and CONTAM Team staff in the WG Fluoride, in the WG on Protocol development, in the WG Genotoxicity, etc. This collaboration is crucial to ensure consistency in the assessments and in the methodologies used.

The CONTAM Panel Chair also raised a point on the importance of the alignment on terminology used within the Panel and across EFSA Panels when reporting, e.g. on health concerns/no health concerns. It was suggested to prepare a briefing note and have further discussion at the next plenary meeting in April.

6. Feedback from the EFSA

6.1. Presentation on the new Declaration of Interest tool

The SC members were presented with the new tool for the submission and assessment of declaration of interest. Experts were invited to contact the SC secretariat in case of doubts or issues to be resolved.

6.2. Authorship of Panel's opinions

The chair of the Animal Health and Animal Welfare Panel provided an overview of some aspects of the risk assessment process that are under discussion in the panel.

The panel identified some areas of improvement that have been presented for further reflection and discussion. These include, among others, better negotiation of the terms of reference with requestor; structure and organisation of long opinions and preparatory work done for WGs and discussion at the plenary meeting.

The Scientific Committee was also reminded that the authorship of EFSA opinions is explained and available at this link: https://www.efsa.europa.eu/en/efsajournal/pub/e14091

6.3. 20 years of zoonoses reports: looking back and moving ahead

The SC was presented with an overview of the data collection taking place to produce the EU One Health Zoonoses reports (EUOHZ). These joint annual EFSA-ECDC scientific One Health Zoonoses reports give an important and comprehensive account of standings after each year of joint efforts to reduce human burden of food-borne disease in the EU. The latest EUOHZ has been published in December 2022 (link here).

Zoonotic diseases are infections or diseases that can be transmitted directly or indirectly between animals and humans, for instance by consuming contaminated foodstuffs. Common foodborne zoonotic diseases in the European Union (EU) are caused by bacteria such as *Campylobacter* and *Salmonella*.

EFSA monitors and analyses the situation on zoonoses, zoonotic microorganisms, antimicrobial resistance, microbiological contaminants and foodborne outbreaks across Europe. It is assisted by the Network for zoonoses monitoring data, a pan-European network of national representatives and international organisations that assist EFSA by gathering and sharing information on zoonoses in their respective countries. Data collection on human diseases from Member States is managed

by the ECDC who has provided data on zoonotic infections in humans, as well as their analyses, since 2008.

In 2021, there was an overall increase in reported cases of zoonotic diseases and foodborne outbreaks compared to the previous year, but levels were still well below those of the pre-pandemic years. Campylobacteriosis remains the most frequently reported zoonosis, with the number of reported cases increasing to 127,840 compared to 120,946 in 2020. Meat from chickens and turkeys was the most common source. Salmonellosis was the second most reported zoonotic disease, affecting 60,050 people compared to 52,702 in 2020. There were 4,005 foodborne outbreaks in the EU – a 29.8% increase compared with 2020.

EFSA has updated its interactive tools (story maps and dashboards) on foodborne outbreaks, *Campylobacter*, *Salmonella*, and *Listeria monocytogenes* (link here). The story map provides general information on foodborne outbreaks and the foodborne pathogens, whereas the dashboards allow users to search and query the large amount of data EFSA has collected from EU Member States and other reporting countries since 2016.

6.4. Feedback from relevant WGs:

WG Bromide

Outcome of the public consultation on protocol

The SC was updated on the activities of the WG on Bromide that has undertaken the European Commission mandate (M-2021-00105) to assess the risks to human and animal health from the presence of bromide in food and feed. The public consultation was launched on 14 December 2022 and ended on 8 February 2023. The aim of this public consultation was to collect constructive input on the approach and strategy of the risk assessment for bromide as described in the draft protocol. The approach and strategy are guided by the scope of the mandate and the timeframe for delivery of the assessment. No comments were received.

The WG is reviewing literature associated with animal health, animal exposure through feed and transfer of bromide to food of animal origin. Screening of literature related to health effects of bromide in humans was outsourced and is nearing completion. Literature on the kinetics of bromide is under review. Data of bromide occurrence in food and water have been identified and a comparison to the existing MRLs as requested in the mandate will follow.

EFSA has engaged with the European Medicines Agency (EMA) for available information on adverse effects identified from the use of bromide for medical purposes. However, it was noted that exposure to bromide in the medical context is out of scope of the mandate which concerns the general population.

Regarding the presence of bromide ion in fish, algae, crustacea and seaweed originating from brominated contaminants, it was clarified that brominated compounds that do not release bromide ion are out of scope of the mandate, as specified in the Protocol. However, a targeted search focused on the potential release of bromide ion from brominated contaminants will be discussed in the working group.

Cross Cutting WG Gentox

The cross-cutting WG on Genotoxicity (ccWG Gentox) is currently working on two requests for scientific advice, both received from the Pesticides Peer-Review (PREV) Unit. The first is a request for assistance following a mandate from the European Commission on the genotoxic potential of

2,4,6-trichlorophenol (TCP), which is a metabolite of the active substance pydiflumetofen; and the other request concerns assessment of the genotoxic potential of buprofezin. For both requests the WG has made significant progress and the work will be finalised at the next meeting.

Furthermore, during the last WG meeting, an upcoming EC mandate about the genotoxic potential of styrene and styrene oxide was presented, following the EFSA Opinion by the Panel on Food Contact Materials, Enzymes and Processing Aids (CEP Panel). The WG provided input on how the mandate should be approached and will be later consulted to peer-review the Food Contact Materials WG's genotoxicity assessment.

Cross Cutting WG Nano

The cross-cutting Working Group on Nanotechnologies (ccWG Nano) is continuing to support EFSA's Panels and Units in the implementation of its Guidances on nanomaterials (the Guidance on Particle - Technical Requirements[4] and the Guidance on risk assessment of nanomaterials[5]). In view of the workload expected for 2023, two new experts were appointed to cover the expertise of nanogenotoxicity and feed additives risk assessment.

Furthermore, the SC was informed about the ongoing activities organised internally to facilitate a smooth and harmonised implementation of the Nano Guidances across different EFSA sectors. A meeting with the different EFSA Units was organised to ensure harmonisation on the implementation of the Guidances on nanomaterials across different sectors, gather input on the Guidances applicability domain and identify any issues and difficulties in the implementation process. Dedicated discussion on how to further support applicants will be held at the next WG meeting, which is scheduled for 21 February 2023.

WG Risk Benefit Assessment (RBA)

The Working Group on the update of the guidance for the risk-benefit assessment (RBA) of foods has expanded with five additional experts involved in RBA methodology development. The WG has reviewed a number of RBAs conducted since the EFSA 2010 guidance (https://www.efsa.europa.eu/en/efsajournal/pub/1673) was published with the purpose of understanding their limitations, exploring avenues for improvements and for fit-for-purpose options to support future RBAs within their context. The WG is currently exploring different methods and ideas and is capitalising on experience gained from related EFSA activities, such as approaches for risk ranking, one of the RBA methodologies, and from RBA for novel foods (food substitution RBAs).

EFSA has engaged with other agencies interested in applications of RBA in other contexts, such as the WHO and the US FDA, and is planning meetings with WGs of the European Commission and with Member States.

The Scientific Committee endorsed an extension of the timeline by six months (until June 2024) requested for finalising the guidance.

WG Epidemiological Studies

The SC was informed that work will restart to finalise the guidance on the risk assessment of epidemiological studies. Thor Halldorsson was reconfirmed as chair of the WG. Work will resume

[4] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6769
[5] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2021.6768

soon. The final complete draft of the guidance will be also published for public consultation before its finalization foreseen by spring 2024.

7. Any Other Business

7.1. Workshop for the Analysis and Evaluation of EFSA Panel System

The SC was informed about the workshop organised by EFSA in March 2023 for the analysis and evaluation of the EFSA panel systems. All panel chairs are invited together with some EFSA staff and some international organisations. The outcome will be further analysed to see if the present way of working of the panels is still fit for purpose or if changes are needed to make it more in line with present challenges.

7.2. Draft agenda April 2023 SC Plenary

The SC was informed about the main topics on the agenda of the 113th SC plenary meeting that will take place in Athens, hosted by the Benaki Phytopathological Institute.

7.3. SC Highlights for 2023

The SC was presented with a summary of the main activities included in the work programme of the Methodology and Scientific Support Unit (MESE) and in the SC panel for the year 2023.

7.4. Timelines for Panels renewal (2024-2029)

The SC was informed about the launch of the call for the renewal of the panel (link here). The call will close on 3rd April. The final list of the proposed new panels members will be presented to the Management Board in March 2024. The new panels will be appointed and will be effective as from July 2024 for a period of 5 years. A webinar to inform interested people has been organised by EFSA for the 7th March in the afternoon.

7.5. 2024 SC Plenary meetings

The meeting dates of SC plenary have been presented. Panels chair will infom the secretariat in case of conflicting dates with their respective panels.

7.6. Next meeting

The next meeting will be held on 19-20 April in Athens.