SCIENTIFIC COMMITTEE
113th Plenary meeting

19 - 20 April 2023
10:00-18:00 / 9:15-12:00
MINUTES - Agreed on 24 April 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Benaki Phytopathological Institute, Athens, Greece

Attendees:

- Scientific Committee Members:
  Simon More (chair), Susanne Hougaard Bennekou (vice-chair), Diane Benford (vice chair) Vasileios Bampidis, Claude Bragard, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Ewen Mullins (online), Søren Saxmose Nielsen, Josef Schlatter, Dieter Schrenk, Dominique Turck, Maged Younes.
- European Commission: Athanasios Raikos (online DG SANTE Unit E1)
- EFSA:
  EFSA Executive Director: Bernhard Url (online on day 1 until coffee break)
  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, Davide Arcella, Maria Bastaki, Daniela Maurici.
  Communication and Partnership Department (ENGAGE): Barbara Gallani, James Ramsay (both online)
  Biological Hazards & Animal Health and Welfare Unit (BIOHAW): Andrea Gervelmeyer (online)

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received for this meeting.

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 Independence1 and the Decision of the Executive Director on Competing Interest Management2, EFSA screened the Annual Declarations of Interest filled out by the Working Group 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.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

4. Scientific topic(s) for discussion

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

The European Commission requested EFSA to prepare a scientific opinion on fluoride in food and drinking water. Specifically, an updated consumer risk assessment will be performed for human health related to fluoride in food and drinking water. This risk assessment will take into account new information on the hazards of fluoride, available information on the occurrence of fluoride in food, and exposure assessment considering the levels of fluoride in food and drinking water and the contribution from other known sources of exposure.

An updated draft of the opinion was presented to the SC for information and discussion. The draft included summaries of the evidence from human and animal studies for the prioritised endpoints of neurotoxicity and developmental neurotoxicity and updated exposure assessment including contribution from dental care products. Following appraisal of the literature for neurotoxicity and developmental neurotoxicity (relevant health effects that may impact the health-based guidance values), more detailed assessment of the evidence was performed and additional checks for consistency of the risk-of-bias assessment were made during this process.

The appraisal of the literature demanded a considerable amount of time for detailed review due to the complexity of the studies of neurotoxicity and developmental neurotoxicity. The literature on other endpoints will be reviewed narratively. Data extraction of prioritised studies was outsourced and has been completed since the last plenary. Outsourcing of data extraction for other endpoints is underway.

The updated draft included refinements in sections of analytical methods for fluoride detection and of kinetic modelling. Contribution from dental care products and fluoridated salt and specific supplements (based on literature data) was added to the updated exposure assessment as anticipated at the last plenary.

The WG has been monitoring the outcome of the assessment conducted by the National Toxicology Program (NTP) on potential effect of fluoride exposure on neurodevelopmental and cognitive health in humans. EFSA contacted NTP experts, as recommended at the last SC Plenary, in order to exchange views and information possibly as part of one of the upcoming WG meetings. It has been announced that the NTP will hold a public meeting to present their final report on 4 May 2023.

The European Medicines Agency (EMA) was also contacted to request information on the use of fluoride tablets to be considered as part of the exposure. EFSA was invited to present the mandate to the CMDh3 (consisting of Members States representatives) who agreed to conduct surveys for relevant information and return to us by mid-May.

The WG envisions that endorsement for public consultation of the draft opinion will be probably done by end of 2023, with possible finalisation of the opinion by mid 2024.

4.2. WG Epidemiology: towards the finalisation of the guidance – workplan and timeline.

The draft Scientific Committee (SC) guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments was published in 2020 for a testing

[3] Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)

phase (EFSA Journal). It starts with an introduction of different types of epidemiological studies, an explanation of the strengths and limitations of different epidemiological study designs for establishing causality, and an explanation of reliability and relevance of studies. These sections are mainly addressed at non-epidemiologists. Following these introductory descriptions of key principles, the guidance explains the appraisal of epidemiological studies, including an overview of risk of bias (RoB) assessment tools and worked examples of their use for different study types.

In 2022, the SC decided to complete the work on the guidance. EFSA Panels and their respective supporting units/teams have been asked for their feedback from applying the guidance in their risk assessments and for suggestions regarding their Panel-specific issues that should be addressed in missing chapter(s) of the guidance document. This request resulted in several suggestions also for enhancing some sections of the existing guidance.

The proposal was discussed and several suggestions for further developing the outline of the content of the guidance were made. The WG will prepare an enhanced, detailed overview of the topics to be covered in this chapter and submit it to the SC for review by written procedure. The proposed workplan will also be revised with view to the possibility of extending the time available for finalising the guidance document. The guidance is scheduled for adoption by the end of the mandate of the present SC.

5. Feedback from the Scientific Committee

5.1. Overview of the Animal Health and Animal Welfare (AHAW) panel work program

The chair of the Animal Health and Animal Welfare panel, Soren Nielsen, presented the ongoing work program. Eight mandates are ongoing within the Animal Health area, and in particular: Avian Influenza Surveillance, Avian Influenza Monitoring, Highly Pathogenic Avian Influenza Vaccination, Freedom from Echinococcus multilocularis, One Health Surveillance, African Swine Fever, Aquatic Diseases - Listing and Categorisation and on Aquatic Diseases- Vectors. For the Animal Welfare area, two applications on stunning of animals are assessed. A series of farm-to-fork mandates, requesting to assess on-farm welfare and welfare during transport of several livestock species has been dealt with in 2021-2023. This work on animal welfare represented the biggest part of the workload and will be continued in the coming years on other animal species. The chair also clarified that because the welfare mandates cover several production systems and animal species (like aquatic animal species, horses, sheep and goats, mink, raccoon, dogs and foxes etc.) different expertise is needed in the panel.

In presenting the ongoing work, the chair also highlighted the need to better clarify upfront the terms of reference to then speed up the risk assessment process. Close dialogue with mandates requestor should help in clarifying what is needed, and it should frame the extent of the assessment to be performed.

Regarding risk assessment on animal welfare, a methodological guidance for the development of animal welfare mandates in the context of the farm to fork strategy was published in 2022. A taskforce and a standing WG have been established to cover the requests in this field.

5.2. Overview of FAF panel work program

This agenda item was postponed to the next meeting due to time constraint.

6. Feedback from the EFSA

6.1. Coordinated communications: an update on 2023 activities and recent EFSA coverage in the media

The head of Unit Communications, James Ramsay presented an overview of the activities in the area of media relations, social media, multimedia, website, multilingualism and on the EFSA Journal.
EFSA's target audience for communication is very different and comprises risk managers, risk assessors, policy makers, the public, etc., and therefore communication should be carefully targeted to the different audiences.

The SC was also informed about the EFSA campaigns as for example the #StopASF, #EUChooseSafeFood, plant health campaign etc. Experts were requested to help in the dissemination of the campaign among their networks whenever possible.

An update on the EFSA Journal was also presented, including the status of the Food Risk Assess Europe (FRAE), an open access repository of selected scientific articles from the national food safety agencies of the EU Member States. The articles are selected to inform the work of the European risk assessment community for food and feed safety and to leverage the knowledge generated by the national agencies for the benefit of all.

The SC was asked to provide suggestions on how to improve external communication activities. Several suggestions were discussed including the possibility to develop layman summaries of the most relevant opinions to provide clear messages to the public. Clarity of the abstracts of opinions would also help in providing support to risk managers. It will be desirable to reach high level of standardisation in the writing of abstracts of opinions.
EFSA will continue to work proactively for increasing the impact factor of the EFSA Journal, accessibility and clarity of opinions.

In the end, some reflections were made on what EFSA can do in external communication to further support the SC and the experts in general. It was suggested to increase the frequency of the reports of panel achievements after plenary meetings, and not limit this report to meetings open to observers.

6.2. EFSA's approach to the EU partnerships under Horizon Europe

The SC was presented with an overview of the EFSA's approaches to the EU partnerships. Under the Horizon Europe research framework programme, a new strategic instrument has been introduced, namely the European Partnerships. These Partnerships are large research programmes aiming to avoid duplication of research efforts and support European policies, including the Farm to Fork Strategy. They also may help to develop foresight capacity to increase preparedness for future threats.

As indicated at the last Risk Assessment Research Assembly (RARA), EFSA is committed to dedicate resources, as appropriate, in the European Partnerships within its remit, such as the Partnership on Chemical Risk Assessment (PARC), in which EFSA has signed up as associated partner.

EU partnerships are very important to the work of EFSA and they can help creating knowledge, methodology, data and tools that are useful for risk assessment and the work of the SC and other panels. A lot of science is produced that may be of use to the SC members to fulfill their work. The chief scientist office (CSO) is trying to position the EFSA EU partnership initiative in as many

agendas as possible to "raise" interest and support as this will at some point reflect in monetary and time commitments.

7. Any Other Business

7.1. Draft agenda June 2023 SC Plenary

The highlights for the agenda of the June plenary were briefly presented. The meeting will be open to observers.

7.2. Update on Panels renewal (2024-2029)

The call for the renewal of the panels closed on the 17 April. More than 1500 candidatures were received.The next step will be the eligibility screening and then the units could start assessing the CVs to arrive to a short list of candidates by end of the year. The list will be presented at the Management Board in March 2024 for final approval and the new members will be appointed as from July 2024.

7.3. Presentation of panel chairs to Management Board (MB) and Advisory Forum (AF) meetings

The SC was informed that the MB has asked to receive a short overview on panel activities on a regular basis. A calendar will be set up so that every panel chair will have the opportunity to present the ongoing work at the MB meetings.

For the Advisory Forum, the SC was informed that the highlights from the activities performed by the different panels will be reported on a regular basis. A calendar will be circulated for better planning of these 2 activities.

7.4. Experts Microsite:

The SC was informed that on the EFSA portal, a virtual space has been created where experts can find all relevant information that may be needed (e.g. how to fill in a declarattion of interest, experts reimbursement, etc). The SC welcome this initiative that will help experts working for EFSA to find all the necessary information in one place.

8. Next meeting

The next meeting will be held on 28-29 June in Parma and will be open to observers.

Annex to the minutes of the 113th Scientific Committee plenary

Report on the thematic discussion on the speed of Risk Assessment

A workshop was organised to gather feedback and ideas from the SC members on how to increase the speed of EFSA's risk assessments by ensuring actionable and fit for purpose advice. After a brief introduction, the SC members were divided in two break-out groups with the first one asked to suggest procedures and standard practices that EFSA panels could adopt **to optimise** the existing risk assessment framework mainly in terms of speed and efficiency of the process, whereas the second one was requested to suggest **innovation initiatives** (tools, databases, projects, …) that EFSA could carry out to reduce the time needed to deliver opinions.

The break-out group 1 discussed short terms and long terms measures to improve the speed of the risk assessment, based on current practise. In order to have a better understanding of the present situation, it was suggested to also consider long opinions and collect information on the time spent in the different phases of the risk assessment (literature search, protocol development, exposure assessment etc). Suggestions were made in order to balance the time invested in systematic literature reviews, probably not to be done for all opinions developed following generic mandates. For some opinions, simple literature search would be sufficient if a risk assessment is needed within a short timeframe. Criteria to decide upfront which sort of literature search is needed should be discussed and agreed. In relation to the definition of the mandate with the Commission, it was recognised that better framing of the Terms of questions would be needed as sometimes they are too broad and to address them, a lot of time is required.

The role of guidance documents was also discussed. The support of the cross-cutting WGs supporting guidance implementation was acknowledged as very useful. Guidance documents should be fit for purpose, and to the extent possible not open for different interpretation. At the same time, it should be possible to quickly update them, when needed. Development of guidance documents with other agencies were perceived as an opportunity but, at the same time, to be carefully considered as legal frameworks are different and may be subject to different requirements. The role of WG and Panel chairs was also highlighted as very important to steer the discussion and ensure effective meetings. With respect to the procedures, a declaration of interest "pass" to work across panels was suggested to speed up the activities of the various WGs.

The break-out group 2 also discussed procedures and standard practices to optimise the risk assessment framework. In this context, a large consensus was expressed on the need for a dialogue with the mandate requestor to agree on the right balance between the resources and time used versus the scientific excellence of the final deliverable. Problem formulation and protocol development were proposed to facilitate this dialogue. It was stressed that, if complemented with an upfront scoping review and supported by templates and tools (as the Web-based tool/repository for protocol development), they could really help in reducing the time needed for the risk assessment.

It was suggested to further invest in machine learning tools for systematic review of the literature and in standard critical appraisal tools. The development of repositories to capitalize the information generated for each opinion was also recommended together with the definition of standard structures for data extraction. These tools are likely to facilitate the possibility for outsourcing specific steps of the risk assessment process (e.g., title and abstract screening, data

extraction, etc.) and encourage the publication of the raw data in scientific publications. The development of a communication tool to replace TEAMS and of a software for recording and producing text during meetings were also mentioned.

Conclusions and Way forward

This was the first opportunity for the SC to brainstorming on this very important topic. Follow up discussion will be held in house and probably some measures will be soon piloted in order to ensure that the demand for a fit for purpose risk assessment in a reasonable timeframe is addressed.

End of the meeting