SCIENTIFIC COMMITTEE
120th Inaugural Plenary meeting

11-12 September 2024
9:00-18.00 - 9:00-13.00
MINUTES - Agreed on 8 October 2024

Location: EFSA Parma Board Room

Attendees:

- **Panel Members:**
  Susanne HOUGAARD BENNEKOU, Ana ALLENDE, Angela BEARTH, Josep CASACUBERTA, Laurence CASTLE, Tamara COJA, Amélie CREPET, Thorhallur HALLDORSSON, Ron HOOGENBOOM, Helle KNUTSEN, Kostas KOUTSOUMANIS, Claude LAMBRÉ, Søren SAXMOSE NIELSEN, Dominique TURCK, Antonio VICENT CIVERA, Roberto VILLA, Holger ZORN.

- **European Commission:**
  Athanasios RAIKOS (DG Sante E1)

  Eleni GKANA (2nd day) online (DG Sante E1)

- **EFSA:**
  Head of Department ENABLE - Nikolaos KRIZ

  Head of Department ASSESS – Guilhem DE SEZE

  Head of Communication – Barbara GALLANI (1st day a.m. and for agenda item 7.1)

  Chief Scientist office: Carlos DAS NEVES

  Methodology and Scientific Support (MESE) Unit: Claudia RONCANCIO PEÑA, Daniela MAURICI, Davide ARCELLA, Maria BASTAKI, Lucian FARCAL, Alicia PAINI.

1. Welcome and apologies for absence

The Head of MESE Unit welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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.

4. Tour de table of SC members and EFSA's management

[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

The Head of MESE Unit, charing the first part of the meeting, welcomed the participants and asked to the members of the Scientific Committee to introduce themselves and their background.

EFSA staff from the Methodology and Scientific Support Unit (MESE) and the EFSA management present at the meeting introduced themselves and their background.

5. Election of the chair and vice chairs of the SC

Elections of the SC Panel chair and two vice-chairs were carried out according to the Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups[3].

Susanne HOUGAARD BENNEKOU was elected as chair of the EFSA Scientific Committee. Thorhallur HALLDORSSON and Konstantinos KOUTSOUMANIS were elected as vice chairs of the EFSA Scientific Committee.

6. Scientific outputs submitted for discussion/adoption

6.1 Draft opinion on fluoride EFSA-Q-2021-00358

The draft opinion on the risk assessment of fluoride was presented to the Scientific Committee (SC) for discussion and feedback on the clarity of the presentation, appraisal, and interpretation of the evidence and on the approach to establish a Health Based Guidance Value (HBGV). The approach adopted by the working group (WG) was to examine whether the evidence available may warrant the revision of the existing tolerable upper intake levels for fluoride, established in 2005 by the Nutrition, Novel Foods and Food Allergens Panel, that are based on dental fluorosis in children and skeletal fractures in adults.
Three health endpoints were prioritised as most relevant to the assessment. These include effects on neurodevelopment and nervous system, the thyroid and bone health, for which a systematic literature review, including an appraisal for risk of bias was conducted, according to the SC guidance.
Input was provided from the WG on endocrine disruptors on possible effects on the thyroid and neurodevelopment, from EFSA staff of the Pesticide Review Unit on interpretation of histopathological evaluations, and from EFSA staff of the Nutrition Unit on the presentation of the evidence.
The proposed HBGV was supported by detailed assessment of the weight of evidence, according to the SC guidance. The uncertainty assessment on the proposed HBGV was underway at the time of this meeting.
The SC discussed in depth the evidence provided and the rationale of the proposed HBGV and proposed revisions for clarity and more detailed argumentation to support the rationale for the identified HBGV. The SC agreed to reconvene on 18 October for an online Plenary meeting to discuss the revised document and finalise conclusions. Upon agreement, the document will be tabled for endorsement for public consultation at the November plenary meeting open to observers.

6.2 Overview of the activities related to the revision of the guidance on the Margin of Exposure

The revision of the guidance on the use of the Margin of Exposure (MoE) approach was presented to the SC. This included an overview of the initiation phase of the self-tasked mandate, the presentation of the scoping document that was designed to outline the Terms

[3] https://www.efsa.europa.eu/en/corporate-pubs/establishment-and-operations-scientific-committee-scientific-panels-and-their

of Reference (ToR) and the findings from the public consultation that occurred over the summer. The ToR and the composition of the WG were also presented. The SC welcomed the initiative and raised some questions about the scope of the WG/mandate. Experts expressed a preference not only to revise the guidance for the use of the MoE for substances with both genotoxic and carcinogenic properties but also to develop a more comprehensive document that offers guidance on using MoE for various endpoints (such as neurotoxicity, developmental and reproductive toxicity, etc.). In addition, there were suggestions regarding the WG composition, in order to include members from relevant panels and from the SC.

A final point was raised on the importance of aligning this document with ongoing WGs focused on the use of default values in the absence of actual data and on the benchmark dose approach. The comments received will be considered to refine the ToR that will be presented and discussed at the November SC plenary.

6.3 Overview of the activities related to the use of biomarkers of effect in risk assessment EFSA-Q-2024-00128 and EFSA-Q-2023-00583

The SC was provided with an overview of the project and highlights of the draft Scientific Report ("Conceptual basis for the development of guidance for the use of biomarkers of effect in regulatory risk assessment of chemicals"). This was followed by information on the outcomes of the recent collaboration and engagement activities, that included a stakeholder workshop (24-25 Jun 2024) and a public consultation on the draft of the Scientific Report (19 Jun - 31 Jul 2024, link here). The feedback received within these activities is used by the WG to refine the draft Scientific Report, while separate reports for each of these activities will be included as Annexes. The updated version of the report will be presented to the SC at the November plenary for possible endorsement for publication (expected 20-21 Nov 2024).

Further, the outcomes of the discussions with stakeholders will be used for planning Phase 2 of the project on guidance development. Regarding this, the SC was informed and consulted on the plan for the co-creation of guidance with other organisations. The proposal includes the development of a draft guidance within a partnership established with other EU Agencies and with the support of EU Members States, engaged within a scientific Network. The SC welcomed the proposal for co-creation of a guidance on biomarkers of effects, reinforcing the importance of establishing a clear collaborative process, including the responsibilities and the needs for each organisation involved. To achieve this, EFSA will start communicating with partners regarding the joint project.

The SC will be informed on the status of the project and will be asked to provide comments on the new Terms of Reference for the development of the guidance in one of the next SC plenary meetings.

Feedback from the Scientific Committee/Scientific Panels/EFSA/EC
Overview of the SC work-programme 2024-2025
AOB

7. Other scientific topics for information/discussion

8. Discussion on structure of EFSA's scientific opinions

The SC was provided with a presentation to introduce the discussion on the structure of EFSA's scientific opinions. Four points were raised:

- Is the current structure of EFSA Scientific Opinions adequate and fit for purpose?

- Would the existing Guidance on structure and content of scientific opinion need adjustments?
- Are there new technical solutions that can be incorporated into the production process of opinions and can help increase impact/fit for purpose/adequacy (addressing new needs, speed, …)?
- Are there new formats that can help risk managers (EU/EP/MS) to make better use of EFSA outputs?

Some ideas have been already collected in different fora and can be summarised as follows:

- The conclusions of opinions must be as clear as possible, leaving no room for interpretation or ambiguity.
- It is crucial to clearly differentiate research from the regulatory context, as both differ in scope and objectives.
- It is important to have a background in each scientific opinion that provides the overall picture and refers to former deliverables/achievements (e.g. former scientific opinion(s) relevant for the topic at hand). Any changes/revisions to former risk assessment outcomes/conclusions/recommendations must be highlighted clearly and explicitly in the Scientific Opinion. A separate text on the historical context of the assessment is considered useful.

The "recommendations" section is considered not always useful, especially when referring to risk management measures if these were not specifically requested in the Terms of Reference. A possible way forward could be to replace the term "recommendations" by a different term that does not appear to interfere with the separate roles of risk assessors/risk managers.

All the comments received will be considered for the drafting of an internal document that will be presented to the EFSA executive director to agree on the next steps to improve the structure of EFSA's opinions.

9. Feedback from the Scientific Committee/Scientific Panels/EFSA/EC

9.1 Overview of the SC work-programme 2024-2025, background of ongoing mandates and Scientific Committee way of working

The SC was presented with a series of presentations in relation to the remit and areas of activity, the ongoing and future planned work for the Panel, and a number of good working practices for the Panel, e.g. organisation of plenary meetings, setting up of ad hoc WGs, the system used to share information and documents with the Panel, the discussion, preparation and adoption of panel outputs and the expected contributions by Panel members in preparation of and during plenary meetings.

The SC was also informed about a new EC mandate that was received to develop guidance on critical appraisal of evidence as part of the systematic review methodology and update the EFSA guidance on open literature review in the context of the Regulation (EC) No 1107/2009 (M-2024-00115). A SC WG will be established and a guidance on critical appraisal tools will be developed with deadline of 18 months from the kick-off meeting.

In relation to the ongoing work-program, the SC was informed about the appointment of Professor Qasim Chaudhry, also member of the DG SANTE Scientific Committee on Consumers Safety (SCCS), as a chair of the EFSA WG on particles risk assessment. This WG will revise the two existing EFSA guidances for the risk assessment of nanomaterials and will also have

a subgroup dealing with requests for advice from the units/Panels on the implementation of the existing guidance documents.

In addition, the composition of the WG on genotoxicity has been revised and Kevin Chipman, member of the CONTAM panel, was appointed as a chair of the WG responsible for revising the existing guidance documents for the genotoxicity assessment and also to provide advice to the Units/Panels on the applicability and implementation of the EFSA guidance for the genotoxicity assessment of chemicals. A scoping document is in preparation to explain the proposal for the revision of the genotoxicity guidance currently applied in EFSA. The draft will be presented and discussed at the November SC plenary. The scoping document will be then published for public consultation to gather feedback before finalization of the terms of reference. In the end, the SC was informed about the nomination of Josef Schlatter as chair of the WG with the mandate to review the 2010 guidance on the use of default values in the absence of actual data (mandate M-2024-00067).

Other activities were also presented including: 1) Guidance on the characterization of microorganisms in support of the risk assessment of products used in the food chain; and 2) Guidance on the use of read across approach in food safety assessments.

10.AoB

10.1 2024-2025 Calendar of SC Plenary meetings

121st 18 Oct 2024 online
122nd 20-21 Nov 2024
123rd: 19 - 20 Feb 2025
124th: 14 – 15 May 2025
125th: 2 - 3 July 2025
126th: 24- 25 Sep 2025
127th: 26 - 27 Nov 2025

The SC agreed to have all but the first meeting as physical meetings.