SCIENTIFIC COMMITTEE
127th Plenary meeting

24 - 25 September 2025
9:00-13:00 / 9:00-15:30
MINUTES – agreed on 17 October 2025

Location: Valencia, Spain

Attendees:

- Panel Members:
Susanne HOUGAARD BENNEKOU, Ana ALLENDE, Angela BEARTH, Josep CASACUBERTA, Laurence CASTLE, Tamara COJA, Thorhallur HALLDORSSON, Ron HOOGENBOOM, Pikka JOKELAINEN, Helle KNUTSEN, Claude LAMBRÉ, Søren SAXMOSE NIELSEN (2nd day), Dominique TURCK, Antonio VICENT CIVERA, Roberto VILLA, Holger ZORN.
- Hearing Experts[1]:
- European Commission:

Sabine AMSLER – DG SANTE E1(online)

- EFSA:

Executive Director: Nikolaus Kriz (online, only for the opening)

Head of Risk Assessment Services Department (ENABLE): Benedicte Vagenende (acting Head of Department, online)

Head of Risk Assessment Production Department (ASSESS): Guilhem de Seze (online)

Methodology and Scientific support Unit (MESE):

Claudia Roncancio Peña and Daniela Maurici

Maria Bastaki, Josè Cortiñas Abrahantes, Marios Georgiadis, Alexis Nathanail, Efisio Solazzo (online).

Feed & Contaminants Unit (FEEDCO): Montserrat Anguita Freixa (online, for agenda item 4.1)

Food Ingredients & Packaging Unit (FIP): Carla Martino (day 2 only, for agenda item 5)

Nutrition & Food Innovation Unit: Océane Albert (for agenda item 5)

1. Welcome and apologies for absence

The Chair welcomed the participants, apologise was received from Amélie Crepet and from Søren Saxmose Nielsen on the 1st day. Carlos Das Neves, EFSA chief scientist, also sent apologies.

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[2] and the Decision of the Executive Director on Competing Interest Management,[3] EFSA screened the Annual Declarations of Interest filled out by the Scientific Committee (SC) 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.

[1] As defined in Article 34 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] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf
[3] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

4. Scientific output(s) submitted for discussion/adoption

4.1 Draft Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain (EFSA-Q-2024-00438)

The draft guidance on the characterisation of microorganisms to support the risk assessment of products used in the food chain was presented to the Scientific Committee for discussion and possible adoption. This self-tasking mandate was established to develop guidance aimed at facilitating the preparation of applications for products intended for use in the food chain that contain, are derived from, or are produced using microorganisms—whether genetically modified (GM) or not—which require risk assessment within EFSA's remit prior to their placement on the EU market. The draft guidance had previously been endorsed for public consultation by the Scientific Committee in November 2024. The public consultation was open until the 7th of February 2025 and circa 760 comments were received. Subsequent to the public consultation, the draft guidance was revised to incorporate the feedback received. The outcome of the consultation will be published alongside the final guidance.

The Scientific Committee was briefed on the comments submitted, the resulting modifications, and the rationale for any instances where changes were not made. The feedback received contributed to substantial improvements in the clarity and comprehensiveness of the document. Notably, the section outlining the scope underwent a thorough revision to enhance its focus and clarity. Overall, the approaches initially endorsed required minimal amendment, except for the chapter addressing the impact on the food/feed and gut microbiome. Following deliberation, this chapter was removed from the guidance; however, Panels may still request relevant data on a case-by-case basis.

Members of the Scientific Committee provided further comments and sought clarifications, all of which were addressed either in advance or during the meeting. Following these discussions, the guidance was unanimously adopted. It is anticipated that the guidance will be published within 28 working days of adoption. EFSA Panels responsible for the risk assessment of products containing, derived from, or produced using microorganisms will implement the guidance in due course and communicate relevant information to applicants accordingly.

4.2 Draft guidance on critical appraisal of evidence for food and feed safety assessments (EFSA-Q-2024-00584)

The Scientific Committee was presented with a draft of the 'guidance on critical appraisal of evidence for food and feed safety assessments', for first reading. During the meeting, the European Commission mandate was presented, as was the framework for the development of the work.

The structure and content of the various parts of the document were explained and a first version of the catalogue of existing critical appraisal tools (CATs) was shown. Several members of the Scientific Committee had provided comments and requests for clarification. All comments (provided previously and during the meeting) were discussed and ways to move the text forward were agreed. Some specific methodological issues that were discussed, included the relation of internal validity and methodological quality of a study, the importance of quality of reporting of a study in evidence appraisal and the judgement of the possible direction and magnitude of bias when appraising a study.

The draft guidance will be tabled for discussion and possible endorsement for public consultation at the November plenary meeting.

5. Other scientific topics for information/discussion

5.1 Consultation on toxicity testing strategies for food additives and novel foods

The Scientific Committee (SC) was consulted on the draft revision of the 'Guidance for submission for food additive evaluations' (EFSA-Q-2023-00713).

The SC was presented with the proposed toxicokinetic and toxicological testing strategy, which had been revised following the comments received after the public consultation phase. This was compared with other existing EFSA guidance documents on regulated products similar to food additives, particularly the 'Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283'. The existing differences in these guidance documents, owing to the different regulatory background for the safety evaluations, were described and explained to the SC members.

The SC was asked to comment on the approach proposed considering the already existing EFSA guidance documents and the implication of the approach proposed for the food additives. The SC agreed, provided the underlying reasons for the approach proposed are clearly communicated to applicants. In addition, the SC was asked whether future alignment on general principles for the toxicokinetic and toxicity testing strategy of food products across EFSA's sectors should be pursued under the guide of the SC. This proposal was endorsed in principle and will be further discussed at a forthcoming meeting.

5.2 Merging the existing weight of evidence and biological relevance guidance

A draft self-tasking mandate proposing the update of the 'Guidance on the use of the weight of evidence approach in scientific assessment' (EFSA Scientific Committee, 2017a) and the 'Guidance on the assessment of biological relevance of data in scientific assessment' (EFSA Scientific Committee, 2017b) and their merging into a single document was presented to the Scientific Committee. A draft scoping paper of the proposed activity and the reasoning behind was also presented for discussion and possible endorsement for public consultation.

The reasons for the update and merging of the two guidance documents were discussed. An extension of time for input in the scoping paper requested by a few members of the Scientific Committee was granted. The document will be finalized and endorsed by written procedure for endorsement for public consultation. At the next meeting, the outcome of the public consultation will be presented together with the finalized terms of reference. A working group (WG) of the SC will be set up to undertake this work. The SC endorsed the nomination of Thorhallur Ingi Halldorsson as the chair for this WG.

5.3 Key aspects proposed to be considered for genotoxicity guidance revision

EFSA is organising a Stakeholder Genotoxicity Guidance Revision Workshop in Brussels (3-4 November 2025) to present and discuss key aspects relevant to the on-going genotoxicity guidance framework revision with relevant stakeholders (Member States, industry, etc.).

A presentation was provided on the key aspects considered by the Genotoxicity Working Group – Guidance sub-group – in relation to the ongoing revision of the existing genotoxicity testing strategy and related documents. The key areas discussed are listed below:

- General Genotoxicity Testing Strategy
- Aneugenicity assessment
- Consideration of QSAR applicability
- Consideration of quantitative genotoxicity assessment
- Genotoxicity assessment of mixtures

- Bone marrow and target tissue exposure
- Genotoxicity assessment of nanomaterial

Feedback was provided on the consideration of use of in vitro data for aneugenicity assessment of substances. Another comment concerned closer collaboration with the WG on the Margin of Exposure that is also exploring and implementing quantitative assessment of genotoxic carcinogens. Overall, the SC was supportive of the proposals developed by the Genotoxicity WG and requested some clarifications on certain matters, which were addressed.

5.4 Brainstorming on Benchmark Dose Response (BMR)

During the SC meeting, a short presentation was given to define the Benchmark Dose (BMD) and to describe current practice for establishing BMR values according to EFSA, US EPA and WHO. These practices are rooted in biological expertise and aim to identify an appropriate threshold of adversity. The SC agreed that the establishment of BMRs for BMD modelling, and subsequent risk assessment, is endpoint-dependent and cannot be based purely on statistical grounds. Consequently, BMR values will not be the subject of investigation by the BMD working group.
In response to a question raised on whether it would be possible to agree on biologically relevant BMRs for common endpoints (e.g. liver weight, relative liver weight, body weight) to serve as starting points for EFSA panels conducting BMD modelling, both the complexity and the broad range of expertise required to derive common BMR values for each endpoint, were highlighted.
To assist Panels and Working Groups in selecting appropriate BMRs, the Methodological and Scientific support Unit (MESE) agreed to explore the feasibility of compiling BMR values from existing EFSA reports and opinions, together with all the information deemed useful (endpoint, animal species and strain, type of toxicity) and including the rationale supporting each selection.
Preliminary work has been done via a procurement and published on EFSA website (link here)
This repository would provide a starting point for new opinions requiring BMD modelling; however, the suitability of any candidate BMR (i.e., whether the value reflects the dose at which an effect becomes adverse) will still need to be assessed on a case-by-case basis.

The possibility of consulting other WGs of the SC to assess the possibility of setting such BMRs for common endpoints, which clearly need other expert profiles to derive such percentage change needed to be considered adverse was also discussed.

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

6.1 Feedback from the Scientific Committee:

6.1.1 Overview of the ongoing work-programme of the Food Additives and Flavourings panel (FAF) and Food Contact Materials panel (FCM)

An overview of the organisation and current workload of the FAF Panel for its 2024–2029 mandate was presented. The update included progress on the re-evaluation of food additives, with particular emphasis on sweeteners, as well as the workload related to new applications, flavouring assessments, and follow-up of food additive re-evaluations. High-priority requests from the European Commission were also highlighted.

An overview of the organisation and current workload of the Food Contact Material (FCM) Panel was presented. The update included progress on the processing of applications on the safety of FCM substances and of recycling processes used for plastic intended for food contact. The progress on more specific mandates, such as those on the definition of the requirements needed for the assessment of hazardous bisphenols, on the requirements for FCM intended for infants

and on microplastics released from the use of FCM was also given. The advancement on the safety assessments of phthalates and plasticisers, on extraction solvents, and on substances used to reduce microbial contamination from products of animal origin was finally highlighted.

7. AoB

The next SC plenary meeting will be held on 26-27 November in Parma, Italy. This meeting will be open to observers.