SCIENTIFIC COMMITTEE
125th Plenary meeting

14-15 May 2025
9:00-18:00 / 9:00-13:00
MINUTES - Agreed on 4 June 2025

Location: EFSA, Parma

Attendees:

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

- Hearing Experts[1]:
Josef Schlatter(for item 4.2), Dieter Schrenk (for item 4.3), Gilles Rivière (for item 4.5), Martin Wilks (for item 4.6)

- European Commission:

Athanasios RAIKOS, Eleni GKANA – DG SANTE E1(online);

- EFSA:
Head of Risk Assessment Services Department (ENABLE): Nick Kriz

Head of Risk Assessment Production Department (ASSESS): Tobin Robinson (ad interim), replacing Guilhem de Seze

Chief Scientist: Carlos das Neves

Methodology and Scientific support Unit (MESE): Claudia Roncancio Pena, Daniela Maurici, Petra Gergelova, Maria Bastaki, Irene Cattaneo, Alicia Paini, Laura Martino.

Food Ingredients & Packaging (FIP): Eric Barthélémy (for agenda item 4.5)

Nutrition and Food Innovation Unit (NIF): Ariane Titz (for agenda item 5.1.3)

Knowledge, Innovation and Partnership Management (KNOW): Bernard Bottex (for agenda item 4.4)

Pesticides Peer Review Unit (PREV): Arianna Chiusolo (for agenda item 4.6)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Angela BEARTH.

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] 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

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

4.1 Draft opinion on fluoride (EFSA-Q2021-00358)

The draft opinion on fluoride with revisions based on the outcome of the public consultation was presented to the Scientific Committee for discussion and possible adoption. Key comments submitted by the stakeholders and related aspects of the opinion, including terminology and reasoning in establishing health-based guidance values, were discussed. The SC reached agreement for clarifications to be made in the document. The draft opinion was unanimously adopted pending agreed language revisions. It will be published in the beginning of July.

4.2 Draft guidance default values: overview of the default values to be revised (EFSA-Q-2011-00852)

The list of default values proposed for a revision in the updated guidance, including both the default values already present in the existing 2012 guidance and the additional default values not tackled in the original document, was shared with the Scientific Committee. For each individual topic and related default values, the proposal for revision was presented and further aspects and considerations were discussed in detail. Comments and suggestions were noted and will be followed-up. It has been clarified that the updated guidance shall be a document applying to a wide range of the EFSA Panels' assessments rather than reflecting specific requirements applicable to specific areas. A first reading of the revised guidance is planned by the end of the year.

4.3 Draft statement on the Margin of Exposure (EFSA-Q-2025-00033)

The draft statement on the definitions and applications of MOE by EFSA (ToR 1 of the MOE revision mandate) was presented for endorsement for targeted consultation. Comments and suggestions received from the SC will be included in the final version of the document to be sent for targeted consultation to EFSA's panels in June. The statement will be tabled for possible adoption at the July plenary.

4.4 EFSA Horizon Scanning – consultation on identified signals

EFSA's preparedness for future risk analysis needs is one of the strategic objectives for EFSA. In 2022, the emerging risks identification and analysis workflow addressing Art. 34 of Reg. (EC) 178/2002 has been complemented with a "horizon scanning" workflow to ensure the identification and analysis of weak signals, trends and upcoming policy developments that could impact EFSA work program and/or strategy. Both workflows are run at least twice a year.

As part of the horizon scanning workflow, key EFSA groups among which the Scientific Committee, are consulted on the identified signals for possible feedback and additional information. The consultation was also an opportunity for the Scientific Committee to bring additional signals for the consideration of the KNOW Unit and the Chief Scientist Office.

4.5 Draft safety assessment of Food Contact Materials (FCM) substances present in food intended for infants below 16 weeks of age

The possible implementation of the EFSA SC guidance (2017) to the risk assessment of FCM substances present in food intended for infants below 16 weeks of age and for which a standard chemical risk assessment has not been performed was presented to the Scientific Committee and discussed. Comments were noted and will be considered for the implementation through a draft Annex.

4.6 Update on the draft opinion on the use and reporting of Historical Control Data (HCD) for regulatory studies

The methodology developed by the Panel on Plant Protection Products and their Residues (PPR)l was presented to the Scientific Committee, including changes made based on the public

consultation comments and on the outcomes from the testing by the German Institute for Risk Assessment (BfR) though two outsourced projects. The draft opinion, just peer reviewed by the PPR Panel, will be presented for adoption during the plenary in June. The Scientific Committee was also informed about the follow-up activities on communication and stakeholders' engagement.

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

5.1 Feedback from EFSA:

5.1.1 Consideration on length and readability of EFSA scientific opinions

At the last plenary (31st March 2025), the Scientific Committee was presented with the topic "Structure of scientific opinions", where some actions were identified to improve readability and length of EFSA's scientific opinions. The request for the panel chairs of the SC was to discuss these actions with the respective panels and come up with a list of possible actions to be piloted until next spring (2026), having a midway exchange towards the end of the year to provide feedback on the pilot.
Some discussion took place on what level the SC wants to implement some of these actions in relation to guidance development. Feedback from BIOHAZ and FEEDAP panels is shared for info as they have already discussed in their plenary meetings the actions to be piloted.
At the July SC plenary, the full list of actions per panel to be piloted until spring 2026 will be presented and discussed.

5.1.2 Finalisation of SC work-program 2026-2027

The EFSA Scientific Committee launched the consultation to collect proposals for the development of new cross cutting guidance and/or scientific opinions to be included in the work-programme 2026-2027.
The EFSA panels and the Units were consulted in autumn 2024 and a preliminary discussion on the proposals collected took place in the SC plenary in November 2024 and in February 2025. All the proposals were presented by the respective panel chairs. A total of 9 proposals were submitted from 5 panels, some of them were complementary and therefore were merged, while other proposals are addressing multiple areas and for practical reasons were summarised under one of the areas of work. In addition, during the discussion at the SC plenary in February 2025, additional proposals were made.
The following "common triggers" were identified from the proposals made:

1. EC developing roadmap towards phasing out animal testing for chemical safety assessments (to be finalised by the end of 2025),
2. Considering innovative approaches for risk assessment methodologies to overcome the difficulties encountered in the current way of working (e.g. component-based approach for mixtures assessment),
3. Improve alignment between sectors and consistency in the risk assessment of substances submitted/evaluated under different Regulatory framework.

EFSA initiated consultation with the i) Advisory Forum ii) relevant EU agencies iii) DG Sante Scientific Committee for Consumer Safety and iv) the EC to gather feedback (by replying to a set of questions), to identify priorities, ongoing work at different levels and to explore possible synergies for the future.
To support the prioritisation, EFSA has considered the following elements:

i) The cross-cutting nature of the activity, and how many panels are impacted by the initiative,
ii) Alignment of the proposals with EFSA's strategic priorities and other EU relevant priorities (e.g. OSOA),

iii) Existing activities in EFSA, that allow to work together on a specific initiative,
iv) MS feedback and priorities,
v) EU relevant agencies feedback and priorities,
vi) EC priorities according to needs in the regulatory environment

The SC, as outcome of the discussion, identified two priorities to be included in the work-programme 2026-2027:

- Guidance on the establishement and application of relative potency factors
- Guidance defining a tiered approach for an ADME testing strategy and on the use of kinetic data and qualification/validation of Physiologically based kinetic (PBK) models in human and environmental risk assessment

The final proposals for Scientific Committee work-programme 2026-2027 will be published in the EFSA's website.

Priorities already identified for 2025-2026 were confirmed, namely:

- Revision of the "Guidance for the risk assessment of botanicals and botanical preparations" (EFSA J, 2009). The revised guidance will also include considerations of substance of natural origins used as food contact materials.
- Merging of the "Guidance on weight of evidence approach (Efsa J, 2017) and "Guidance on the assessment of biological relevance" (Efsa J, 2017), to produce one practical guidance covering both aspects.

5.1.3. Use of the Margin of exposure (MoE) approach in the safety assessment of fennel fruit preparations – for information and discussion

The European Commission (EC) requested EFSA to evaluate the safety of preparations from the fruits of sweet and bitter fennel (*Foeniculum vulgare* Mill. and *Foeniculum piperitum* (Ucria) C.Presl) in the framework of Article 8(2) of Regulation (EC) No 1925/2006 on the addition of substances other than vitamins and minerals to foods. These preparations contain estragole, a *p*-allylalkoxybenzene, whose mode of action includes metabolism to a metabolite capable of binding to DNA.

In a protocol, which underwent public consultation in 2023, the NDA Panel proposed to use the MoE approach in the assessment in line with what was used by the FEEDAP Panel in 2022 (for which the Scientific Committee was consulted). When genotoxic carcinogens are present in a food, the MoE approach is only applicable when the genotoxic carcinogen is an unavoidable chemical or an avoidable impurity in a mixture. As the NDA Panel did not consider that all uses of fennel fruit preparations fell within the before-mentioned scope of the MoE approach, a distinction was made by the Panel between food groups and their uses to which the MoE was applied and to which it was not applied. To verify the correct application of existing Scientific Committee guidance documents on the matter, the NDA Panel decided to ask the Committee for advice on the approach taken. The Scientific Committee proposed to slightly revise the wording of the current draft and asked to consult the cross-cutting Working Group on genotoxicity on the hazard identification and hazard characterisation steps. Note a posteriori: The WG genotoxicity confirmed the assessment made regarding the genotoxicity of estragole.

5.2 Feedback from the Scientific Committee:

5.2.1 Overview of the ongoing work-program of Contaminants in the food chain CONTAM and Food Enzymes FEZ panels

Work-program Panel on Contaminants (CONTAM)

The Chair of the Panel on Contaminants in the Food Chain (CONTAM), Helle K Knutsen, provided an overview of the recent and on-going activities and achievements. The CONTAM Panel and the EFSA CONTAM Team provide scientific advice on contaminants in the food chain and undesirable substances such as natural toxins, mycotoxins and residues of unauthorised substances mainly through generic mandates. To address the work programme 2025-2027, the Chair listed the 16 current CONTAM Working Groups in the remit of the Panel. The Panel chair provided an overview of the key aspects of the adoptions and public consultations foreseen in 2025, namely:

- Update of the Opinion on perchlorate in food
- Scientific opinion on the derivation of a health-based guidance value (HBGV) for delta-8-tetrahydrocannabinol (Δ8-THC)
- Risk related to the presence of plant lectins in food
- Update of the Opinion on Emerging and Novel BFRs in food
- Update of the Opinion on PCDD/Fs and DL-PCBs in food and feed

The Chair also highlighted the foreseen work programme for 2026 and 2027, and the main needs to develop the risk assessment on contaminants, i.e. guidance on the establishment/application of Relative Potency Factors, guidance on the qualification/validation of PBK models used for risk assessment, guidance on the selection of BMR for BMD modelling of most common endpoints from animal studies and guidance on BMD modelling of human data. The CONTAM Panel held its 150th Plenary in March 2025 and an overview of the CONTAM outputs and their impact regarding, e.g. citations, downloads, Altimetric scores and media coverage was given.

Work-program Panel on Food Enzymes (FEZ)

The Chair of the Panel on Food enzymes (FEZ), Holger Zorn, provided an overview on the FEZ panel, the food enzyme safety assessment and challenges ahead. The current FEZ panel was established in July 2024, consisting of 13 members with expertise on food chemistry, food technology, molecular biology, microbiology, genotoxicity, general toxicity, pathology, immunology and dietary exposure.

The general food law and the sectorial law in Europe mandates the FEZ panel to provide scientific advice on the safety of enzymes that are used to manufacture foods. The FEZ panel delivers this task by evaluating enzyme applications submitted to the European Commission and publishing the evaluation in scientific opinions. This task is done with strong support of the EFSA staff team on enzymes. EFSA has published about 390 scientific opinions on food enzyme safety assessment and received about 50 new applications per year. Currently, the FEZ panel has about 140 applications to evaluate. The workload, legal deadline and consistency across hundreds of scientific opinions are the main challenges of the FEZ panel and the EFSA staff team. The chair presented the workplan for 2025 and 2026.

The trend of using enzymes to produce foods or food ingredients is increasing. The chair explained the legal definition of food enzyme in the EU, which is an intermediate enzyme product before marketing. This definition is important to understand the interplay between the food enzyme safety assessment and the safety assessment of other regulated products such as food additives, food flavorings, novel foods and protein hydrolysates for special populations. It is worth noting that the same food enzyme can also be found in feedstuff as a feed additive.

To support applicants in preparing good quality technical dossiers, the FEZ panel provides two guidance documents and one webtool. One guidance document outlines the safety assessment approach and data requitement (EFSA J, 2021), the second guidance document provides a catalogue of food manufacturing processes to which food enzyme may be added (EFSA J, 2023). The webtool enables calculation of cumulative chronic dietary exposure to food enzymes via regular diet.

6. AoB

6.1 Evaluation of EFSA's performance

EFSA was established in 2002 by Regulation (EC) No 178/2002 ('Founding Regulation/General Food Law'). Prior to 2021, EFSA was required to commission external independent evaluations of its achievements in collaboration with the Commission every 6 years. Accordingly, EFSA published evaluations in 2005, 2012 and 2018 (the latest evaluation, covering the period 2011-2016).

Following the entry into application of the "Transparency" Regulation in 2021, which amended amongst others EFSA's Founding Regulation, it is now for the Commission to review EFSA's performance in relation to its objectives, mandate, tasks, procedures and location in line with Commission guidelines every five years.

The first EFSA performance evaluation to be carried by the Commission is due by 28 March 2026 (evaluation of EFSA's performance). In 2024, the Commission initiated the preparatory work for evaluating EFSA's Performance. Pursuant to Article 61 of the General Food Law, and in line with the evaluation criteria set out in the Commission's Better Regulation guidelines (i.e. effectiveness, efficiency, relevance, coherence and EU added value) the evaluation will focus on EFSA's performance in achieving its objectives, mandate, tasks, procedures and location.

As part of this evaluation, an external contractor is conducting various consultations, including targeted interviews with EFSA's key stakeholders, bodies, and external experts. Each Scientific Panel chair is now asked to designate at least one member of its panel for these interviews with the contractor. Interviews will be conducted online and the contractor may cover topics such as quality of scientific advice, efficiency of the risk assessment process, harmonization of risk assessment methodologies, cooperation with national risk assessors and EU sister agencies, divergence of scientific opinions, added value of EFSA's scientific advice.

7. Next meeting

The next SC plenary meeting will be held on 2-3 July at EFSA.