Location:Teleconference

Attendees:

- **Panel Members:**
  Susanne HOUGAARD BENNEKOU, Ana ALLENDE, Angela BEARTH, Josep CASACUBERTA, Laurence CASTLE, Tamara COJA, Amélie CREPET, Ron HOOGENBOOM, Pikka JOKELAINEN, Helle KNUTSEN, Claude LAMBRE, Søren SAXMOSE NIELSEN, Dominique TURCK, Antonio VICENT CIVERA, Roberto VILLA, Holger ZORN.
- **Hearing Experts[1]:**
  Josef Schlatter (for item 4.1)

  Dieter Schrenk (for item 4.2)

  Qasim Chaudrhy (for item 4.3)

  European Commission:
  Athanasios RAIKOS - DG SANTE Unit E1

  Frans Verstraete: Agenda items 4 (default values guidance) and 5 (margin of exposure guidance), agenda item 9 and 10.

  Francesca MORETTI: Agenda item 5 (margin of exposure guidance)

  Konstantinos EVANGELOPOULOS : Agenda item 6 (nano guidance)

- **EFSA:**
  Executive Director: Nick Kriz (day 1 until coffee break)

  Ad interim head of Risk Assessment Services Department (ENABLE): Bénédicte Vagenende

  Chief Scientist: Carlos das Neves (for agenda item 5.1)

  Methodology and Scientific support Unit (MESE): Claudia Roncancio Pena, Daniela Maurici, Maria Chiara Astuto, Maria Bastaki, Lucian Farcal, Marios Georgiadis, Petra Gergelova, Alicia Paini, Elisa Aiassa, Davide Arcella

  ED Office: Stef Bronzwaer (for agenda item 5.1)

  Communication Unit (COM): Anthony Smith (for agenda item 5.2)

  Integrated Data Unit (iDATA): Sofia Ioannidou (for agenda item 5.2)

1. Welcome, apologies for absence

The Chair welcomed the participants. Guilhem de Seze sent his apologies.

2. Adoption of the 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 Scientific Committee 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.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration(s) of Interest made at the beginning of the meeting, please refer to the Annex.

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

4.1 Draft revised guidance on default values (EFSA-Q-2024-00409)

The Scientific Committee was presented with a draft revision of the 'Guidance on default values and uncertainty factors to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data' for a second reading and possible endorsement for public consultation. This draft guidance focuses on the selection and application of default values and uncertainty factors to be used in EFSA's scientific assessments when actual measured data are lacking.
Following the initial discussion at the 128th SC Plenary in November 2025, the guidance has been updated to reflect all feedback received from the SC, including revisions and additional development of several sections. Further work clarified default body weight values, refined methods for conversion of test compound concentration in feed into daily dose in pregnant and lactating rodents, and extended the discussion of mechanistic studies, emphasising their importance in reducing uncertainty in risk assessment. Comments and observations from the SC were examined and deliberated, and the recommendations were thoroughly evaluated and formally approved.
The draft was endorsed for public and targeted consultation and will be published in March 2026. Consultation will run for about 8 weeks. Finalisation of the guidance is expected in summer.

4.2 Draft revised guidance on Margin of Exposure (EFSA-Q-2025-00490)

Since the publication of the EFSA Scientific Committee opinion in 2005, the Margin of Exposure (MOE) approach has been widely applied across EFSA's remit, including for contaminants, natural constituents and impurities in regulated products. Building on this work, the Scientific Committee initiated a self-tasked revision of the 2005 opinion with the aim of producing a comprehensive and updated guidance document.
The mandate calls for revision and update of the 2005 EFSA opinion on the use of the MOE for substances that are both genotoxic and carcinogenic, incorporating methodological developments and addressing ambiguities that have arisen over time . The SC was presented with an outline of the table of content of the revised guidance. Some comments and suggestions were addressed during the presentation and will be incorporated in the draft that will be tabled for first reading at the May plenary.

4.3 Draft scoping paper on Absorption, Distribution, Metabolism, and Excretion (ADME) and Physiologically Based Kinetic (PBK) modelling in risk assessment

The revised scoping document titled "Scoping Paper – Strengthening the Use of ADME/Toxicokinetic (TK) Data and PBK Modelling in EFSA Risk Assessment" was presented to the SC members. The revised version took into account EFSA's needs and the discussion points raised at the SC 128th Plenary in November 2025. The scoping paper was discussed, and comments were addressed during the meeting. The scoping paper containing the terms of reference, the

[1] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independence-policy-2024.pdf
[2] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/decision-ed-on-competing-interest-management-2024.pdf

engagement activities, and the timelines to develop a guidance was then endorsed for public consultation. The public consultation will be launched in March, and it will run for about 6 weeks. In the end, the comments received will be addressed and, if needed, the Terms of reference of the mandate will be revised before establishing a working group (WG) with the task to initiate the development of a guidance.

4.4 Preliminary discussion on draft protocol for the opinion on risk benefit assessment in fish (EFSA-Q-2025-00746)

The EC mandate, presented at the November 2025 plenary, calls for a risk-benefit assessment (RBA) of fish in the context of the combined presence of several contaminants. This mandate is the first opportunity to implement the updated RBA guidance published in 2024 (link here). It is also the first opportunity where MSs may engage with EFSA on a real case of RBA after the guidance update.
The SC was presented with the draft protocol for the RBA of fish for an initial discussion of the main assessment questions and the general approach.
The protocol is still under development since the WG had its first meeting only earlier in February. The discussion identified the challenges this assessment presents, primarily the difficulty with defining a 'reference scenario' to which fish consumption patterns can be compared, the complexity with multiple hazards within scope, the feasibility of assessing risks from contaminants based on evidence from human studies designed to assess the food as the unit for the assessment, the challenge of assessing risks and benefits of different types of fish that may impact different population subgroups, and the feasibility to assessment at country level. A completed draft of the protocol is expected at the next meetings of the WG and will be presented to the Scientific Committee for endorsement for public consultation.

5. Other scientific topics for information/discussion

5.1 Draft paper "Future of science"

The SC was presented with an outline of the EFSA's strategic scientific needs to address emerging challenges in food safety risk assessment, among evolving food systems and regulatory landscapes. This is part of the process for the preparation of the new EFSA strategy. To help the process, a core group of EFSA staff has drafted a paper that presents key scientific needs under five interconnected pathways. EFSA will need to submit this document to the Management Board group for the 2034 strategy in April 2026.

The SC was presented with five pathways along which to strengthen EFSA's regulatory science capabilities regarding innovation, methodological advances, one health, preparedness, and effective communication. The Chair welcomed the presentation and opened for discussion that raised suggestions:

- Quantitative Adverse Outcome Pathways are very helpful, but while they have been a priority for years, significant obstacles remain in implementation. Could Artificial Intelligence (AI) help to overcome long-standing barriers? The need to translate Adverse Outcome Pathways (AOPs) to policy should be brought to the attention of DG RTD.
- System-based approaches used in sustainability could be applied more broadly and become a fil-rouge across the five pathways.
- Sustainability and complex exposure scenarios are scientifically more developed than topics like microbiome but are often hampered by political sensitivities. EFSA should set its scientific agenda based on scientific needs rather than public opinion or political pressure.
- While the Biotech Act and other legislation may extend EFSA's mandate (it is still only a legislative proposal) EFSA should continue to operate within its current legal responsibilities while planning for the future.

- EFSA should draw lessons from past vulnerabilities to handle interconnected challenges (e.g. regarding the transition towards sustainable food systems).
- There is a need for a more comprehensive integration of the exposure concept, considering exposure across different life stages, to reflect real-world complexities.
- A clear distinction should be made between the concept of the "exposome" and the technical tools used to study it.
- Finally, a critical issue in the foresight process was highlighted, on how to move from identifying "weak signals" to deciding on which ones to take proactive, concrete actions.

Overall, the Committee expressed strong interest in the draft paper and welcomed the possibility to provide comments as soon as the paper will be made available.

6. Scientific report "Frequency of consumption of fish and seafood contributing to methylmercury exposure and consumer awareness of related national advice"

The presentation offered a comprehensive overview of the European survey on fish and seafood consumption and the degree of consumer awareness around the benefits and risks associated with different fish species, particularly those with higher mercury levels (link to the published report https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.9865)

The survey targeted adults, adolescents, and pregnant women in all EU Member States, Iceland, and Norway, using a combination of telephone and online methods. Two survey waves were conducted: one before and one after updates to national advice in selected countries, with a total sample of over 15,000 in the first wave and around 8,000 in the second.
Results showed that approximately 60% of Europeans are fish and seafood consumers, with taste, price, and desire for a healthy diet being the main drivers. An increase in consumption was observed between the two surveys, including for species with higher mercury levels, regardless of whether national advice had been updated.

Awareness of mercury as a contaminant was relatively high, especially among pregnant women, but overall awareness of other contaminants was low. Knowledge of the risks associated with fish consumption was generally lower than knowledge of benefits. Around four in ten respondents in countries with updated advice reported awareness of the advice, but this did not consistently translate into reduced consumption of high-mercury species.
The survey found that national advice had limited impact on actual consumption behaviour, with other factors such as taste and price being more influential. Family, friends, television, and health-related locations were key information sources, while official websites played a secondary role. The team suggested that communication strategies should consider audience segmentation and leverage trusted intermediaries.
In drawing conclusions, the presenters observed that while awareness of updated national advice often corresponds with self-reported changes in consumption habits, the data indicate that actual patterns are driven more strongly by factors other than awareness. They also highlighted several uncertainties and methodological limitations.
The surveys relied on food frequency questionnaires, which can introduce recall errors, particularly given the 12 months reference period. The two survey waves were conducted during different seasons, which may have affected consumption patterns independently of any real behavioural changes. Sample sizes were relatively small—500 per country, with only around sixty seafood consumers—limiting representativeness, especially for high frequency consumption estimates. Finally, the sampling approach for pregnant women may have introduced further biases.
The presentation concluded with acknowledgements to the experts, collaborators, and partners who contributed to the project, as well as to the European Commission for its support and engagement throughout the process.

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

7.1 Update on the project of guidance architecture

The project's background and deliverables were summarised. The project was started to improve clarity and retrievability of EFSA guidance documents (GD) and increase the efficiency, predictability, and engagement of GD processes. To address these needs, it delivered:
1) a revised Definition of EFSA GD with five GD categories by purpose, content, and adopting body;
2) a GD Catalogue and Library of EU Food Safety GD (the latter produced in collaboration with Advisory Forum members);
3) a unified Governance model for both cross-cutting and sector-specific GD and two new/revised processes: process for GD Work Programme (WP) and process for GD Lifecycle.
The Governance coordinates the WP ensuring that each GD is evaluated by the SC/SPs at least 5 years from publication or last evaluation and that each year, by November, the SC and all SPs update their plans for GD (new/to update). The WP will be publicly available on EFSA's website and regularly disseminated.
The revised GD Lifecycle includes a series of engagement modalities to select case-by-case depending on the GD and outline in the GD Mandate. It also implies drafting and executing an implementation plan for each GD as well as allowing a transition period after each GD publication and continuously collecting feedback on GD use (to provide input to the GD evaluation phase).

Next project steps include: 1) end of March 2026: release on EFSA's website of revamped EFSA GD webpage with new definition of EFSA GD and GD Catalogue;
2) Spring 2026: testing of new processes and formalization of procedures;
3) end of 2026: execution of new processes;
4) 2027: new way of publishing EFSA GD.

The SC welcome the results achieved by this project and the publication of the guidance catalogue on EFSA website.

8. Update on the revision of the Nano Guidance documents (EFSA-Q-2024-00439)

The Scientific Committee was presented with the recent updates related to the ongoing revision of EFSA's 2021 Nano Guidance documents (Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health and Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles).
The presentation provided an overview of the revised scope and structure of the draft Guidance, which have been refined in response to feedback gathered from various stakeholders during the first engagement activities held in 2025. These activities included a call for views on the mandate and terms of reference, the consultation on a scoping document, a workshop and ad hoc meetings with stakeholders, and the 15th NanoNetwork meeting with EU Member States, Agencies and international players[3,4,5]. Additionally, a refined workplan was shared for comments, considering

[3] https://www.efsa.europa.eu/en/events/workshop-risk-assessment-nanomaterials-and-materials-containing-smallnanoparticles-food-and
[4] https://www.efsa.europa.eu/sites/default/files/2024-11/minutes-wg-particle-risk-assessment.pdf
[5] https://www.efsa.europa.eu/en/events/15th-meeting-efsa-scientific-network-risk-assessment-nanotechnologies-food-and-feed

the need to incorporate major scientific updates (originally foreseen in Phase 2 of the current mandate) and to commence systematic reviews to support the guidance revision.
The Scientific Committee endorsed the revised workplan, merging Phases 1 and 2 of the original mandate and narrowing the scope to exclude environmental risk assessment of nanomaterials from this phase, due to the need for further scientific development and ad hoc expertise.

9. Overview of the work-program of Panels on Additives and Products or Substances used in Animal Feed (FEEDAP), Panel on Genetically Modified Organisms (GMO) and Panel on Nutrition, Novel Foods and Food Allergens (NDA)

Presentation work-programme FEEDAP panel

The chair of the FEEDAP panel, Roberto Edoardo Villa, presented an update on the main ongoing activities and achievements of the panel.

He recalled that the panel evaluates the safety and efficacy of feed additives, considering impacts on animals, consumers, users, and the environment. Most of the workload continues to concern additives under Regulation 1831/2003, which span several categories and require broad scientific expertise. A newer task is the assessment of feed for particular nutritional purposes (PARNUTs), a small but growing share of submissions. The panel also occasionally evaluates feed materials when specific safety concerns are raised by the Commission.

The chair described the panel's organisation, highlighting the collaboration between FEED unit drafting teams and five specialised working groups, each addressing a distinct part of the opinion. Increasing support from external advisors and Article 36 organisations contributes significantly to handling the workload.

In 2025, the panel adopted 121 scientific opinions—74 of them on new additives. Several opinions were finalised through written procedure, while others concerned renewals and re-evaluations of older additives. Stakeholder engagement remained strong, with more than 60 teleconferences and an increasing number of hearings, enabling early clarification of data needs.

The chair shared examples of notable assessments, including an additive for bees and bumblebees, amino acids produced with genetically modified microorganisms, renewals requiring additional consumer safety data, and botanical flavourings assessed with advanced modelling tools. He also mentioned an innovative additive aimed at reducing Salmonella in poultry.

Looking ahead, the panel expects a similar number of applications in 2026, including further PARNUT evaluations and several generic mandates such as environmental risk assessment for trace elements and development of PARNUT guidance. He noted ongoing work on 3-nitrooxypropanol used to reduce methane in dairy cows, following reports of adverse effects in Denmark.

The chair concluded by presenting the work plan for the coming year and emphasising the importance of maintaining strong communication with applicants as guidance documents evolve. He thanked the FEED unit team for its effective collaboration.

Presentation work-programme GMO panel

The chair of the GMO Panel, Josep Casacuberta, presented an update on the main ongoing activities and achievements of the panel.

The chair reviewed the past year's activities and outlined upcoming challenges for 2026. Because GMOs are regulated products, the work continued to focus on risk assessment of applications,

mandates received from the European Parliament and Commission, and the development of new guidance documents.

Challenges identified in the previous year were reviewed. A high number of renewal applications were expected—and indeed received—alongside with new applications. This led to a record number of outputs, some of which were particularly complex. Thanks were expressed to the Panel and Unit for their efficient work.

Increasingly complex GMO applications were highlighted, with multiple newly expressed proteins and more sophisticated traits. One case demonstrated significant variability linked to genetic background, prompting a change in the assessment approach to reach a conclusion under specific use conditions.

Two key mandates were addressed: reviewing the adequacy of the GM animal guidance and initiating a revision of protein safety assessment, incorporating advances such as AI-based structure prediction. Work began on implementing these advances into routine assessments.

A major focus was the development of a new regulatory framework for GMOs obtained through new genomic techniques. EFSA conducted a prospective literature analysis—an unprecedented effort—to support this process. This work will continue in 2026.

For the coming year, a high number of applications and renewals is again anticipated, with increasing complexity in traits and stacked events. Work is ongoing to optimise data requirements, including revising approaches for stacked event assessment and exploring possible data waivers, particularly for field trials, based on 20 years of experience. Efforts also continue to improve the clarity and conciseness of opinions.

The upcoming adoption of the new genomic technique (NGT) legislation will require extensive work on implementing and delegated acts, as well as new guidance for NGT plant applications. This is expected to be a significant but valuable task for the Panel moving forward.

Presentation work-programme NDA panel

Dominique Turck, Chair of the NDA Panel, presented an update on the panel's remit and ongoing work. The panel provides scientific advice on human nutrition to support EU legislation, covering both safety and health benefits, including assessments for health claims.

The panel handles five types of regulated product applications, with dossier quality varying considerably and often requiring clock stops. In 2025, most adopted opinions concerned novel foods and nutrient sources, alongside five health claim opinions and one on goat's milk based infant and follow-on formula. No applications for permanent labelling exemptions were examined.

Novel foods remain the core workload, with about 100 dossiers under evaluation and active collaboration with the Scientific Committee and crosscutting working groups. A major achievement was the updated cannabidiol statement adopted in February, which set provisional safe intake levels and clarified remaining evidence needs. Emerging dossiers increasingly involve alternative protein sources—such as cultured meat, fungi and microbial biomass—as well as pharmacologically active substances, including nootropics. Additional precision fermentation dossiers are expected following the Biotech Act discussion.

The chair also addressed Article 8 assessments of non-vitamin, non-mineral substances that may pose safety concerns. These evaluations focus mainly on plant preparations and operate without a formal application process, limiting interactions with operators. He outlined EFSA's role in producing generic opinions and informing potential regulatory decisions under Annex III of Regulation 1925/2006.

EFSA is currently progressing three mandates on fennel, berberine containing preparations and isolated hydroxycitric acid (HCA). The first fennel opinion was endorsed in June and extended following new exposure data; the berberine opinion has also been endorsed, with public consultation planned; HCA work is advancing similarly.

Feedback from the public consultation highlighted concerns about limited use of epidemiological evidence and the application of the Margin of Exposure (MoE) approach. Broader challenges persist, including unstructured data submissions, limited toxicological information and difficulties in assessing complex botanical mixtures, particularly for genotoxicity.

Looking ahead, the chair noted the arrival of further mandates (three ongoing and twelve under negotiation), the development of sectoral principles to harmonise Article 8 assessments and the need to provide clearer guidance to food business operators regarding data expectations. The chair highlighted the importance of the ongoing work at the SC for the update of the guidance on the use of the MOE approach, the revision of the guidance documents on genotoxicity testing strategies, weight of evidence approaches and botanical safety evaluation.

The chair closed by thanking colleagues involved in preparing the assessments.

10. Any other business

- Draft proposal for 2027 meeting dates will be shared soon via email.

- The SC was informed that an EC mandate for co-developing with ECHA and EMA a guidance on biomarkers of effects, has been received (M-2025-00074). Work has already started and will continue. The finalisation of the guidance is expected in April 2029 (link to the mandate https://open.efsa.europa.eu/question/EFSA-Q-2026-00116)

11. Next meetings

The list of the meeting dates in 2026 has been shared:

· 7-8 May, online

· 7-8 July in person, Parma

· 23-24 September online

· 18-19 November, in Parma (meeting open to observers)

An additional plenary meeting in April is under discussion and dates will be communicated soon.

Annex:

With regard to this meeting, Dr Pikka Jokelainen declared the following interest:

"I am a member of Emerging Infections Subcommittee (EIS) of ESCMID. The EIS was created to offer its strategic perspective to ESCMID, advising on matters related to the surveillance, monitoring, preparedness, and response to emerging infections. The EIS aims to timely recognise emerging infections by continuously monitoring and analysing epidemiological signals from different networks and sources, and to communicate and educate about emerging infections. The work does not include risk management tasks".

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of interest for the expert concerned.

With regard to this meeting, Laurence Castle declared the following interest:

"I participated in a one-day workshop on the revision of EU food contact materials (FCM) legislation, held by DG-SANTE at their offices in Brussels on 11 February 2026. The specific topic of discussion was the information requirements to support accountability. I participated as an individual in a private capacity, with my laboratory background with regards to migration analysis for compliance testing/enforcement for consumers interests. I did not participate in any risk management /decision-making tasks and these were anyway outside the scope of the workshop".

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a conflict of interest for the expert concerned.