

19-20 February 2025  
9:00-18:00 / 9:00-12:30  
MINUTES - Agreed on 11 April 2025

**Location:** EFSA, Parma

**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, Androniki NASKA (vice-chair NDA Panel), Søren SAXMOSE NIELSEN, Antonio VICENT CIVERA, Roberto VILLA, Holger ZORN
- Hearing Experts<sup>1</sup>:  
Qasim Chaudhry and Emilio Benfenati (for item 4.1)
- European Commission and/or Member States representatives:  
Athanasios RAIKOS, Eleni GKANA – DG SANTE E1(online);
- EFSA:  
Executive Director: Bernhard Url (day 1 until coffee break)  
Head of Risk Assessment Services Department (ENABLE): Nick Kriz  
Head of Risk Assessment Production Department (ASSESS): Guilhem de Seze  
Head of Communication and Partnership Department (ENGAGE): Barbara Gallani (for item 5.1.2)  
Chief Scientist: Carlos das Neves  
Methodology and Scientific support Unit (MESE): Claudia Roncancio Pena, Daniela Maurici, Maria Chiara Astuto, Maria Bastaki, Irene Cattaneo, Lucian Farcal, Marios Georgiadis, Petra Gergelová, Sara Levorato, Alexis Nathanail, Alicia Paini,  
Communication Unit (COM): Joana Sousa Lourenço, Anthony Smith

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Dominique TURCK, replaced by Androniki NASKA (vice-chair NDA Panel).

## 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<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management,<sup>3</sup> 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.

<sup>1</sup> 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>

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](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 The revised compendium on botanicals database

The Botanicals WG has updated and expanded with new information the open-source database – the existing published Compendium of Botanicals (link [here](#)) – which includes plants that are reported to be used in the EU as food, including use as food supplements, that may contain naturally occurring substances of potential concern.

The updated Compendium of Botanicals, to be published soon, contains information obtained from an extensive literature review of botanicals, along with information on adverse effects of substances of potential concern present in the plants. In addition to the data obtained from literature, also QSAR predictions were generated by three state-of-the-art QSAR platforms (VEGA-Hub, Danish EPA QSAR and T.E.S.T.). The endpoints for which predictions were produced are: acute toxicity (LD50), genotoxicity (AMES, in vitro/in vivo micronucleus, Comet, etc.), carcinogenicity, reproductive toxicity and systemic toxicity (hepatotoxicity, nephrotoxicity and cardiotoxicity).

An overview of the work performed on the Compendium by the WG Botanicals was presented to the SC, including a description of the plant and substances characterisation activities. The focus of the presentation and follow-up discussion was on the QSAR predictions of substances of potential concern identified to be present in botanicals during the plant screening activity. Specifics on the QSAR models, their reliability and applicability domain were also provided, together with the consensus strategy that was developed by the WG used to reach a final outcome on a single endpoint from multiple predictions that may have conflicting results.

After a fruitful discussion, the SC agreed to review the final updated version of the Compendium of Botanicals database to get a hands-on evaluation of the updated dashboard and new data in order to provide further feedback prior to the publication on the EFSA website, foreseen in Spring.

### 4.2 Draft guidance on read-across

The Scientific Committee was provided with an overview of the guidance developed within the self-task mandate of the Scientific Committee (M-2020-0093) and related question no. [EFSA-Q-2020-00413](#). The objectives of the mandate are to develop a framework and guidance on the use of read-across in risk assessment and to identify applicability domains for the use of read-across in food safety. The development included several iterations in which the guidance on the read-across approach was designed, described, discussed, and refined.

The draft guidance was proposed for endorsement for public consultation. The version presented reflects the comments and feedback received during the previous targeted consultation with the EFSA Panels. It provides a detailed explanation of the key aspects that need to be considered at each step of the read-across approach, serving as a support tool for the overall risk assessment process. Additionally, the document introduces background information, reviews existing frameworks and guidance, presents the context and requirements at EFSA, and discusses the applicability domain of the read-across approach.

The feedback received from the SC members refers to the possible applications of read-across and clarifications of different technical aspects or terms, especially regarding the uncertainty assessment steps (e.g., the acceptability of uncertainties, clarifications on the uncertainty workflow, and the overall uncertainty assessment). Additionally, it was mentioned that adding a section with conclusions could be beneficial for the readers. These comments will be taken into consideration by the WG to prepare a revised version of the guidance.

Following the presentation and discussion, the SC endorsed the draft guidance for public consultation, which is expected to be launched in mid-March 2025.



In addition, the SC was informed about the [workshop](#) that will be organised by EFSA on 27-28 March 2025 in Brussels, aiming to collect further views on this topic in general and on the guidance in particular.

#### **4.3 Draft guidance on risk assessment of food additives**

The SC was informed about the ongoing revision of the “Guidance for submission for food additive evaluations” ([EFSA ANS Panel, 2012, revised in 2020](#)) carried out by the FAF Panel. The revision started in November 2023, a first draft was endorsed by the FAF Panel and published for public consultation from 18 November 2024 until 21 February 2025 ([link here](#)).

The guidance describes the scientific data requirements to be considered by applicants when submitting an application for a new food additive or for a modification of an already authorized food additive under Regulation (EC) No 1333/2008.

In updating the guidance, the FAF Panel took into account: i) the experience gained in assessing applications for food additives; ii) consistency with EFSA's cross-cutting guidance documents and up-to-date risk assessment methodologies; and iii) alignment with the data requirements of other recent EFSA guidance documents on similar types of regulated products, i.e. food flavourings and novel foods.

A presentation was made summarising the main changes introduced in the new draft compared to the 2012 Food Additives Guidance. The discussion focused mainly on the revised tiered approach for toxicokinetic and toxicity studies to evaluate the core areas of safety assessment of food additives, i.e. genotoxicity, toxicokinetics, repeated dose toxicity (including subchronic, reproductive, developmental, chronic toxicity and carcinogenicity).

The SC acknowledged the update of the Food Additives Guidance and made some suggestions to improve its content, which will be considered by the FAF Panel together with the comments received during the public consultation before the final adoption of the guidance.

#### **4.4 Dietary exposure tools @EFSA**

This item focused on dietary exposure tools developed by EFSA highlighting methodologies, principles and underlying data needed to perform exposure assessments. An overview of the tools, explaining their development and use within EFSA was provided, emphasising the importance of combining chemical occurrence data with food consumption data to estimate acute and chronic exposure, ranging from deterministic to probabilistic models. It was showed how a deterministic tool computes the exposure to a population.

The different types of exposure tools developed by EFSA were presented. A practical demonstration of the DietEx (Dietary Exposure, [link here](#)) tool was provided, showcasing its features in a user-friendly interface and the ability for users to save and reuse templates, as well as exporting results to work in other applications (e.g. MS Excel). The item ended with a discussion about future perspectives, aiming to integrate features, simplify the access and harmonize the tools, offering a single point of access, and ensuring a consistent presentation of information (e.g. documentation, tutorials).

Finally, the plan for 2025 was detailed, including updates to the comprehensive food consumption database ([link here](#)), migration to a new platform for Food Additives Intake Model (FAIM - [link here](#)), and the release of an alpha version of a harmonized exposure tool in October 2025 for public consultation.

Questions were raised also about the methodology of self-report surveys for consumption data. EFSA explained the process, including the use of 24-hour recall and food diaries, and the measures taken to ensure accuracy. A concern about the accuracy of the tools and the number of decimals reported was raised and acknowledged by EFSA mentioning the ongoing efforts to improve the reliability of estimates and fixes of similar issues. The idea of integrating and unifying tools to simplify the access is supported by the SC. A suggestion to incorporate probabilistic modelling into



the tools was proposed, however EFSA explained that probabilistic modelling is more relevant for acute exposure assessments and retrospective assessments with sufficient input data.

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

### 5.1 Feedback from EFSA:

#### 5.1.1 Update on EFSA's guidance architecture

The project, started in April 2024, aims at increasing clarity about EFSA guidance documents (GD) and defining a new operating model for this type of EFSA scientific outputs. Currently there is not a commonly agreed process for deciding on the need for new GD or for revising an existing one, the expected content of guidance is not defined and the status of EFSA GD (e.g. if valid/obsolete/phasing out/...) is also not always reported. In addition, guidance are published under different output types and in different platforms (EFSA Journal being the main channel, Zenodo and EFSA website) and an easily accessible catalogue of EFSA GDs does not exist.

The project clearly identified the need for an overall Governance for GD and the creation and maintenance of a GD Work Programme. The need for the revision of the single GD lifecycle was as well proposed as a priority, since the current one is clearly incomplete.

A new definition of EFSA GD and GD categories based on their applicability, scope and content was presented, together with a preliminary catalogue of guidance, in which these documents are organised according to the new GD definition and categories and new metadata (e.g. application area, status, revision status). The Catalogue will be complemented by a section 'EU Library of Food Safety GD docs' (GD from MSs) and will be accessible internally and externally. Overall, these deliverables are expected to increase GD clarity and findability and facilitate the usage internally and for stakeholders, including applicants.

The need for new publication features for EFSA GD, enabling a more flexible approach to updating these types of documents was outlined. A high-level overview of the draft Target Operating Model (TOM) under development was given. The TOM will cover cross-cutting and sector-specific GD in terms of Governance (roles and responsibilities), Work Programme and single GD lifecycle. To increase predictability, the TOM will include mechanisms for engaging with third parties in GD Work Programme and will address how to seek interest of e.g. other EU Agencies in GD co-development.

Comments were made on the need to develop clear criteria to decide when a new GD is needed or when an existing GD shall be revised or marked as no longer necessary. These criteria will fall under the remit of the Governance for EFSA GD, along with the responsibility for ensuring their harmonisation and fit for purpose. The SC and EC will be consulted on a draft version of the TOM in summer 2025. A final version of the TOM will be released in the beginning of 2026.

#### 5.1.2 Social Science at EFSA

The use of evidence and expertise from social science at EFSA was first formalised in 2018. Social science is now a well-established function, with an in-house team providing research and advice services across the organisation with the support of external expertise, in particular the Working Group on Social Research Methods and Advice. The first appointment of a social scientist to EFSA's Scientific Committee for 2024–2029 marked an important step in these developments. EFSA's social scientists use primary and secondary social research to inform risk communication and the targeting of audiences for communication on scientific work and for public information campaigns. These research activities also support risk managers on sensitive or emerging topics



of interest. Social science approaches and methods are also used at an organisational level to support corporate initiatives.

EFSA's Social Science Roadmap is linked to the EFSA Strategy 2027 and was recently updated following a mid-term review and endorsed for 2025-2027 by EFSA's Management Team. The review took stock of progress on the objectives included in the Roadmap in 2022 and updated subsequent projects and targets for the coming three years.

Social science can also contribute to scientific risk assessment as has been done already at EFSA in a few cases. Part of the role of the social scientist member of the Scientific Committee is to help to identify areas or specific outputs that could benefit from this type of extended interdisciplinary approach.

The SC welcome the presentation and highlighted the position of social science across both risk assessment and risk management. The EFSA's social research support to Member States was mentioned in this context. The relevance of identifying possible "triggers" for social science support to risk assessment was discussed, and EFSA's social science team will explore this further. The discussion continued on how social scientists can support efforts to improve the accessibility of EFSA's scientific opinions. The work of a task-force led by the Chief Scientists Office was also discussed as relevant in this context. A regular exchange (every 6 months) between Panel Chairs/Coordinators and EFSA social scientists was suggested to flag future issues.

### **5.2.1 Overview of the ongoing work-program of FEEDAP and GMO panels**

#### **Work-programme FEEDAP Panel**

The Chair of the FEEDAP Panel presented the ongoing work of the Panel. The remit of the FEEDAP Panel is to assess the safety and/or efficacy of additives and products or substances used in animal feed and to evaluate their safety for the target species, the consumer of products of animal origin, the user, and the environment, as well as to assess the efficacy of the additives. The main work of the Panel is linked to the assessment of applications for the authorisation of feed additives under Regulation (EC) No 1831/2003, although on occasions, the Panel is asked to assess feed materials and other generic questions.

The Chair of the Panel provided details on the organisation of the work, the different working groups supporting the Panel and the support from the FEED Team of the FEEDCO unit. The majority of the opinions adopted by the Panel deal with applications for the authorisation of new feed additives or new uses of an already authorised product (Art. 4), the modification of the terms of authorisation for authorised products (art 13) and the follow up of inconclusive opinions. Approximately 26% of the applications assessed in the last year were for the renewal of the authorisations (Art. 14). Some work is still ongoing on the assessment of applications for the re-evaluation of existing products (Art. 10), which is mainly limited to botanical products and a few technological additives. The work on this is expected to be finalised by 2027.

Another important task of the Panel is the development of guidance documents which guide the applicants in the preparation of the technical dossiers. The Panel has adopted the update of two guidance documents in the last couple of years, that related to the assessment of user safety and the one related to efficacy and is taking an active part in the guidance on the characterisation and risk assessment of microorganisms used in the food chain, which was endorsed by the SC in November 2024. The Panel has also started the work on a self-mandate to develop a guidance document for the assessment of feed additives containing small particles including nanoparticles,



which is expected to be finalised by the June 2029. The Panel is also working on other generic questions, such as the 'Environmental risk assessment of additives containing trace elements: cobalt, copper, iodine, manganese, molybdenum, selenium and zinc' and the 'Request to EFSA and EMA for scientific and technical assistance on the development of a harmonised tool for calculating human dietary exposure to residues from veterinary medicinal products, feed additives and pesticides'.

Finally, the Chair of the Panel provided some statistics on the number opinions adopted by the Panel, which have steadily increased over the course of the year and reached approximately 1500 in 2025.

### **Work-programme GMO Panel**

An overview on the current activities of the GMO Panel and of the challenges ahead was presented. The GMO Panel provides scientific advice on food and feed safety, as well as environmental risk assessments primarily on GM plants but also on micro-organisms and animals. The main activities of the panel include the work on 1) the evaluation of applications for the GMO market registration, on 2) generic mandates received from the EC or self-tasked and on 3) the development of technical documents to complement applicable guidelines and provide recommendations.

About applications, the GMO Panel is currently assessing 13 applications and 17 applications for renewals of the authorisation. For some of the GM plant applications received in the last years, the assessment is increasingly challenging due to the high number of proteins to be tested. For this reason, EFSA initiated a self-task mandate to develop complementary/alternative testing strategies.<sup>4</sup> This activity is currently ongoing, and the scientific opinion is under public consultation and the GMO Panel is expected to adopt the opinion in June 2025. In the same period, June 2025, the Panel is also expected to endorse the scientific opinion on the new development in biotechnology applied to animals (NGT-GMA) for food and feed and other agricultural uses.<sup>5</sup>

The presentation also highlighted the activities of the GMO Panel to support the EC to develop regulatory proposals for new genomic techniques (NGTs)<sup>6</sup> and the upcoming challenges and opportunities of the GMO Panel might face such as the possibility to develop new guidelines to frame the risk assessment of plants obtained by NGTs.

### **5.2.2 Building SC work-programme 2026-2027**

In order to build the 2026-2027 work-programme for new cross cutting guidance and/or scientific opinions, 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. At this plenary, all the proposals were presented by the respective panel chairs and comments were collected in a draft document. With this document, EFSA aims to provide information on the topics proposed by the Panels and is starting the consultation with the i) Advisory Forum ii) relevant EU agencies iii) DG Sante Scientific Committee for Consumer Safety and iv) the EC. The aim of the consultation is 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.

<sup>4</sup> <https://www.efsa.europa.eu/en/events/webinar-protein-safety-assessment-gmos>

<sup>5</sup> <https://www.efsa.europa.eu/en/topics/topic/genetically-modified-animals>

<sup>6</sup> [https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology\\_en](https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en)



The outcome of the consultation will allow EFSA to identify priorities to build the Scientific Committee (SC) multiannual workprogramme. It is expected that discussion will take place at the SC plenary next May. To support the prioritisation, EFSA will consider 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 following "common triggers" were identified from the proposals made:

- EC developing roadmap towards phasing out animal testing for chemical safety assessments (to be finalised by early 2026),
- 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),
- Improve alignment between sectors and consistency in the risk assessment of substances submitted/evaluated under different Regulatory framework.

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.

The final proposals for Scientific Committee work-programme 2026-2027 will be re-discussed towards the end of the year to confirm priorities before initiating the activities in 2026.

### **5.2.3 Update on the project "Speed of risk assessment "**

The SC was presented with an overview and update of the Speed of Risk Assessment initiative, focusing on improving data readiness, process efficiency, available capacity, and fit-for-purpose conclusions to reduce the backlog and improve the overall efficiency of EFSA's risk assessment process. Further internal discussion will be needed before finalising a workplan.

#### **Feedback from Scientific Committee including its Working Groups**

##### **Cross-cutting WG Particle Risk Assessment - Advice**

In October 2024 the EFSA WG on Particle Risk Assessment (former cross-cutting WG on Nanotechnologies) was established. The WG is currently divided in two subgroups, Advice and Guidance. The SC was provided with an update on the activities of the WG Particle Risk Assessment –subgroup Advice, which is tasked to provide support to EFSA Panels & Units in the implementation of the 2021 EFSA Nano Guidance documents<sup>7,8</sup> and identify issues/gaps for the Subgroup Guidance to address in the context of the ongoing work of Guidance update. After the kick-off meeting of the WG Particle Risk Assessment as Plenary meeting in October 2024, one meeting of the subgroup

<sup>7</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/6769>

<sup>8</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/6768>



Advice was held to discuss requests for advice from EFSA Panels & Units. Additional meetings of the subgroup Advice and Plenary meetings with both sub-groups, to discuss key content issues for Guidance update, are planned in 2025.

The SC was also provided with an update on the outcome of the 14<sup>th</sup> Meeting of the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed (NanoNetwork), held on 26-27 November 2024 in Parma<sup>9</sup>. The EFSA NanoNetwork is a fit-for-purpose network with the aim to facilitate harmonisation of methodologies by sharing guidance, best practices and experience, promoting information exchange and cooperation in the area of Nanotechnologies.

### **Cross-cutting WG Particle Risk Assessment - Guidance**

The SC was provided with an update on the activities of the WG Particle Risk Assessment - Guidance subgroup, which is tasked to work on the update of 2021 EFSA's Nano Guidance (M-2024-00062<sup>10</sup>). After its establishment and kick-off meeting in October 2024, two additional meetings were held to start brainstorming on guidance update, allocate task among WG members and agree on an engagement plan. As a first step of the engagement activities foreseen, a "Call for Views" on mandate objectives and Terms of Reference was open for feedback from regulators and stakeholders from December 19<sup>th</sup> to February 14<sup>th</sup> 2025<sup>11</sup>. As a next step, the WG will analyze the input received from this preliminary consultation and refine the strategy for guidance update accordingly. Further initiatives to engage regularly with partners and stakeholders are foreseen throughout guidance development, such as the publication of a scoping document to gather input on the proposed structure and key elements of the updated Guidance, as well as the organisation of a dedicated workshop to discuss with interested parties.

### **Cross cutting WG genotoxicity – Advice**

An update was provided on the activities of the WG Genotoxicity – subgroup Advice. Three WG meetings have been held since its establishment in September 2024, to provide support to EFSA Panels & Units in the implementation of the genotoxicity guidance documents. The subgroup Advice will also support the work of the subgroup-Guidance by identifying issues and gaps in the existing EFSA genotoxicity guidance documents where an update is needed. In this regard, plenary meetings with the two subgroups are planned in 2025 to facilitate exchange and discussion.

### **Cross cutting WG genotoxicity – Guidance**

An update was provided to the SC regarding the on-going preparatory activities in anticipation of the kick-off meeting of the Genotoxicity WG – Guidance sub-group on the 31<sup>st</sup> of March. The Public Consultation of the scoping paper was concluded on the 31<sup>st</sup> of January and an overview was given on the type and content of comments received. Furthermore, information was shared on the current activities to further develop and refine the engagement activities with sister agencies, EC and all other relevant stakeholders. Lastly, the current expert composition of the WG was presented. The kick-off meeting for the revision of the guidance documents is planned for the end of March.

### **Update on guidance Cross-Cutting WG BMD modelling**

The SC was informed on the recent developments about the Benchmark Dose approach WG, its mandate and composition. The SC was further informed about the planning of first WG meeting that will be held online on the 11<sup>th</sup> of March. The meeting will be focusing on the feedback from the EFSA-RIVM meeting held on the 11<sup>th</sup> of February and the follow up actions of relevance for the BMD activities including drafting of user manual to guide the users in the application of the BMD

<sup>9</sup> <https://www.efsa.europa.eu/it/events/14th-meeting-efsa-scientific-network-risk-assessment-nanotechnologies-food-and-feed>

<sup>10</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00439>

<sup>11</sup> <https://www.efsa.europa.eu/en/topics/topic/nanotechnology>



guidance and in the interpretation of the outcomes of the BMD modelling. The SC was also updated on the ongoing training activities by EFSA to SC and panel members.

### **WG Biomarkers of effect**

The SC was informed on the nomination of expert Antonio Hernández-Jerez as the new Chair of the WG on biomarkers of effect.

Additionally, the SC was briefly informed about the ongoing activities of this project, which is now entering its Phase 2, focusing on guidance development. These activities include discussions with the EU Agencies, EMA and ECHA on the possible joint mandate to co-develop the guidance, the establishment of a new Advisory Group on biomarkers of effect (within the Advisory Forum), exchanges with the OECD on the envisaged international guidance, and the ongoing activities of the WG of the SC that supports this project.

### **WG Default values**

The SC was updated on the progress of the WG on Default Values and recent developments in the composition of the WG.

The current state of the art and the next steps planned for the mandate were presented. The WG concluded the initial phase evaluating the list of default values as present in the current guidance as well as additional default values identified in the preliminary phase as relevant to be included in the revised version. The proposal on the revision for each default value will be presented at the May SC Plenary and the SC will be requested to provide its feedback and possible endorsement.

The WG is currently discussing the possibilities of collaboration with the WG Margi of Exposure (MoE) for the cross over tasks, in particular with respect to use of the MoE for substances which are not carcinogenic and genotoxic. The SC was also informed about the needs to further develop the engagement activities which are currently explored internally.

### **WG Evidence Appraisal**

The SC was informed about the updating of the composition of the WG on evidence appraisal with two new members and the progress of the work towards the relevant guidance document (GD) as requested by the EC mandate. The work is done in close communication with EFSA colleagues from different Units, while colleagues from ECHA and EMA also participate in the WG. The interpretation of the Term of Reference 1 of the mandate by the WG was outlined and two important points were stressed: a) The primary focus of the GD will be risk of bias assessment (reliability). Assessment of relevance will not be part of the GD, but the concept and its relationship with reliability will be clarified; b) the requested catalogue of Critical Appraisal Tools (CATs) will focus on EFSA needs and experiences.

### **WG Fluoride**

The SC was informed on the outcome of the public consultation on the "Draft scientific opinion on updated consumer risk assessment of fluoride in food and drinking water including the contribution from other sources of exposure", held from 11 December 2024 until 9 February 2025. The EFSA WG Fluoride will address the comments received during upcoming meetings and come back to the SC with a final draft for possible adoption at the May plenary.

### **WG Margin of Exposure**

The SC was provided an update on the acceptance of the mandate and initiation of the working group (WG) tasked with the revision of the EFSA opinion on the Margin of Exposure (MoE). The key points discussed during the WG kick-off were presented. The experts agreed that EFSA should apply the term MoE and not Margin of Safety (MoS). However, when it came to define MoE, there



was some disagreement between WG experts on whether to use the term “reference point” (EFSA terminology) or “point of departure” (commonly used internationally). Due to time constraints and the need for additional information requested by SC, this will be discussed at the May SC plenary.

## 6. AoB

### 6.1 Preliminary list of strategic topics for next meetings in 2025

The chief scientist Carlos das Neves presented a preliminary plan for strategic and thematic discussion to be organized back to back to SC plenary in 2025. Topics on the agenda are for the moment: strategic discussion on the use of NAMs and the EU roadmap towards facing out animal testing, social science initiatives, EFSA strategic research agenda, environmental foresight for emerging risks identification. More topics will be probably considered at a later stage, according to emerging needs.

### 6.2 Proposal for 2026 plenary meeting dates

Meeting dates for plenary in 2026 were proposed and will be finalized at the May plenary

### 6.3 Feedback from Nov 2024 open plenary

The SC was informed about the positive feedback received following the survey distributed to the observers participating at the November SC plenary.

## 7. 2 Next meeting

The next SC plenary meeting will be held on 31 March online.