Location: Teleconference

Attendees:

- **Panel Members:**
  Simon MORE, Vasileios BAMPIDIS, Diane BENFORD, Susanne HOUGAARD BENNEKOU, Claude BRAGARD, Thorhallur HALLDORSSON, Antonio HERNÁNDEZ-JEREZ, Kyriaki MACHERA, Josef SCHLATTER, Dieter SCHRENK, Kostas KOUTSOUMANIS, Claude LAMBRÉ, Ewen MULLINS (only 1st day), Søren SAXMOSE NIELSEN, Dominique TURCK, Maged YOUNES.
- **Hearing experts:**
  Laurence Castle (for item 5.3)
  Jean-Charles Leblanc (for agenda item 4.1)
- **European Commission:**
  DG Dante E1 Unit: Athanasios RAIKOS and Eleni GKANA (2nd day)

  SANTE E4 (Pesticides): Silvia NICOLAU-SOLANO, for agenda items 4.1 and 5.1

  SANTE E2 (food additives): Katleen BAERT, for agenda item 4.1
- **EFSA:**
  Executive Director: Bernhard URL (only day 1 until coffee break and in the afternoon)

  Head of Department ENABLE - Nikolaos KRIZ

  Head of Department ASSESS – Guilhem DE SEZE

  Chief Scientist office: Carlos DAS NEVES, Yann DEVOS

  Methodology and Scientific Support (MESE) Unit: Claudia RONCANCIO PEÑA, Daniela MAURICI, Davide ARCELLA, Maria BASTAKI, Maria Chiara ASTUTO, Lucian FARCAL, Irene CATTANEO, Petra GERGELOVA, Alicia PAINI, Francesca RIOLO, Elisa AIASSA

  COM Unit: Tony SMITH

  Knowledge innovation and partnership Unit (KNOW): Gisèle GIZZI

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2,] EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific outputs submitted for discussion/adoption

4.1 Draft Opinion on Fluoride

The Scientific Committee (SC) was presented with chapters of the draft opinion on fluoride, related to the introductory sections and to the exposure assessment, for discussion and possible endorsement for public consultation.

The comments of the SC received during the last plenary meeting were addressed. The draft sections on exposure assessment included data sources, methodologies and outcome of the total aggregated fluoride exposure assessment. The latter included exposure from dietary (drinking water and food including discretionary salt) and non-dietary (oral hygien products) sources. The relative contribution of each of the major sources of exposure was presented. The chronic dietary exposure to fluoride was assessed according to four scenarios of water fluoridation, 2 scenarios based on concentration as derived from available occurrence data of fluoride in water (basic and water P95 scenarios) and 2 scenarios based on legal limits of water fluoridation set by Directive 2020/2184/EC on the quality of water intended for human consumption and Directive 2003/40/EC on the constituents of natural mineral waters (1.5 and 5 mg/L).

The non-dietary exposure assessment was based on fluoride concentration and consumption data for oral hygiene products obtained from the literature. Toothpaste was considered as the major regular non-food source of exposure to fluoride ion. Medicinal products under medical prescription or food supplements were not considered in this assessment, as they are not regular sources for the population. Use of F-containing oral tablets that do not require medical prescription was explored through an EU-wide survey of Member States in collaboration with EMA.

The SC endorsed the sections of the draft opinion presented for public consultation. The sections of the draft opinion on hazard assessment and remaining sections, will be presented to the SC for endorsement in the next plenary.

5. Other scientific topic for discussion

5.1 Draft concept paper for the revision of the guidance on the margin of exposure

The preliminary draft of the Margin of Exposure (MoE) concept paper was submitted to the SC for comments. The aim of the concept paper is to inform interested stakeholders about EFSA's plan to revise the SC opinion published in 2005 (link here) related to a harmonised approach for risk assessment of substances which are both genotoxic and carcinogenic, and to ask for comments on the proposals via a public consultation process. This process will allow for feedback on the proposed problem statement and related discussion points. The feedback received will be considered by EFSA when finalising the terms of reference, action plan, and timelines for the development of the guidance.

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

During the discussion, the SC provided comments that will be considered in the revision of the concept paper. The revised concept paper will be tabled for possible endorsement for public consultation at the May plenary.

5.2 Draft scientific report on feasibility study towards a guidance on the use of biomarkers of effect in regulatory risk assessment of chemicals (EFSA-Q-2023-00583

The SC was provided with an update on the ongoing activities on biomarkers of effect (EFSA-Q-2023-00583), specifically regarding the Scientific Report with the title "Basic concepts for the development of a guidance for the use of biomarkers of effect in regulatory risk assessment", that represents the main outcome of the first phase of the project (EFSA-Q-2024-00128). The report was made available to the SC for the first reading and discussion. It includes several aspects related to the context and scope of the work, the definition and description of biomarkers, and other concepts and discussion on the use of biomarkers of effect in risk assessment. These should create the basis of the next phase of the project and be considered for the possible guidance development. This work is supported by a mapping study that looks at relevant projects, publications and databases/tool for this area.

In addition, the SC was informed on collaboration and engagement activities for this project, that include the ongoing survey with Member States, and a stakeholder workshop on 24-25 June 2024.

The SC discussed and provided comments or suggestions for the improvement of the Report that will be considered for the next version that will be tabled at the May plenary for possible endorsement for public consultation.

5.3 Technical report "Principles that could be applicable to the safety assessment of the use of mixtures of natural origin to manufacture food contact materials".

The use of plant derived additives (fillers) to manufacture materials and articles of natural origin intended for food contact has triggered discussion and specific consideration for their risk assessment. To support a request from the CEP panel, EFSA started to collect and analyse approaches-used and experiences-gained with the aim to clarify principles for the assessment of substances derived from natural sources and used to manufacture food contact materials (FCM). A report was approved in October 2023 (EFSA 2023) and the summary of this report was presented to the SC.

This work was also triggered by the increasing interest in the use of substances obtained from renewable biological resources (non-fossil) to manufacture materials and articles? intended for food contact. They can be single substances or simple well-defined mixtures, but more commonly they are complex mixtures with a substantial fraction that is uncharacterised. The usual source materials are plant biomass and (to a lesser degree) animal biomass. Natural compounds and/or complex mixtures are assessed in several sectors under the EFSA remit dealing with regulated chemicals, including novel foods, food enzymes, botanicals, food and feed additives, food flavours and FCM. These sectors have been consulted to learn from their experience. Waiving part of the data requirements for substances derived from edible food sources (e.g. food as such or the non-eaten parts, and or food ingredients) seems acceptable. Substances that migrate and give rise to concern (based on their chemical, physical or toxicological properties), but are already present in the diet, may not be (re-)evaluated, but rather, their exposure from FCMs should be compared with that from the diet. All other components and impurities in the mixture should be assessed using the established FCM guidelines and cross-cutting EFSA guidance documents.

The SC welcomed the report and commented on the recommendation included in the end of the report.

5.4 Draft guidance on read across

The SC was provided with an update on the status of the Guidance on the use of read-across in food safety assessment" (EFSA-Q-2020-00413). The document was made available in advance to the SC, for discussion. The guidance provides a stepwise approach to carry out a pragmatic read across, with detailed explanation of the key aspects that need considering at each step of the assessment. In addition, different case studies, templates (e.g. for uncertainty analysis) and other support information are included, in order to help the users for the read-across application.

The SC was also informed on the collaboration and engagement activities planned until the end of the mandate and finalisation of the guidance (e.g. targeted and public consultation, workshop). The SC acknowledged that it is a very technical document, including detailed information to perform read-across assessments and made several suggestions for improvements. The comments provided by the SC will be considered in the revision of the guidance that will then tabled at the next plenary for possible endorsement for targeted consultation to the different EFSA panels and sister agencies.

6. Feedback from the Scientific Panels/EFSA/EC

6.1 Ongoing work-programme of the Panel Additives and Flavourings Panel(FAF)

The chair of the FAF panel provided an overview on the ongoing work-programme. The FAF panel is responsible for the safety assessment of food additives, flavourings and also to develop sectoral guidance. In 2023, 18 opinions were adopted by the FAF panel, eight of which related to the evaluation of dossiers for the renewal of authorisation of smoke flavourings primary products. At present, the Panel is dealing with a significant number of assessments related to dossiers submitted for new food additives and flavourings, while a backlog still exists for the re-evaluation of food additives permitted for use in foods as of January 2009. The re-evaluation programme has been significantly affected by delays in the submission of data requested for incomplete data packages often requiring follow-up. Call for data has been published in 2024, with more specific and targeted data requirements, tailored on the food additives included in the calls. The ongoing follow-up assessment of silicon dioxide (E 551) is requiring a lot of efforts not only from the FAF Panel but also from the supporting Units of EFSA and is aimed at completion by the end of June 2024, coinciding with the end of the terms of office of the Panel in its current composition. From the beginning of 2024, the FAF panel has adopted 3 scientific opinions and priority will now be given to the adoption of new food additives and new flavourings opinions submitted under the Common Authorisation Procedure.

6.2 Ongoing work-programme of the Plant Health Panel (PLH)

The PLH panel has the following activities : risk assessment for single plant pests, climate suitability assessment, commodity risk assessment for multiple pests, databases, research to reduce risk assessment uncertainties, outreaching the scientific community.

The risk assessment for single plant pests is currently done in 2 phases: in the first phase a rapid pest categorisation is done, then, after interaction with risk managers, the assessment may be closed or can continue with a second phase on quantitative pest risk assessment (probabilistic assessment with uncertainties and scenarios analyses), where a second opinion is issued. For the first phase, in the last year 17 pests were categorised for arthropods and 10 for plant pathogens. For the quantitative pest risk assessment (phase 2), these were conducted for 6 plant pests, for 2 of which also with scenarios of climate changes.
Upcoming work already started foresees still 18 pest categorisations (phase 1), for actionable pests identified by the Panel's commodity risk assessment, a categorisation of a large (more than 6000 species) group of beetles of broadleaved trees, and one quantitative pest risk assessment (phase 2).
New mandates are currently expected to update some risk assessment conducted previously based on new scientific evidence (e.g. on *Xylella fastidiosa*) or on the risk of new trade scenarios.
Sixteen opinions on Commodity Risk Assessment (High Risk Plants and requests of derogations to EU plant health law provisions) were published during the last 12 months. The *Xylella* host plant database has also been further updated and now it contains 696 plant species, and in 439 of them *X. fastidiosa* was identified with at least two detection methods.
Several Art.36 Grants have been awarded by EFSA to conduct research to reduce key uncertainties in the Risk Assessment of some new and emerging plant pests. For example: for *Xylella fastidiosa*, there are three projects investigating the biology of native insect vectors in Portugal, the biology of a new invasive American sharpshooter insect vector which was recently introduce in an area at the border of Spain and France, and the risk of *Xylella* for temperate trees and shrubs; one project is studying the European and global occurrence of plant pathogenic fungi of the genus *Colletotrichum*; another the European host range of the American elm borer *Saperda tridentata*; research is conducted in Europe and North Africa to study the epidemiology and control of the Citrus Black Spot disease in its first outbreak in the Mediterranean in Tunisia).

6.3 Overview of the architecture of EFSA's guidance portfolio:

The SC was informed about the main objectives of the new project on the Guidance Architecture Portfolio, which are: 1) Mapping and organising all EFSA guidance documents, 2) Developing a Multiannual Work Programme for revision/update of cross-cutting and sectoral guidance, and 3) Developing a roadmap for an EU-wide Food Safety / Risk Assessment guidance library.

The SC also started the annual review of existing cross-cutting guidance and the discussion on their possible revision. Procedural and cross-cutting guidance documents were considered in this Plenary, whereas chemical risk assessment and toxicology guidance documents (also cross-cutting, but relevant to some EFSA areas only) will be discussed at the May Plenary.

The SC did not prioritise for revision in 2024 any of the procedural and cross-cutting guidance documents. It was agreed that the project on the Architecture of EFSA's Guidance should produce a new document updating the current procedural guidance documents. To ensure harmonization of risk assessment methodologies applied by panels and WGs, EFSA was suggested to work on: 1) innovative fit-for purpose tools to simplify the implementation of the Expert Knowledge Elicitation (EKE) guidance document and 2) domain specific harmonized approaches for the Guidance on Uncertainty Analysis in scientific assessment.

The SC as well expressed the need to collect more feedback on the use of guidance documents related to the use of the weight of evidence approach in scientific assessment (EFSA J. 2017), on the assessment of biological relevance in risk assessment (EFSA J. 2017) and statistical reporting (EFSA J. 2014).

At the next plenary, the cross-cutting guidance documents related to chemical risk assessment will be reviewed.

6.4 Role of the EFSA Scientific Committee in strategic scientific advice

The role of the SC is to develop cross-cutting guidance documents and cross-cutting risk assessment and also to provide strategic scientific advice to EFSA. In addition, a central role is to ensure alignment and build links between Panels.

In relation to the role of providing strategic advice, the SC was asked to reflect on:
WHAT?
- What strategic scientific advice *[the scope, nature, focus, areas]* could the SC make to assist EFSA with the strategic objectives 1 of the EFSA strategy 2027 (i.e. deliver trustworthy scientific advice and communication of risks from farm to fork) and with the strategic objective 2 (i.e. ensure preparedness for future risk analysis needs)?
- What have been the key constraints and challenges faced by the current SC in providing strategic scientific advice to EFSA over the last 6 years?

HOW?
- What processes could the next SC implement to address these key constraints and challenges, and thereby provide ongoing, impactful and timely strategic scientific advice to EFSA?
- More generally: What recommendations would you make to ensure the next SC is as effective as possible in each of its roles within EFSA?

A general discussion was made to gather feedback that will be compiled in a document to be presented to the new SC that will meet for its inaugural plenary in September 2024.

7. Any other business

7.1 Draft agenda May SC Plenary

The SC was presented with a draft outline of the possible topics for the May plenary that will be held in Parma, Italy, as physical meeting.

7.2 Additional online SC Plenary 25th June

The SC was informed about a half-day extra plenary that has been scheduled on the 25th June in the afternoon to complete the ongoing work of the present SC.