

METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## Scientific Committee

### Minutes of the 110th Plenary meeting

**Held on 21-22 September 2022  
(Agreed on 13 October 2022)**

#### **Participants**

- Panel Members  
Simon More (chair), Susanne Hougaard Bennekou (vice-chair), Vasileios Bampidis, Claude Bragard, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Wim Mennes (day 1 online), Ewen Mullins (online), Josef Schlatter, Dieter Schrenk, Dominique Turck (online), Maged Younes (day 2).
- Hearing Experts<sup>1</sup>:  
Greg Paoli (online for agenda item 4.2)  
Javier Moreno (for item 6.2)
- European Commission and/or Member States representatives:  
Luis Vivas Alegre (online DG SANTE Unit D1, Farm to Fork Strategy)  
Athanasios Raikos (online DG SANTE Unit D1, Farm to Fork Strategy)
- EFSA:  
Bernhard Url, EFSA Executive Director (on day 1 until coffee break)  
Risk Assessment Production Department (ASSESS): Guilhem De Seze

Methodology and Scientific support Unit (MESE): Claudia Roncancio-Peña, Daniela Maurici, Elisa Aiassa, Maria Chiara Astuto, Fulvio Barizzone, José Cortiñas Abrahantes, Petra Gergelova, Djien Liem, Alexis Nathanail, Agnes Rortais, José Tarazona.

<sup>1</sup> As defined in Article 15 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/sites/default/files/corporate\\_publications/files/expertselection.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf)

Feed & Contaminants Unit (FEEDCO) Paola Manini (for agenda item 5.2.1)

Knowledge Innovation & Partnership Management Unit (KNOW): Didier Verloo and Bernard Bottex (for agenda item 5.2.2.)

## **1 Welcome and apologies for absence**

The Chair welcomed all participants. Apologies were received from Diane Benford, vice-chair of the Scientific Committee, Søren Saxmose Nielsen, chair of the AHAW Panel and Nik Kriz, Head of the ENABLE Department at EFSA. Maged Younes, chair of the FAF Panel, was replaced by the vice-chair Wim Mennes on the first day.

## **2 Adoption of agenda**

The agenda was adopted without changes

## **3 Declarations of Interest of Scientific Committee/Scientific 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 Panel 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 and/or possible adoption:**

### **4.1 Draft updated guidance on benchmark dose approach (EFSA-Q-2020-00137)**

The updates made on the draft guidance on the benchmark dose (BMD) approach, after the public consultation (i.e. comprising both public and targeted consultations) were presented to the Scientific Committee (SC). It was clarified to the SC that the comments and changes made were mainly of editorial and technical nature, and the amendments brought more information on the methodologies as well as more clarity on the rational and concepts used.

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<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)

The key changes made to the draft guidance were on (i) the inclusion of a harmonized set of models for quantal and continuous responses, (ii) the distributional assumptions (i.e. Bernoulli distribution for quantal responses & Normal and Log-Normal for continuous responses), (iii) the addition of a procedure to flag any potential lack of information in the data about the BMD, (iv) the definition of *ad-hoc* criteria to assess the uncertainty of the results obtained, (v) the development of a probabilistic interpretation of the results of the model and, (vi) the possibility to incorporate additional information in the BMD modelling through priors. Finally, the conclusions and recommendations were streamlined to provide a clear message to the user of the BMD guidance.

The next activities related to BMD, including the update of the R4EU BMD analysis platform foreseen by October 2022, a workshop/Info Session on the BMD methodology (probably by end of 2022 or beginning of 2023) and future activities on the use of the BMD approach for modelling human epidemiological data were also presented to the SC. The latter is further discussed in section 5.2.3.

After having reviewed the changes made to the draft guidance, the SC unanimously adopted the guidance on BMD approach. The publication will be due in the coming weeks and in line with the current procedures.

#### **4.2 Draft guidance on Protocol development ([EFSA-Q-2019-00256](#))**

The draft guidance (GD) on protocol development (PD) was presented to the SC members for a first reading.

The background of this project, its terms of reference (ToRs), scope, structure of the draft guidance and the working group (WG) composition were introduced. In addition, the SC was presented with the framework for problem formulation (PF) (including the new 'APRIO' paradigm - Agent Pathway Receptor Intervention Output) that was developed by Risk Sciences International (RSI) via an EFSA outsourced project ([link](#)). It was explained that this framework for PF was revised by the WG and integrated into the draft GD.

The guidance aims at providing a harmonised yet flexible framework for developing or updating protocols for EFSA 'generic mandates', i.e. mandates not related with applications of regulated products and defined by Art. 29 and Art. 31 of Regulation (EC) 178/2002, and Art. 43 of Regulation (EC) 396/2005. It was outlined that these mandates are

relevant to all EFSA scientific panels and units, including those mostly dealing with applications. It was also specified that the GD is useful especially for the cases when domain-specific guidance does not already exist and that the process for protocol development described in the GD starts after the acceptance of the mandate.

The starting point was EFSA's draft framework for protocol development (endorsed by the SC and published in 2020 – [link](#)) and, in particular, the areas for improvement that were identified during its formal testing on 21 EFSA mandates. The guidance is going to be structured into multiple outputs: i) the draft GD, covering the background, rationale, theoretical aspects related to EFSA protocols and the new framework for problem formulation based on RSI's report including the APRIO paradigm; ii) a 'Template for protocols', i.e. a practical tool to guide the users step by step through the process of developing a EFSA protocols; iii) further examples of EFSA questions and sub-questions formulated using the APRIO paradigm; and iv) a harmonised classification of EFSA assessment questions and sub-questions. Outputs ii-iii will be submitted to the SC for first reading at the November 2022 plenary, while the harmonised classification will be introduced then.

The SC gave positive feedback on the overall GD and acknowledged the progress made. The APRIO paradigm was extensively discussed, and clarifications were asked on the concepts of "Agent" and "Intervention". The SC acknowledged the value of this new paradigm for EFSA, substantiated by the huge analysis done by the contractor RSI. However, the need for multiple examples from the various EFSA fields was emphasised. To this end, the WG is working on the addition of examples which will be presented at the next SC plenary. It was emphasised that the existing examples are not exhaustive and other options are possible.

## **5 Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission Feedback from the panels:**

### **5.1 Feedback from Panels:**

#### **5.1.1 Chemical versus microbiological risk assessment – for discussion**

The Chair of the Biological Hazards (BIOHAZ) Panel provided an overview on the differences and commonalities between the chemical and microbiological risk assessments to stimulate an open brainstorming discussion on a common risk assessment framework. The presentation started with an outline on cumulative risk assessment for chemicals *versus* microbiological risk assessment.

The SC agreed that a move in this area would be fruitful but that further harmonisation, at an international level, would be needed. The SC also acknowledged the potential methodological support from NAMs and biomarkers. The Commission noted Research and Innovation opportunities that may be offered for developing NAMs through the Horizon Europe Partnership on the Assessment of the Risk of Chemicals. The SC suggested that EFSA continues this discussion internally for further elaboration with the idea to table it again for further discussion in one of the next SC plenary meetings.

### **5.1.2 Overview of the work programme on Food Contact Materials, Enzymes and processing aids - CEP Panel**

The Chair of the CEP Panel provided an overview of its activities, which covers 3 areas, namely the food contact materials (FCM), the food enzymes (FE) and the Processing Aids.

Within the area of FCM, the Panel is re-evaluating the risks of phthalates, with already ongoing work (i.e. identification & prioritisation of substances published in May 2022, protocol development for hazard to be presented to the Panel in October 2022 and call for data to be launched in November 2022). The work on the RA of phthalates is pending upon completion of the ongoing work and it relies on cooperation both within and outside EFSA (ECHA, DG Santé /GROW/ENV). The work is piloted and compliant with recent EC strategies such as the Chemical Strategy for Sustainability and the One Substance One Assessment (OSOA) approach where the focus is on hazard and genotoxicity as knock criterion. An update on the re-evaluation of Bisphenol A (BPA) was provided to the SC indicating that the opinion is foreseen for adoption in December 2022.

Regarding the applications on the recycling of plastic materials and articles, there is a significant and steady increase in the number of mandates received since 2020. This increase is expected to continue with the Transparency Regulation and the new Recycling Regulation to come into force as of October 2022 and replace Reg. 282/2008. The new framework of FCM legislation is under discussion with EC and since April 2022, new discussion is ongoing on natural compounds (complex mixtures, cross cutting topics). The panel is engaged with other EFSA Panels (CONTAM) on cross-cutting issues such as nanoparticles and application on waxes and with ECHA/EC on drinking water materials and articles. An upcoming mandate on styrene is also underway.

Within the area of FE, it was noted that the FE submission guidance was implemented as of April 2022, which coincided with an improvement on the quality of new dossiers received. 37 calls-for-data have been launched and is reaching almost the end, which enabled a great increase of opinions adopted (e.g. 39 adoptions in the first eight months of year 2022). It was also highlighted that there was high pressure on the evaluation and adoption of the FE dossiers given that Industry waits for the Union list which cannot be published before these dossiers are adopted. Finally, it was announced to the SC that the call for data for the Food Enzyme Intake Model (FEIM) is completed and that more calculators will be released as of October 2022.

Within the area of Processing Aids, the panel adopted 2 opinions in 2022, one on food hygiene (lactic acid to reduce microbiological surface contamination on carcasses) and the other on extraction solvents (2-methyloxolane).

### **5.1.3 Overview of the work programme of the Panel on Additives and Products or Substances used in Animal Feed - FEEDAP Panel**

The Chair of the FEEDAP Panel provided an overview on the remit of the panel (which is on both safety and efficacy) and the supportive EFSA Unit within the new EFSA organisational structure. The bulk of the Panel's work is on assessments of dossiers submitted by applicants.

The authorisation process for feed additives, which establishes the need for a risk assessment, is set in Regulation (EC) No 1831/2003. It was highlighted to the SC that since March 2021, the Transparency Regulation applies to new incoming dossiers.

About 330 applications, including 89 renewals (for substances placed on the market for 10 years), were processed during the last 3 years (the figures remain stable). For the re-evaluation (exercise started in 2010) a total of 338 opinions have been adopted. Since the beginning of EFSA (2003-2022), a total of 1269 opinions were delivered by FEEDAP Panel. Regarding guidance documents, a self-mandate is on-going to update the guidance on the safety for the user. The endorsement of this guidance is foreseen by the end of 2023. In addition, 2 other guidance documents require to be updated (on characterisation of microorganisms and efficacy).

The cooperation of the FEEDAP Panel within and outside EFSA is wide, including the evaluation of botanicals, the genotoxicity assessment, the risk assessment of bromide, on the maximum levels of cross contamination for

24 antimicrobial active substances in non-target feed; and with EMA on the harmonisation of exposure and on guidance on the use of bacteriophages as veterinary products.

## 5.2 Feedback from EFSA

### 5.2.1 Applicability of the margin of exposure in the risk assessment of botanicals and botanical preparation used as feed additives - follow up

An overview on the application of the margin of exposure (MoE) in the risk assessment of botanical preparations containing used as feed additives was presented to the SC. In the process of the re-evaluation of feed additives (flavourings), the FEEDAP Panel is assessing more than 200 botanical preparations.

In November 2020, the FEEDAP Panel requested the advice of the SC on the appropriate methodology to assess the safety for the target species of botanical preparations. Depending on the toxicological dataset available, the approach proposed by the FEEDAP Panel and endorsed by the SC foresees three different approaches: (i) the MoE; (ii) the threshold of toxicological concern (TTC) using the value of 0.0025 µg/kg bw per day, or (iii) a comparative intake from other dietary sources.

In 2021-2022, the MOE(T) approach has been applied to the risk assessment of botanical preparations containing of p-allylalkoxybenzenes (methyleugenol, estragole, safrole, elemicin, myristicin and apiole).

Until now preparations containing low concentrations of p-allylalkoxybenzene have been assessed, resulting in an MOE(T) >10,000. Since these substances are naturally present in plants, their presence in low concentrations in botanical preparations intended for use as feed additives cannot be fully avoided.

For the evaluation of botanical preparations for which these substances are “characteristic” constituents, the FEEDAP Panel asks the SC whether the use of MoE approach, intended for unavoidable contaminants in food and feed, is still considered appropriate.

The SC discussed extensively the questions asked by the FEEDAP Panel and suggested to bring the issue to the attention of relevant EFSA Panels/Units to verify if similar situations have been encountered in their experience and to discuss the possible implications for the respective sectors, if the MOE approach is applied to the risk assessment of botanicals and botanical

preparations. More discussion will be held at the next SC plenary in November 2022.

### **5.2.2 Scientific Committee's involvement in environment scanning and strategic options**

The objectives of the EFSA's process EXPLORE (i.e. anticipation and identification of gaps and emerging risks and the contribution to the definition of EFSA's working agenda and long-term strategy) were presented to SC, making emphasis on their contribution to the environmental scanning and the definition of the EFSA strategy. At the start of the process (when collecting signals/data), the SC could be consulted on the EFSA methodology development needs as well as later, when assessing the relevance of the signals and readiness for regulatory science. The goal of this project is to widen EFSA's capacities for being prepared to future challenges (in terms of sources, experts, expertise, partnership, etc.) with the support of dedicated tools developed by EFSA to enhance the mapping of connections and partnerships.

### **5.2.3 Finalisation of the Scientific Committee work-programme 2023-2024**

The SC was provided with an overview of the process leading to the work-programme 2023-2024 (including also 2022) preparation, highlighting the various steps, i.e. consultation with Units/Panels, feedback from EC on regulatory relevance, and prioritisation of the work. The EFSA's Advisory Forum was also informed on the process. A total of 22 proposals were submitted by the Units/Panels to the MESE unit, including 4 already agreed or ongoing at EFSA, 6 new proposals, 6 addressed by other EFSA's or EU initiative, 6 addressed by other means (under the mandate of existing Units or covered under the provisions of the Regulations).

The 6 ongoing or already agreed activities are: the development of a guidance for biomarkers of effects, the implementation of the honey bee colony model for RA (ApisRAM), the revision of the guidance on the use of the Margin of Exposure, the creation of the living guidance on expert knowledge elicitation (EKE), the finalisation of the guidance on appraising and integrating evidence from epidemiological studies and the revision of the guidance on default values to be used in risk assessment in the absence of actual measured data. Six new proposals were presented to the SC, including the comments after the EC consultation in relation to regulatory relevance. The proposals were as follow:

- Refinement of the allergenicity RA in food and feed products derived for biotechnology products, considered as a very high priority in the GMO area:

- Guidance for RA of microorganisms used in agri-food chain, considered as a high and medium priority in the GMO and FAF/CEP areas, respectively;
- Guidance for the evaluation of natural materials and food components, considered as a high priority for the evaluation of Food Contact Materials;
- Guidance for the establishment/application of relative potency factors, as considered a highly relevant in the area of contaminants;
- Guidance on environmental aspects not covered by the existing sectoral guidance (e.g. food additives, flavourings) considered a highly relevant in the area of food improvement agents and future sustainability labelling of foods;
- Guidance to support the assessment of *in vitro* mode of action studies, considered of medium relevance for food improvement agents.

Finally, as a follow up of the discussion initiated under section 4.2 on the use of the BMD approach on human epidemiological data, the SC suggested to add this activity under the work programme 2023-2024, with some preparatory work (in relation to what has been done in different organisations/countries when dealing with such type of studies and data in the context of BMD analysis) to be developed by EFSA through a dedicated WG together with an outsourcing activity that could be focused on scoping such preparatory work. An update on this follow up will be provided to the SC in due time.

#### **5.2.4 Update on WGs activities:**

##### **WG Bromide**

This agenda item was moved to the next SC Plenary in November 2022.

##### **WG Fluoride**

This agenda item was moved to the next SC Plenary in November 2022.

##### **WG Copper**

This agenda item was moved to the next SC Plenary in November 2022.

##### **WG MUST B (Multiple Stressors in Bees)**

The SC was presented an overview of the new activities to be undertaken under the MUST-B2 WG. This included a presentation on the main achievements from the start of MUST-B project (as background information), on the new timeline that needs to be updated, on the Terms

of Reference of the WG which are articulated on ApisRAM implementation (self-task mandate) and on the new WG composition to support the implementation of ApisRAM towards version 3, i.e. a model for the risk assessment of pesticides ("single product/singe use") by 2024. The model will be developed by Aarhus University over the next 4 years starting in September 2022 and under a framework partnership agreement with EFSA.

The SC highlighted that it would be important to reflect on lessons learned during this project and that the SC could explore further how experience and knowledge gained from this project could be applied in other fields.

## **WG Read Across**

The SC was presented an update on the Read Across WG, in particular on the timelines and procurement project linked to this activity. Regarding the timelines, the WG, which was set up in 2020, led to the outsourcing of a project on the identification of the applicability domain for the use of read across in food safety in autumn 2021. This activity, foreseen for a period of 30 months and led by Fraunhofer ITEM, aims to achieve successful integration of metabolite data into a read across workflow. The final report from this activity is due by mid-2024. In parallel, a guidance on the use of read across is in preparation. It is foreseen finalisation of the guidance by the end of 2024, including also the step of the public consultation. Finally, the SC was informed on the organisation of a workshop on the use of read across in food safety assessment to occur in the beginning of 2025.

## **Cross-cutting WG Genotoxicity**

For the WG on Genotoxicity, two main updates were reported from the latest meeting on the 6<sup>th</sup> of September. First, the EU request for technical advice on hydroxyanthracene derivatives (EFSA-Q-2022-00282<sup>4</sup>) was completed and at the moment the report is being submitted to the requesting Unit. In this request, EFSA was asked to assess whether the data from two new scientific publications presented by the Italian Society of Toxicology (SITOX) were sufficient to revise the conclusions of EFSA's ANS Panel 2018 Opinion on the safety of hydroxyanthracene derivatives for use in food.

In addition, a new request for assistance from the Pesticides Peer Review Unit (PREV) was received, following a mandate from the European Commission (M-2022-00167<sup>5</sup>) on the assessment of the genotoxic potential of 2,4,6-trichlorophenol, a metabolite of the active substance Pydiflumetofen.

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<sup>4</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00282>

<sup>5</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2022-00590>

## Cross-cutting WG on Nanotechnologies

The SC was presented an overview of the recent activities of the cross-cutting WG on Nanotechnologies. The WG is currently providing support to EFSA Panels and Units to promote smooth and harmonised implementation of its recently published Nano Guidances<sup>6,7</sup> across EFSA sectors. In the last meeting, the WG discussed five requests for assistance received from the NIF, FIP and FEEDCO Unit about different application dossiers. In relation to ongoing dissemination activities with EFSA Panels, the SC was informed that a workshop was organised in the morning of 16 September 2022 with members of the WG on Toxicology and the WG on Animal Nutrition of the FEEDAP Panel to discuss the implementation and applicability of the Nano Guidances to the risk assessment of feed additives. Lastly, the SC was informed on the ongoing activities for the organisation of the 12th meeting of the Network on Nanotechnologies in Food and Feed (NanoNetwork), which will be held in the mornings of 24-25 October 2022 by WEB-conference.

## 6 Other topics for information and discussion

### 6.1 Activities in the area of NAMs

The SC was provided with an overview on the EFSA's ongoing activities in the area of New Approach Methodologies (NAMs). These activities aim at promoting the implementation of NAMs to specifically address the data gaps identified in the context of EFSA's assessments thought the incorporation of existing information and the generation of NAM-based data (i.e. *in vitro*, *in silico*). The EFSA Project on NAMs comprehends a series of NAMs case studies that represent real proof of concept cases covering different areas under EFSA's remit. The undertaken approach for the establishment of these case studies consists of a first co-design phase between researchers and risk assessors to define the strategy for the assessment, the development of Integrated Approaches to Testing and Assessment (IATAs), and real implementation phase followed by validation of results into the regulatory context.

The SC was presented with a general overview of ongoing NAMs Case Studies (i.e. EFSA Pilot Project on NAMs for the risk assessment of the pesticide Tebufenpyrad, EFSA Project on NAMs for the hazard assessment of nanofibers, EFSA Project on the use of NAMs to explore the immunotoxicity of the contaminant PFAS, EFSA Project on the use of NAMs

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<sup>6</sup> <https://doi.org/10.2903/j.efsa.2021.6769>

<sup>7</sup> <https://doi.org/10.2903/j.efsa.2021.6768>

to explore interspecies metabolic differences on essential oils as feed additives) and respective timelines.

A parallel project is also ongoing with the aim of exploring the use of Artificial Intelligence (AI) for extracting and integrating NAM-based data for chemical risk assessment. In line with the EFSA strategy 2027, the final goal of these activities would be to gather experience and lesson learnt and develop a dedicated Guidance on the use of NAMs for EFSA's risk assessments.

In parallel, efforts are ongoing to increase the international cooperation under the International Liaison Group for Methods on Risk Assessment of Chemicals in Food (ILMERAC).

Lastly, the SC was presented with a general overview of a new project called NAMs4NANO, which was designed to follow up to the EFSA Roadmap on NAMs published in 2022<sup>8</sup>. The NAMs4NANO project is aimed at integrating NAM-based results in chemical risk assessments and will make use of case studies addressing nanoscale considerations.

The SC acknowledged the great potential and usefulness of NAMs and also the need for strong collaboration at international levels as presented in this overview. The SC will be regularly updated on the progress of these activities.

## **6.2 Overview of the ongoing grant work (LOT 1) on Evaluating the impact on/by gastro-intestinal (GI) tract microbiomes (human and domestic animal) in assessments under EFSA's remit**

The SC was provided an overview of the ongoing grant work (LOT 1) on evaluating the impact on/by gastro-intestinal (GI) tract microbiomes (human and domestic animal) in assessments under EFSA's remit. This project is part of the EFSA thematic grant scheme on preparedness for future challenges in specific areas of EFSA's work (GP/EFSA/ENCO/2020/02). The work was outsourced by EFSA and the first part running from May 2021 to July 2022 was presented to the SC by the contractor Javier Moreno, on behalf of the contracting consortium from CSIC (Consejo Superior de Investigaciones Científicas), CIAL (Instituto de Investigación en Ciencias de la Alimentación), CNB (Centro Nacional de Biotecnología), INGENIO (Instituto de Investigación mixto del CSIC y la

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<sup>8</sup> Escher, SE, Partosch, F, Konzok, S, Jennings, P, Luijten, M, Kienhuis, A, de Leeuw, V, Reuss, R, Lindemann, K-M, Hougaard Bennekou, S, 2022. Development of a Roadmap for Action on New Approach Methodologies in Risk Assessment. 19( 6): 153 pp. doi:10.2903/sp.efsa.2022.EN-7341

Universidad Politécnica de Valencia), IPBLN (Instituto de Parasitología y Biomedicina López-Neyra) and ANSES (Agence Nationale de Sécurité Sanitaire de l'alimentation), a multidisciplinary and international team. The main objective of the project was to build capacity for evaluating the impact of potential modulators on the human and animal gut microbiomes and determine their applicability to risk assessments under EFSA's remit. The LOT 1 comprises assessments (exposure to modulators of the GI microbiome via dietary pathway) in gut for human and domestic animals, all grouped under the project RIMICIA (Review Impact MICrobiome In Assessment). The specific objective 1 (May 2021-Nov 2022) reviewed the state of the art and appraised the evidence, technologies and models (in vitro/in silico/in vivo) and the specific objective 2 (Nov 2022-Nov 2023) will draft a roadmap to advance research in this area and for RA purpose. A comprehensive overview on objective 1 was provided to the SC, listing the various tasks for the review of the scientific evidence organised within 8 domains (macronutrients, micronutrients, food and feed additives, microorganisms, other chemical modulators, other biological modulators and dietary patterns) representing the gut microbiome, and the databases used for performing the scientific literature searches. These searches have been processed through an ad-hoc web interface developed under RIMICIA. A summary of the outcome of the searches was provided for each of the 8 pre-identified domains and for each of the searched database. Most studies focus on the potential health benefits.

It was proposed to identify potential key events and biomarkers following exposure to harmful diet-derived components (e.g. gut epithelium inflammation and disturbance of gut barrier). Finally, the SC was provided a list of conclusions reached within LOT 1 which led to 2 main recommendations, on the identification of elements on the scientific topic of the gut microbiome which may inform risk assessors and the identification of gaps/uncertainties on this topic to be addressed.

## 7 Any other business

### 7.1 Highlights of draft agenda November SC Plenary

The SC was provided with a highlight of the topics to be presented to the next Plenary (111th SC Plenary) scheduled on 16 and 17 November 2022. The next SC plenary will be the opportunity to present an update on the protocol development. The draft opinion on copper will be tabled for possible adoption. A presentation on the work-programme of the PPR and GMO Panels will be done at the next SC Plenary meeting that will be held as web meeting.



## **7.2 Feedback received from the Open Plenary held on 5-6 July 2022**

EFSA provided feedback to the SC regarding the topics and discussions led at the previous open SC plenary (109<sup>th</sup>) which overall was good. The comments made by observers were mainly on technical aspects.

## **7.3 General matters arising**

The SC was provided with a document summarising relevant activities that took place since the last plenary meeting with a focus on the activities of the EFSA Management Board, interagency and international scientific cooperation and EFSA Stakeholders Meetings.

End of the meeting