Scientific Committee

Minutes of the 108th Plenary meeting

Held on 27-28 April 2022, web meeting,

(Agreed on 20 May 2022)

Participants

- Panel Members

  Simon More (chair), Diane Benford (vice-chair), Susanne Hougaard Bennekou (vice-chair), Vasileios Bampidis, Claude Bragard, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Kostas Koutsoumanis, Claude Lambré, Kyriaki Machera, Ewen Mullins, Søren Saxmose Nielsen, Josef Schlatter, Dieter Schrenk, Dominique Turck, Maged Younes.

- Hearing Experts[1]:

  Jean-Charles Leblanc (for item 4.1)

  Henk Van Loveren (for item 5.1.3)

  Javier Moreno (for item 4.4)

- European Commission and/or Member States representatives:

  Luis Vivas Alegre (DG SANTE Unit D1, Farm to Fork Strategy),

  Athanasios Raikos (DG SANTE Unit D1, Farm to Fork Strategy),

- EFSA:

  Bernhard Url, EFSA Executive Director (on 1st day until coffee break)

  Chief Scientist office: Claudia Heppner, George Kass, Kostas Paraskevopoulos (for item 5.2.2.)

  Risk Assessment Services Department (ENABLE): Nik Kriz

  Risk Assessment Production Department (ASSESS): Guilhem De Seze

[1] As defined in Article 15 of the Decision of the Executive Director Fconcerning 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

Methodology and Scientific support Unit (MESE): Claudia Roncancio-Peña, Daniela Maurici, Elisa Aiassa, Davide Arcella, Maria Chiara Astuto, Fulvio Barizzone, Maria Bastaki, José Ángel Gómez Ruiz, Djien Liem, Alexis Nathanail, Agnes Rortais, José Tarazona.

1 Welcome and apologies for absence

The Chair welcomed all participants.

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[2] and the Decision of the Executive Director on Competing Interest Management[3], 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 review of the existing health-based guidance values for copper and its exposure assessment from all sources (EFSA-Q-2020-00399)

The Scientific Committee (SC) was presented with a revised draft Scientific Opinion on Copper, which included changes addressing the feedback received during the last SC Plenary Meeting. The draft Opinion was presented for discussion and possible endorsement for public consultation. After a brief overview of the background and critical points in the assessment, the SC was informed about the revisions made since the previous draft. A revised Section on Uncertainty Analysis was added in the main body of the Opinion and the detailed uncertainty analysis was included as a dedicated Appendix, in line with the EFSA SC Guidance on Uncertainty Analysis in Scientific Assessments (2018[4]). The SC acknowledged the high quality of this new Section and identified further elements for

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

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

[4] EFSA Scientific Committee, 2018. Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):5123, 39 pp. https://doi.org/10.2903/j.efsa.2018.5123

improvements, such as to clarify that pregnant and lactating women are not expected to be at greater risk of toxicity from copper than other adults. In addition, the draft Opinion was updated after discussion with the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) and Nutrition and Food Innovation (NIF) Unit, and following feedback received from the EFSA's Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). In agreement with the NDA Panel and NIF Unit, the Health-Based Guidance Value (HBGV) will be expressed as an Acceptable Daily Intake (ADI), in line with the provisions described by the 'Statement on the harmonisation of HBGV for regulated products that are also nutrients' (2021[5]) and the Terms of Reference (ToR) received from the EC mandate. As a follow up activity, the NDA Panel will establish Upper Levels (ULs) for all age groups based on the ADI for Copper established by the SC. After a discussion on the approach proposed for establishing ULs, the SC agreed that further discussion to clarify differences in methodological approaches between sectoral and SC Guidance is needed, and cross-sectoral discussions will be held after the public consultation of this Opinion. Lastly, the SC was presented with the conclusions and the recommendations from the assessment and further elements for improvement were identified, including clarifying that the exceedance of the ADI for infants and children is not of concern due to growth requirements and explaining the need for monitoring long term increase of Copper in the soil from its use as a plant protection product and its presence in fertilisers. The SC unanimously endorsed the document for public consultation, after including the clarifications in the text based on the elements discussed at this Plenary Meeting.

4.2 Draft technical report on a common approach on exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides residues in food of animal origin (Art. 31 request to EFSA and EMA)

The SC was presented with a draft 'Report on a common approach on exposure assessment methodologies to residues from veterinary medicinal products, feed additives and pesticides residues in food of animal origin' for discussion and possible endorsement for public consultation. The SC was presented with the background information for the joint mandate received by the European Commission to EFSA and the European Medicines Agency (EMA). The aim of the mandate is to develop a common approach on exposure assessment methodologies to residues from veterinary medicinal products, feed additives, biocides and pesticides residues in food of animal origin. This joint Scientific Report of EFSA and EMA has been elaborated by a Working Group (WG) of EMA under the umbrella of the Committee for

[5] EFSA Scientific Committee, 2021. Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients. EFSA Journal 2021;19(3):6479, 39 pp. https://doi.org/10.2903/j.efsa.2021.6479

Medicinal Products for Veterinary Use (CVMP). The WG is co-chaired by EFSA and includes the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), and, as an observer, the European Chemicals Agency (ECHA).

After being introduced with the different approaches used for exposure assessment methodologies for veterinary drug residues in EMA and JECFA, residues from feed additives in EFSA, and residues from pesticides in JMPR and EFSA, the SC was presented with the proposals developed for a harmonised approach. It was acknowledged that the draft report can only provide recommendations for key concepts and key parameters of a harmonized methodology rather than technical instructions. A harmonised implementation of these recommendations will require a number of scientific and technical follow-up activities within and between committees concerned. However, the impact of the report on EFSA assessments is expected to be minor since most of the time the recommended "preferred method" is the one already in use by EFSA or the method used is listed among the reasonable alternatives.

The Report has previously been endorsed for public consultation by the CVMP of EMA. The SC endorsed the document for public consultation with unanimity and acknowledged the importance of harmonisation of methodology between EU Agencies, where appropriate and possible. The EU Chemicals Strategy for Sustainability and One Substance One Assessment approach was also discussed.

4.3 New EC mandates

4.3.1 Request for a scientific report on dietary exposure to metals and iodine in seaweed and halophytes in the European population (Art. 31)

The SC was presented with the Mandate and ToRs received from the European Commission on a 'Request for a scientific report on dietary exposure to metals and iodine in seaweed and halophytes in the European population' (M-2022-00016, EFSA-Q-2022-00212[6]). In accordance with Article 31 of Regulation (EC) No 178/2002 the European Commission asked EFSA (1) for a consumer exposure assessment for arsenic, cadmium, lead, mercury and iodine in seaweeds and halophytes and products containing seaweed and halophytes, and (2) for an overview of the available occurrence data on arsenic (total and inorganic), cadmium, lead, mercury (methylmercury and total mercury) and iodine in seaweed and halophytes and products containing seaweed and halophytes. The deadline to produce the Scientific Report is 31 December 2022.

[6] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00212

A preliminary approach to address the ToRs was presented and briefly discussed. Given the cross-cutting nature of the topic, two experts of the EFSA Panel on Contaminants in the Food Chain (CONTAM) will act as peer reviewers of the scientific report. The report will also be presented to the CONTAM Panel for endorsement before its approval for publication.

4.3.2 Draft EC mandate on the risks for human health related to the presence of bromide ion in food/feed (Art. 29)

The SC was presented with the draft Mandate and ToRs received from the European Commission on an Article 29 Request on the risks for human health related to the presence of bromide ion in food/feed. The official mandate is expected soon and the deadline for delivering the opinion will be spring 2024.

The procedures for the establishment of a chairmanship and a dedicated Working Group will start as soon as the mandate is received. Further information will be shared with the SC members by written procedure before the next SC plenary.

4.4 Allergenicity: presentation of the Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology

The SC was presented for information with the 'Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology', recently adopted by the EFSA's Panel on Genetically Modified Organisms (GMO) and published in the EFSA Journal[7].

After being informed on the background, the SC was introduced to the aims of the Scientific Opinion, which addresses the formulation of specific development needs, including research requirements for allergenicity assessment and protein safety, which is urgently needed in the light of a more sustainable food systems. The core approach for allergenicity safety assessment is, in line with the guidelines of the Codex Alimentarius, based on a 'weight-of-evidence' approach because no single piece of information or experimental method provides sufficient evidence to predict allergenicity. Based on the experience gained so far and the new developments in the field, this Opinion describes some key elements and tools which would allow for a modernisation of the risk assessment in place. These should include the consideration of clinical relevance, route of

[7] EFSA GMO Panel, 2022. Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology. EFSA Journal 2022; 20(1):7044, 38 pp. https://doi.org/10.2903/j.efsa.2022.7044

exposure and potential threshold values of food allergens, the update of *in silico* tools used with more targeted databases, and better integration and standardisation of test materials and *in vitro/in vivo* protocols. The Opinion also proposes a 'Roadmap to improved 'Weight-of-Evidence' Allergenicity Risk Assessment' describing future aspects, risk assessment needs, and future safety objectives for food/feed derived from biotechnology.

In the context of the dissemination of this Opinion and future developments, outsourced projects are ongoing to support the implementation of new *in vitro/in silico* tools in the risk assessment practice. Moreover, efforts will increase to further develop the topic and make the issue visible internationally, which will allow to discuss key questions on the topic that need to be addressed to further advance on the methodology.

The SC was informed about new Horizon 2020 projects on the topic which will allow to foster advancement in this area. Furthermore, the SC discussed the complexity and horizontal nature of allergenicity assessment, which is of interest also to other EFSA areas (e.g. NDA and CEP Panels).

5 Feedback from the Scientific Committee/Scientific Panels, EFSA, the European CommissionFeedback from the panels:

5.1 Feedback from Panels:

5.1.1 Overview of the work programme of AHAW panel

The Chair of the Panel on Animal Health and Welfare (AHAW) presented the recent achievements and work programme. In 2021, 33 scientific outputs were produced on several topics related to animal welfare at slaughter, the Animal Health Law, African Swine Fever, and SARS-CoV-2 in mink. At present, the main subject of the activities of the AHAW Panel is related to mandates received from the European Commission on animal welfare in the framework of the Farm to Fork Strategy. Common terms of reference were received for different animal species (e.g. pigs, broilers, calves, laying hens) and the commissioned scientific opinions will describe the current husbandry systems and practices of keeping them, the relevant qualitative or quantitative measures to assess the welfare consequences, identify the hazards leading to these welfare consequences, and provide recommendations to prevent, mitigate or correct the welfare consequences. In addition, EFSA will explore scientific information on the advantages and disadvantages of the several production systems for laying hens, pigs and calves, taking into account their diversity and possibility for improvement. Lastly, the SC was informed on the latest achievement and lesson learnt with regards to the implementation of the SC Guidance on

Uncertainty in scientific assessment (2018)[8] and the draft guidance on Protocol Development (2020)[9].

5.1.2 Overview of the work programme of FAF panel

The Chair of the Panel on Food Additives and Flavourings (FAF) presented the work programme for 2022. Presently, the FAF Panel is dealing with the evaluation of more than 30 new applications on food additives, food flavourings, and smoke flavourings, and the re-evaluation of smoke flavourings and food additives (e.g. sweeteners, and food additives in foods intended for use in infants below 16 weeks of age). Lastly, the Panel is currently working on the development and update of Guidance Documents; the Guidance on smoke flavourings was finalised in 2021[10] and the Guidance on flavourings is expected to be adopted by end of this year.

To cope with the high workload experienced, a priority order of activities was established in terms of urgency and timing. High workload was recently experienced also in the view of the new requirements from the Transparency Regulation, the submission of innovative products, and less familiarity in the application of newly developed SC Guidance Documents, such as the Guidance on Particle – Technical Requirements[11]. For the future, the possibility of outsourcing part of the assessments under new partnership agreements and close interaction with EMA and ECHA on cross-cutting assessments will be explored, also in line with the One Substance One Assessment framework.

5.1.3 Feedback on the draft Scientific Opinion on the re-evaluation of the public health related to the presence of BPA in foodstuff

The SC was presented with recent advancements on the 'draft Scientific Opinion on the re-evaluation of the public health related to the presence of BPA in foodstuff'

A two-step mandate on BPA re-evaluation was received in 2016, the first one to establish a methodology for defining the hazard assessment protocol, and the second request was related to the hazard assessment and risk characterization. The aim of the assessment is to evaluate whether the

[8] EFSA Scientific Committee, 2018. Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):5123, 39 pp. https://doi.org/10.2903/j.efsa.2018.5123
[9] EFSA (European Food Safety Authority), 2020. Draft framework for protocol development for EFSA's scientific assessments. EFSA supporting publication 2020: 17(4): EN-1843. 46 pp. https://doi.org/10.2903/sp.efsa.2020.EN-1843
[10] EFSA FAF Panel, 2021. Scientific Guidance for the preparation of applications on smoke flavouring primary products. EFSA Journal 2021;19(3):6435, 40 pp. https://doi.org/10.2903/j.efsa.2021.6435
[11] EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. https://doi.org/10.2903/j.efsa.2021.6769

new scientific evidence still support the previous temporary Tolerable Daily Intake (t-TDI) established by EFSA (2015[12]). After the evaluation of new evidence available on different endpoints, the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) identified 10 health outcome categories related to immunotoxicity, metabolic effects, neurotoxicity and developmental neurotoxicity, and reproductive and developmental toxicity, which were brought forward for the BMD analysis and the establishment of a Reference Point. Within the hazard characterization step, immunotoxicity was identified as the most sensitive endpoint based on an increment of T helper 17 cells (Th17) as a key intermediate effect which resulted in the establishment of a TDI of 0.04 ng BPA/kg bw per day. Based on the available dietary exposure estimates, the CEP Panel concluded that there is a health concern from dietary BPA exposure for all age groups.

In November 2021, the draft Opinion was endorsed for public consultation, which was launched with the deadline of 22 February 2022. The WG is currently screening the comments received from the public consultation and further exchange with other Stakeholders, EU Member States, and FDA and EMA representatives. The SC discussed the risk assessment approach applied for the production of the draft Opinion.

5.2 Feedback from EFSA

5.2.1 Update on WGs activities:

Cross-cutting WG on Nanotechnology

The SC was presented with a first draft of the Annex on 'Degradation/dissolution rate under acidic conditions', produced to update the recently published Guidance on Particle – Technical Requirements[13]. The document is aimed at integrating the specifications for the dissolution/degradation rate for substances that only dissolve under acidic conditions, based on the feedback received from the EFSA CEP and FAF Panels from applicability of the Guidance to real cases. This Annex will include additional recommendations for the interpretation of the results for substances that only reach the degradation/dissolution test under acidic conditions.

The SC concluded that further discussion on the draft Annex will be needed after consultation with the relevant Panels and Units. After this first step, the Nanonetwork will also be consulted. It is expected that the draft Annex

[12] EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2015. Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: Executive summary. EFSA Journal 2015; 13 (1):3978, 23 pp. https://doi.org/10.2903/j.efsa.2015.3978

[13] EFSA Scientific Committee, 2021. Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles. EFSA Journal 2021;19(8):6769, 48 pp. https://doi.org/10.2903/j.efsa.2021.6769

will be presented to the SC for possible adoption by the end of the year. The annex will then be included in the technical guidance that will be then re-published.

Cross-cutting WG on Genotoxicity

In the last meeting of the cross-cutting Working Group (WG) on Genotoxicity, the main topics addressed were the finalisation of an internal Working Instruction (WIN) document describing a harmonised approach for the assessment of relevance and reliability of genotoxicity studies, and the scientific advice provided to the WG on Flavourings regarding the genotoxicity assessment of a new smoke flavouring product.

For the next WG meeting, a new Article 31 request from the European Commission (EFSA-Q-2022-00282) will be discussed in the context of the EFSA ANS Panel Opinion on the safety of hydroxyanthracene derivatives for use in food (2018[14]). Based on the mandate received by EFSA, the WG on Genotoxicity is asked to assess whether new evidence provided would be sufficient to revise the scientific conclusions of EFSA on the safety of hydroxyanthracene derivatives for use in food. Lastly, a thematic discussion for the use of whole genome sequencing approaches for genotoxicity assessment has been organised with invited hearing experts at the next WG meeting. The aim would be to get information on the state-of-the-art of these methods and their potential for use in genotoxicity assessments in the regulatory areas.

Cross-cutting WG Uncertainty

In the last meeting of the cross-cutting WG on Uncertainty, the main topics addressed were the lessons learnt after the Training Workshop with Risk Managers (held in November 2021), the possible update of the Guidance, the EFSA Expert Knowledge Elicitation (EKE) tool and, in relation to support to EFSA Panels and Units, the uncertainty analyses in the SC draft Opinion on Copper and the Welfare Opinions of the AHAW Panel. Based on the discussion held during the last WG meeting, the areas identified for future work are related to the implementation of the Uncertainty Guidance in EFSA, considering the lessons learned in previous opinions on the methodological priorities for considerations about uncertainty during protocol development, and the feasibility to implement an interactive tool to connect and retrieve all the information related to uncertainty in the EFSA domain.

[14] EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 2018. Scientific Opinion on the safety of hydroxyanthracene derivatives for use in food. EFSA Journal 2018;16(1):5090, 97 pp. https://doi.org/10.2903/j.efsa.2018.5090

WG Botanicals

For the toxicity characterisation activities, the WG on Botanicals continued the discussion on the QSAR models and the data received from VEGA and Danish QSAR systems on 1100 substances, which have been identified as toxicologically relevant from the on-going botanical plant review work. The discussion focuses on the reliability scores and consensus strategies among the different QSARs for all hazard classes and endpoints of interest. The aim is to finalise these parameters in the next meetings and then start consolidating the QSAR data with the available literature data.

WG Benchmark dose (BMD) approach

The public consultation on the draft Guidance on Benchmark dose (BMD) concluded on 11 April 2022 after 7 weeks of consultation. More than 100 comments were received from 21 contributors, who participated either in a personal capacity or on behalf of their organisations. The next WG meeting will serve to screen the comments received and finalise the Guidance. The outcome of the public consultation will be summarised in a dedicated Annex which will be published together with the Guidance. The updated Guidance is expected to be adopted at the September SC Plenary Meeting.

WG Fluoride

The public consultation on the protocol for the fluoride risk assessment closed on 18 April 2022 and no comments were received. Meanwhile, the WG is developing and refining tools and strategies to identify relevant literature on fluoride as foreseen in the protocol. The WG is also working on customising risk-of-bias tools for appraisal of studies on fluoride health outcomes in humans and adverse effects in animals, and on refining tools for data extraction. The screening of the literature on health outcomes and adverse effects is expected to be outsourced due to the workload involved.

WG MUST B (Multiple Stressors in Bees)

In order to monitor and review the implementation of the honey bee colony agent-based model ApisRAM (link here), three new experts in the fields of ecotoxicology, risk assessment of pesticides and bee population modelling were invited to join the MUST-B WG. They have accepted the EFSA invitation, and their Declaration of Interests (DOIs) are currently being assessed. The updated composition of the WG as well as its workplan for the implementation of ApisRAM will be presented at the next SC Plenary in July.

WG Protocol Development

The second phase of the project (2022-23), which implies the conversion of EFSA 2020 technical report 'Draft framework for protocol development for EFSA's scientific assessments'[15] into a SC Guidance, started. The WG is revising and fine-tuning EFSA 2020 draft framework considering the outcome of the pilot phase carried out in 2020-21. Two main documents are under development: i) the Guidance, illustrating the rationale for protocols and in which a new framework for problem formulation is being incorporated, and ii) a 'template', which will be annexed to the Guidance, providing practical suggestions and examples for drafting EFSA protocols. The next steps of the project were presented. Upon endorsement by the SC in due time, a draft version of the guidance will be shared for public consultation and a Workshop will be organised. The Guidance is due for adoption by the SC in June 2023.

WG Read Across

During its 7th meeting, the WG continued drafting the Guidance on the use of the read-across approach in food safety assessment. The experts provided the remaining text to complete a first draft of the read across workflow section. In the next WG meetings, the experts will focus on the development of data matrix and uncertainty templates and trial the workflow with case studies.

WG Risk Benefit Assessment

The WG is drafting the event report of the Scientific Colloquium[16] held in February. The SC was updated on the engagement of the WG in upcoming related activities and initiatives of agencies and academic institutions of EU Member States.

5.2.2 Discussion on draft work-programme Scientific Committee 2022 – 2024 and prioritisation of activities

Overview on SPIDO ongoing activities: zooming in on new approach methodologies (NAMs)

The SC was presented with an overview of EFSA's Science Studies and Project Identification & Development Office (SPIDO) ongoing activities and work-programme for the period 2022-2024.

[15] EFSA, 2020. Draft framework for protocol development for EFSA's scientific assessments. EFSA supporting publication 2020: 17(4): EN-1843. 46 pp. https://doi.org/10.2903/sp.efsa.2020.EN-1843
[16] https://www.efsa.europa.eu/it/events/efsa-scientific-colloquium-26-risk-benefit-assessment-combined-exposure-nutrients-and

The main goal of SPIDO is to enhance EFSA's capacity to identify themes able to fill knowledge gaps to ensure preparedness for future scientific challenges and build partnerships with Member States, EU Sister Agencies, and, if relevant, international partners. This is achieved by identifying data and methodologies needs/gaps, outsourcing regulatory science project, and integrating the results in the risk assessment. The first Roadmaps for action on 'Artificial intelligence in evidence management' and on 'New approach methodologies (NAMs) in chemical risk assessment' have been finalised and currently EFSA is working to translate the outcome of these activities into risk assessment practices.

Other Roadmaps on 'Partnership system-based environmental risk assessment' and 'Risk assessment of combined exposure to multiple chemicals' will be finalised before summer 2022. In addition, Roadmaps on Animal Welfare, Communication Science, Omics, and Exposure Science will be commissioned in the next months.

The SC will be provided with the respective Theme papers and asked to help disseminating these activities.

The outcome of the development of a Roadmap for the use of NAMs in risk assessment was also presented. The main objectives of the project were to map relevant ongoing activities in the field, identify research topics/area requiring further scientific development and related challenges and blockers, provide a list of collaboration opportunities, prioritise working areas and research activities, develop an engagement plan and prepare the complete Roadmap Report.

After being introduced with the assessment and data collection strategy, the SC was presented with the five research areas which were the focus of the project: toxicodynamics, exposome, toxicokinetics, susceptible human population and data integration. Seven research activities were prioritised to differentiate between short- and long-term actions: Adverse Outcome Pathways (AOPs) and networks, exposome, *in vitro*-to-*in vivo* extrapolation (IVIVE) and physiologically-based kinetic modelling (PBK), data integration, advanced cell culture systems and organ-on-a-chip, susceptible human population, new concepts in risk assessment.

As for the engagement plan, the development of a dedicated Forum was also proposed to promote exchange between EFSA, risk managers, researchers and general public. Based on the outcome of the NAMs Roadmap, a new project on data integration is being designed and an open call for grant with Article 36 organisations will open soon. Complementary case studies will be developed in the area of nanomaterials and the aim to develop guidance for the integration of NAMs/animal/human data, tools for reporting NAMs data in IUCLID, and a qualification system for NAM developers.

Toxicokinetics is the second area prioritised and the case studies will aim at the development of advanced *in vitro* and *in silico* ADME models which can be used in quantitative IVIVE-PBK models, and to support the development of advanced *in silico* models and databases to depict ADME processes. These proof of concepts cases will serve to produce guidance on how to integrate QIVIVE and PBK models in human risk assessments and how to conduct Next Generation Risk Assessment (NGRA) of chemicals using illustrative case studies. Furthermore, an open grant for proposals will be launched to cover topics in the areas identified in the NAMs Roadmap complementary to PARC and EFSA´s activity.

Preparation of the SC multi-annual work-programme

The SC discussed topics proposed by the different EFSA Panels to be considered in its work-programme for the period 2022-2024. The proposals received were clustered into three groups: proposals for new activities/guidance development; ongoing projects/proposals agreed at the November SC Plenary; and other proposals that can be addressed by other means. For the first category, a distinction is made for activities that can be integrated within SPIDO and harmonized with respect to its timelines. A proposal of criteria for prioritisation was developed, and the SC members were requested to provide further suggestions in the next weeks.

The first set of proposals was presented and briefly discussed:

The BIOHAZ Panel proposed the development of a 'Guidance Document for the risk assessment of microorganisms used in the agri-food chain'. Microorganisms used in the agri-food chain are very diverse and their use is increasing within different EFSA areas (e.g. plant protection products, feed additives, novel foods, heath claims, enzymes…). Several cross-cutting documents have been published over the years on the topic, but guidance would be helpful for harmonisation purposes and would be supported by several other Panels such as CEP, FAF, FEEDAP, GMO, NDA, and PPR Panels.

The GMO Panel proposed the development of an output for 'Refinement of the allergenicity risk assessment in food and feed products derived for biotechnology products'. The activity should be considered as a follow-up of the recently published 'Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology'[17], also presented at this Plenary Meeting. The reason for the urgency of the activity is related to the need of guidance in

[17] EFSA GMO Panel, 2022. Scientific Opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology. EFSA Journal 2022; 20(1):7044, 38 pp. https://doi.org/10.2903/j.efsa.2022.7044

the assessment strategy for the risk assessment of allergenicity for complex mixtures. The proposal is supported by CEP, NDA, FEEDAP, FAF Panels.

The CEP Panel proposed the development of a guidance on 'Evaluation of natural materials and food components for use in food contact materials'. In the food industry, and particularly but not only in food packaging and processing aids, there is a general trend to use more "natural" materials or even food components. This trend is accompanied by a strong expectation from the consumers to have less "chemistry" involved in the food they eat. Clarification on aspects related to the assessment of materials of natural origin would be needed due to the lack of existing guidances. The proposal is also supported by the CONTAM Panel.

The CONTAM Panel proposed the development of criteria for the 'Establishment/application of relative potency factors (RPFs)'. The proposal is motivated by the increased exposure of consumers to mixtures of structurally related compounds with similar toxic effects, and consequently, by the need to prioritise those compounds with highest contribution to the adverse outcome. The proposal is also supported by the FEEDAP, PPR, CEP and FAF Panels. The activity was also identified as a priority within the SPIDO Mixture Roadmap and the European Partnership for the Assessment of Risks from Chemicals (PARC).

The FAF Panel proposed the development of an output on 'Environmental aspects not covered by the existing sectoral Guidance's (food additives, flavorings)'. As required by the sectoral legislation, the assessment should focus on those substances that after being intentionally added to food reach the environment. The activities were also considered of interest of the NDA and PPR Panels and partly by the CEP Panel. Existing experience within the FEEDAP Panel can be used as well for harmonisation purposes.

In addition, the FAF Panel proposed the development of a 'Guidance to support the assessment of *in vitro* mode of action studies'. The proposal can support the development of a strategy for extrapolation of the concentration observed *in vitro* responsible for a given mode of action occurring at a certain dose in *vivo*. This activity was supported by the NDA, CEP, PPR, CONTAM, and FEEDAP Panels.

The SC discussed criteria to be included for setting priorities, including the timeframe of the project, broader applicability among EFSA areas, feasibility, urgency, and presence of existing work by other food safety regulatory agencies. Also, the prioritisation exercise should consider the obligations prescribed by the relevant legislation and potential co-benefits with foreseen EU policy priorities – for the later feedback from DG SANTE will be sought. Additional input from the SC members will be collected by written procedure and further discussion will be held at the next SC plenary meeting.

6 Any other business

6.1 Feedback from the stakeholders' workshop on small particles and nanoparticles in food, 31 March - 1 April 2022

The SC was presented with the outcome of the 'Stakeholder workshop on small particles and nanoparticles in food', which was held online on 31 March and 1 April 2022. The workshop aimed at promoting the implementation of the published Guidances for the risk assessment of nanoparticles published in 2021, sharing with EFSA Stakeholders the approach established, experiences and lessons learnt. The event was also an opportunity to receive feedback from EFSA Stakeholders (e.g. industry, consultants) that were invited to present examples of practical applicability of the Guidance Documents. The event involved more than 300 participants, mostly representing the private sector.

During the meeting, the participants had the opportunity to ask questions for clarification or technical difficulties identified during the applicability of the Nano Guidances. All questions were addressed in dedicated Q&A Sessions and a document of Frequently Asked Questions (FAQs link) has been published to address them. To further support EFSA Applicants, all presentations and video recordings of the meeting were made available in a dedicated EFSA Webpage[18].

6.2 Update on EFSA ONE Conference 2022

The Scientific Committee was presented with the updates from the EFSA ONE Conference 2022. Registration is open until 29 April 2022 for physical participation[19]. Registration for online participation will remain open during the conference.

6.3 Highlights of draft agenda July 2022

The Scientific Committee was provided with a highlight of the topics to be presented to the next Open Plenary (109th meeting open to observers) scheduled on 5 and 6 July 2022.

6.4 General matters arising

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

[18] https://www.efsa.europa.eu/it/events/stakeholder-workshop-small-particles-and-nanoparticles-food
[19] https://www.efsa.europa.eu/it/events/one-conference-2022

End of the meeting