SCIENTIFIC COMMITTEE
119th Plenary meeting

29-30 May 2024
9:00-17:00 / 9:00-16.30
MINUTES - Agreed on 1 July 2024

Location: EFSA

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 (online), Kostas KOUTSOUMANIS, Claude LAMBRÉ, Tamas DALMAY, Søren SAXMOSE NIELSEN, Dominique TURCK, Maged YOUNES.

- **European Commission:**
  Athanasios RAIKOS, DG Sante Unit E1.

  Eleni GKANA (2nd day) DG Sante Unit E1

- **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

  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, Marios GEORGIADIS

  AHAW Unit: Andrea GERVERMEYER for agenda item 4.1

  FEEDCO Unit: Montserrat ANGUITA Freixa

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Ewen Mullins, chair of the GMO panel who was replaced by the vice-chair, Tamasy Dalmay.

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

[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

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4.1 Draft guidance on epidemiological studies EFSA-Q-2019-00200

The Scientific Committee (SC) was presented with the draft guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments for discussion and possible adoption. The draft report on the outcome of the Public Consultation for this guidance document was also made available to the Scientific Committee for possible adoption for publication together with the guidance.

A short summary of the Public Consultation process and outcomes was presented, including a reference to the most important issues that were commented either positively or critically in the public consultation and how the latter were addressed. Comments of the SC members on the content of the latest draft of the guidance were discussed and addressed. Subsequently, the SC unanimously adopted the guidance document and the associated public consultation report for publication.

4.2 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 Scientific Report "Conceptual basis for the development of guidance for the use of biomarkers of effect in regulatory risk assessment of chemicals" developed within the first phase (EFSA-Q-2024-00128) of the self-task mandate of the SC. The draft report was tabled for discussion and possible endorsement for public consultation.
The presentation and the discussions focused on the actions from the previous (118th) plenary meeting e.g. a simplified structure of the report, terminologies and clarifications on different scientific aspects. Regarding the latter, the SC members discussed on the risk versus beneficial assessments, use of correct terminologies and risk assessment parameters (e.g. Health Based Guidance Values, Dietary Reference Values), the causal link between a biomarker of effect and the adverse outcome, etc.
It was also clarified that the draft report to be used for public consultation does not contain any conclusions and recommendations, section that will be added at the later stage. Finally, the SC was informed on the upcoming stakeholder workshop organised by EFSA on 24-25 June 2024.
Based on the discussion, the SC endorsed the draft report for public consultation, that is planned to be launched in the second half of June 2024, with a duration of six weeks.

4.3 Draft Opinion on Fluoride EFSA-Q-2021-00358

The SC was presented with the hazard assessment sections of the draft opinion on Fluoride for discussion. An overview of the status of the opinion, a summary of the overall evidence collected and an outline of the work in progress were presented.
The major comments provided by SC members in the draft opinion were discussed and preliminary feedback on the hazard and risk characterisation approaches proposed was provided. The SC aknowledged the complexity of this risk asssessment and the quality work done so far by the WG but requested a more developed text, synthetising and integrating all the lines of evidence from human and animal studies following a Weight of Evidence Approach for establishing an Health Based Guidance Values (HBGV), before providing further specific comments to the draft opinion. The revised and complete document will be tabled at September inaugural plenary of the new SC for possible endorsement for public consultation.

4.4 Draft guidance on read across EFSA-Q-2020-00413

The SC was provided with an update on the draft "Guidance on the use of read-across in food safety assessment" (EFSA-Q-2020-00413).
The updated document reflects the discussion in the previous plenary meeting that referred to its overall structure, terminologies used in the report, clarifications regarding the audience of the guidance, but also several technical aspects specifically on the read-across workflow.

Following the presentation, discussion and further clarifications during the meeting, the draft guidance was endorsed for targeted consultation. Accordingly, the guidance will be prepared and shared with EFSA's Units and Panels, but also with other organisations (e.g. ECHA) within a consultation aiming to collect further feedback on its content and usability. This is planned to be launched in the second half of June. Comments will be addressed and the revised guidance will be dicussed and proposed for endorsement for public consultaiton probablyat the November SC plenary.

4.5 Draft guidance on Risk Benefit Assessment EFSA-Q-2022-00211

The SC was presented with the draft guidance on the risk-benefit assessment of foods for discussion and possible adoption.

The comments received through public consultation were addressed and the draft guidance was revised. A technical report of the outcome of the public consultation has been drafted. The SC had no additional comments or requests for revisions. The guidance was adopted together with the report that will be published as an annex of the guidance in July.

4.6 Draft opinion on Bromide (EFSA-Q-2022-00329)

The SC was presented with the draft opinion on bromide for possible endorsement for public consultation. An overview of the main findings was presented and the major comments received from the SC were discussed. The good quality of the document was acknowledged but clarifications on the evidence of thyroid effects and criteria applied to the benchmark dose modelling of animal data were requested. Additionally, proposals were made for improved flow of the text in a few sections. The revised document will be tabled at the next plenary meeting for endorsement for public consultation.

5. Feedback from the Scientific Panels/EFSA/EC

5.1.a Ongoing work-programme of the Animal Health and Welfare (AHAW) Panel

The chair of the AHAW panel, Søren Nielsen, presented the ongoing work-programme. Among the activities were highlighted that the Panel has adopted several opinions on highly pathogenic avian influenza (HPAI) and provides multiple annual reports on HPAI. A migration mapping tool (MTT) is being developed to provide information on the migration connectivity of 50 wild bird species in Europe, to inform the management of avian influenza outbreaks and other diseases transmittable by birds. Regarding African swine fever (ASF), several reports have been produced covering epidemiological analysis and review of risk factors involved in the maintenance and spread of the fever.

Another important project, funded by EFSA, is the ENETWILD project, run by consortium of experts to collect data and analyse risks of diseases shared between wildlife, livestock and humans. Development of objectives predominantly focusses on wild boar in relation to ASF. Data have been collected from literature on 50 disease profiles presented on the EFSA website

(https://animal-diseases.efsa.europa.eu/), information that is crucial as part of rapid risk assessments (https://animal-diseases.efsa.europa.eu/).

In the area of animal welfare, there are several mandates ongoing, e.g. on welfare of fur animals, on slaughtering of horses, on on-farm killing horses and small ruminants. The Panel is also working on the follow up of animal welfare roadmap to develop and implement a methodology for quantitative risk assessment of animal welfare and for the strategic data a collection on welfare indicators.

5.1.b Ongoing work-programme of the Nutrition, Novel Foods and Food Allergens (NDA) Panel

The chair of the NDA panel, Dominique Turck, presented the ongoing work-programme. The role of the NDA panel is to provide scientific advice in relation to human nutrition to support Community legislation e.g. dietary reference values, including tolerable upper intake level for nutrients, opinion on novel foods or on foods specific groups like infant formulae, health claims made on foods etc.

The update of upper level for vitamin E will be completed in June and the safety assessment of plant preparation like berberine plant preparation or hydroxycitric acid plant preparation will be completed by May 2025. Guidance documents are being developed or updated as the guidance on novel food applications, the guidance on applications for new micronutrient sources, and the guidance on notification and application for traditional foods from third countries.

The SC received also an update on the revision of the guidance establishing and applying upper levels for vitamins and minerals. As the European Commission shall set maximum amounts of vitamins and minerals added to food and to food supplements, a mandate was received in 2021. The request was to update the guidance of the Scientific Committee on Food (published in 2000) for the development of Tolerable Upper Intake Levels for vitamins and minerals in the light of available recent scientific and methodological developments and to review existing scientific evidence and provide advice on Tolerable Upper Intake Levels for vitamin A & β-carotene, folic acid/folate, vitamin D, vitamin E, iron, manganese, vitamin B6 and vitamin E.

This guidance establishing and applying upper levels for vitamins and minerals was prepared and endorsed for piloting in 2022 and has been now revised based on gained experience. It will be discussed for possible endorsement for public consultation at the NDA Open Plenary meeting on 27-28 June. Finalisation and adoption is expected by September 2024. Follow up activities foresee dissemination between end of 2024 and beginning of 2025.

5.2 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 started at the last plenary the review of existing cross-cutting guidance and the discussion on their possible revision. The list will be shared with the new SC that will have its inaugural plenary in September.

Procedural and cross-cutting guidance documents were considered in the last plenary Plenary, whereas chemical risk assessment and toxicology guidance documents (also cross-cutting, but relevant to some EFSA areas only) are presented for discussion at this plenary.

An overview of the key cross-cutting guidance used in risk assessment was presented and for some of them, the process of revision has been already initiated, namely guidance on the use of the margin of exposure, the guidance on the use of default values in the absence of actual data, the guidance for the risk assessment of nanomaterials.

In addition, the SC agreed to initiate the revision of the existing guidance documents covering the area of genotoxicity but suggested that, before embarking in this activity, a scoping paper is drafted and public consultation is held to gather feedback to different stakeholders on what are the areas of the genotoxicity assessment that should be revised and updated considering the latest development in the field.

Another guidance where the SC agreed to initiate the revision is the one for the risk assessment of botanicals and botanical preparations. This guidance was published in 2009 and is particularly relevant for the FEEDAP and for the NDA Panel. EFSA will start collecting feedback on its use and will decide how to proceed, considering also possible timelines for embarking in this activity.

In the end, the SC agreed that the guidance on the use of the Threshold of Toxicological Concern (TTC) approach (published in 2019), the guidance on the risk assessment of food for infants below the 16 weeks of age (published in 2017) and the guidance for the risk assessment of chemical mixtures (published in 2019) do not need revision for the moment.

5.3 Draft self task mandates of the Scientific Committee

- **Default values guidance update**

The SC was provided with an update on the ongoing self-task mandate dialogue on the revision of the "Guidance on selected default values to be used in the absence of actual measured data" (EFSA, 2012). The proposal on a composition of the working group (WG) for the preliminary drafting of this mandate, including the expertise in area of chemical toxicology, animal health and human nutrition, was shared and agreed by the SC. The guidance revision should be finalised around 18 months after the first meeting of the WG.

The draft mandate with a specific focus on Terms of reference was discussed. It has been clarified that the revision will focus only on the needs and default values/reference values identified during the preliminary phase and will not tackle more complex issues requiring more global involvement of other relevant international bodies.

The SC raised several suggestions on specific issues to be considered when revising the guidance, i.e., to define the MOE values for non-genotoxic chemicals, to examine the possibility to identify the appropriate threshold body weight change, or % of change, for the maximum tolerated dose identification in the different types of studies/end points/experimental animals and to set up specific criteria for that, to better define the criteria for identification of uncertainty factors in case of limitations in the database. The SC also proposed to further explore the possibility of preparing single documents (rather than one complex guidance), dealing with the issues and respective default values individually that would allow more flexibility and to facilitate the updates in the future.

The SC endorsed the proposed draft mandate with no further modifications.

- **Update on the guidance for the risk assessment of nanomaterials**

Following endorsement of the approach presented for updating the Nano Guidances at the February 2024 SC Plenary Meeting, EFSA initiated the mandate dialogue process for the self-task mandate to develop an updated guidance document for risk assessment of nanomaterials and materials containing nanoparticles in the food chain. During the present meeting, the SC was presented with the draft mandate and specifically the objective of the activity, Terms of Reference, timelines and expertise needed for possible comments and agreement. The SC endorsed the proposed draft mandate with no modification.

The SC was also informed on the decision agreed by the FEEDAP Panel at the 171st Plenary meeting[3] according to which, for any ongoing or new mandates, the risk assessment of feed additives will follow the currently available sectorial guidance documents until practical guidance tailored to feed additive safety assessments of nanomaterials is available. The Panel will continue to characterise feed additives to determine the presence of small particles, including nano particles, according to the Guidance on Technical requirements (Guidance Particle-TR) published in 2021

- **New guidance on characterisation of microorganisms**

The SC was presented with an overview of the ongoing work for the development of a new guidance on the characterisation of microorganisms.

The risk assessment of products containing or prepared/obtained from/with microorganisms considers the characterisation of the microorganisms, genetically modified or not, and their resulting products, their safety for animals, humans and environment, and their efficacy. The data required for the risk assessment may differ depending on the regulatory framework, the type of product, and the intended use.

Given the cross-cutting nature of this topic, it has been decided to assign the mandate to the SC to develop a guidance on the characterisation of microorganisms used in the food chain considering:

- existing guidance documents/reference documents as well as EFSA's current practices in the risk assessment of microorganisms,
- current and future needs for the risk assessments of microorganisms and their products,
- up to date scientific knowledge.

The document should provide guidance for the characterisation and risk assessment of microorganisms, genetically modified or not, used as such or to obtain/produce from/with regulated products.

The preparatory work will be conducted by the FEEDAP Panel working group on Microbiology where also experts from relevant Panels will be participating to the development of the guidance. The guidance will be endorsed for public consultation and adopted by the Scientific Committee and the work will be completed by summer 2025. Consultation with all the relevant Panels is expected. The SC endorsed the proposed draft mandate with no modification.

6. Any other business

6.1 Dratf agenda June SC Plenary, last meeting of the present SC

The SC decided to extend the present plenary of an additional half day, to be held on 25th June p.m. to have the possibility to finalise the ongoing work before the new SC Panel entries into force.

End of the meeting

[3] https://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-nanotechnologies.pdf