SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

# Scientific Committee

# Minutes of the 99th Plenary meeting open to observers

**Held on 23-24 June 2020**

**(Agreed on 15 July 2020)**

*This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.*

## Participants

- **Scientific Committee Members:**

  Simon More (chair), Diane Benford (vice chair, only on day 1), Susanne Hougaard Bennekou (vice chair), Vasileios Bampidis, Claude Bragard, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Kostas Koutsoumanis, Kyriaki Machera, Hanspeter Naegeli, Søren Saxmose Nielsen (only on day 1), Josef Schlatter, Dieter Schrenk, Vittorio Silano, Dominique Turck, Maged Younes, Miguel Miranda (only for agenda item 5.1)

- **European Commission:**

  Marina Marini (DG SANTE DDG.2.D1)

- **EFSA:**

  - **Executive Director**: Bernhard Url (day 1)
  - **Executive Directorate:** Marta Hugas
  - **Risk Assessment and Scientific Assistance Department (RASA):** Juliane Kleiner
  - **Scientific Evaluation of Regulated Products Department (REPRO):** Guilhem De Seze
  - **Communication Engagement and Cooperation Department (COMCO)**:
  - **Scientific Committee and Emerging Risks Unit (SCER):** Tobin Robinson, Daniela Maurici, Ana Afonso, Bernard Bottex, Jean Lou Dorne, Raquel Garcia Matas, Andrea Gervelmeyer, Georges Kass, Djien Liem, Angelo Maggiore, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans, Rositsa Serafimova, Justyna Slodek–Wahlström, José Tarazona, Hans Verhagen.
  - **Transformation Services Unit (TS)**: Marco Conterbia, Alberto Goldoni, Ben Saied Msadeg

- Others:

  **Hearing experts**: NA

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## 1. Welcome, apologies for absence and adoption of the agenda

The Chair welcomed the participants. The agenda was adopted without changes.

## 2. Declarations of Interest of Scientific Committee/Scientific 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 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.

## 3. Guidelines for observers

The observers were reminded about the code of conduct before, during and after open plenary meetings. The Chair may grant observers the opportunity to ask questions either after they have observed a discussion on a given topic or at the end of the open plenary meeting, on other topics which fall within the remit of the Panel. If members of the Scientific Committee are unable to answer questions from observers during the meeting, they may resubmit their questions to EFSA through the #AskEFSA service on the EFSA website.

Bernhard Url welcomed the observers, the SC and EFSA staff and provided a reflection of the last three months under the COVID 19 situation. During this period, all EFSA staff and experts have ensured business continuity with the support of virtual meetings, sometimes for very large groups of participants, with great success. The level of commitment was not impacted as reflected by the number of EFSA's outputs that appeared to be slightly higher than last year, in the same period. The virtual meetings will continue until the end of the year 2020.

In line with the new EFSA Strategy 2027, EFSA will increase innovation, collaboration and co-creation with sister EU agencies (EMA, EEA, ECHA), EC DGs (Santé, ENV, AGRI, CONNECT) and Member States. This will be achieved via the establishment of a new partnership strategy to increase EFSA's capacity in working together with all actors, to create an EU community for risk assessment, to avoid duplications and divergences, to align strategies and streamline frameworks through a joint governance.

## 4. Scientific topics for discussion

### 4.1. EFSA guidance on technical requirements to establish the presence of small particles including nanoparticles (EFSA-Q-2019-00692)[3]

The SC was presented the Guidance on the technical requirements to establish the presence of small particles including nano particles for possible endorsement for public consultation (planned for 8 weeks over summer 2020). This guidance follows a mandate from the EC and complements the 2018 SC Guidance on the risk assessment of nanomaterials (currently under update). 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
[3] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00692

Guidance describes the technical requirements that should be submitted for conventional materials (i.e. materials that do not meet the legal definition for engineered nanomaterials in food and feed established in the Novel Food Regulation 2015/2283) to demonstrate that the material does not consist of, or contain, a fraction of small particles, including particles at the nanoscale, or that this fraction has been properly assessed by the existing safety studies.

The Guidance offers different appraisal routes, grouped in sections according to the terms of Reference (ToRs) and recommendations for conducting new studies. An advanced draft was already presented to the SC at the Plenary meeting in April, and all comments received were addressed by the Nano WG. DG Santé submitted comments regarding the implementation of the Guidance, which were discussed and agreed by the SC. Following the presentation and discussion, the draft was endorsed by the SC for public consultation. The consultation will be launched in July.

## 4.2. New EC mandate on acceptable daily intake for exposure to copper

The SC was informed about the new mandate received from the EC on the determination of the acceptable daily intake (ADI) for exposure to copper (**M-2020-0087).** The ToRs which are 1) on the establishment of an ADI to be used by the EC and 2) on a new estimation of copper intake, taking into account all routes and source of exposure and different approaches and scenarios, were presented.

This work is an overarching activity and all relevant Panels (e.g. CONTAM, PPR, NDA) will be informed in due time, through regular report to the SC and Chairs of the Panels. In addition, EFSA staff from those Panels are involved in the WG. The assessment will be made on copper, whatever the source is (i.e. whether it has a regulated or non-regulated product origin). The deadline for delivering an opinion is 31 December 2021. Jean-Charles Leblanc from the CONTAM panel was nominated as Chair of the WG.

## 4.3. Risk assessment of beeswax adulterated with paraffin and/or stearin/stearic acid when used in apiculture and as food (honeycomb) EFSA-Q-2019-00159[4]

The SC was informed about the publication in May 2020 of the technical report on the risk assessment (RA)of beeswax adulterated with paraffin and/or stearin/stearic acid when used in apiculture and as food (honeycomb). The presentation contained an overview on the reporting of the issue by the RASFF system and Member States, leading to a mandate to EFSA by the EC. The ToRs of the mandate were presented and explained. In addition, the purity criteria defined by the working group and the risk assessments for bees and humans were presented. A way forward was also discussed on the issue of food fraud as an emerging risk, where EFSA could play an important role.

Terminology on mineral oil saturated hydrocarbons and mineral oil aromatic hydrocarbons (MOSH-MOAH) needs further clarification and the Chair of the CONTAM Panel offered to provide some support on this aspect. The issue of food fraud and adulteration is highly relevant and EFSA would need to put more efforts in this area. The need for more traceability and use of batch numbering was found to be challenging in this case of fraud.

[4] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00159

## 4.4. Draft guidance on appraising and integrating evidence from epidemiological studies: chapter 4.1, 4.2 and 4.3. (EFSA-Q-2019-00199)[5]

A brief overview of the mandate background, ToRs and the work done so far of the first three sections of the document was presented to inform the observers. The changes and further additions to the document made since the previous SC Plenary meeting were explained. The draft conclusions and recommendations were presented.

In the discussion, SC members provided their feedback and a limited number of suggestions for changes were made. The WG will address these and add a statement clarifying that the conclusions and recommendations are provisional pending the finalisation of the work. The SC endorsed this draft Guidance for publication as intermediate report to be applied by Panels in a testing phase.

The document will be published by the end of July 2020 and the test phase will be conducted over the next 12 months. It is planned that the final section of the Guidance, addressing ToR 3 and providing further explanations on the use of epidemiological studies in answering Panel-specific questions (e.g. setting reference or health-based guidance values) and on the use of epidemiological studies in the different types of scientific assessments (e.g. nutrition, toxicology, animal and plant health), will be drafted after the test phase has been completed considering the comments from the Panels.

## 4.5. Draft statement on "EFSA approaches for the Derivation of Health Based Guidance Values (HBGV) for food additives, other regulated products and nutrients" (EFSA-Q-2019-00505)[6]

The SC was presented the statement on the derivation of Health Based Guidance Values (HBGVs) for regulated products that are also nutrients for possible endorsement for public consultation (planned for 8 weeks over summer 2020). The EC can ask EFSA to advise about HBGVs for nutrients through generic mandates, addressed by the NDA Panel. This statement covers situations when EFSA has to establish a HBGV for a nutrient under the sectoral framework for regulated products. This can lead to a complex situation in which two assessments requiring the establishment of HBGVs for the same substance (i.e. a nutrient) are carried out under different regulatory frameworks, using similar but not identical scientific methodological approaches. This is a recurrent situation for food additives and pesticides; recent examples include the assessment of phosphates and chlorides as food additives, and copper used as a pesticide. This may occasionally occur for other regulated products.

A review of EFSA approaches was presented to the SC in February and a proposal for the risk characterisation and main recommendations was presented and discussed by the SC in April. In addition to the SC comments, an advance draft was distributed to the relevant Panels and units, and all comments have been addressed by the WG. Following the presentation, several elements were further clarified. Comments from DG Santé were also discussed. After the discussion, the SC mandated the WG to consider the additional comments from the SC and endorsed the statement for public consultation.

[5] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00199
[6] http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2019-00505

# 5. Feedback from the Scientific Committee/Scientific Panels, EFSA, The European Commission

## 5.1 Feedback Scientific Panels

The various Panel Chairs provided feedback on the three following horizontal topics: (1) Challenges in the implementation of SC cross cutting guidance; (2) Methodologies development; (3) Risk assessment on cross cutting issues.

**Food Contact Materials, Enzymes and Processing Aids (CEP) Panel**

The Chair of the Panel provided an overview on the activities of the CEP Panel. In particular, a thorough description of the present core activities and the self-tasking activities of the enzyme working group. Most of the food enzymes remain to be evaluated (70%) and an updated scientific guidance on data requirement for food enzyme applications will be initiated in July 2020. The WG published a statement on the exposure assessment of food enzymes in 2016. EFSA launches regularly open calls for data to assess food enzymes (the next being in 2020 on milk, dairy, fruit and vegetable processing). A statement on the characterisation of microorganisms used for the production of food enzymes was published in June 2019.

The Panel is also involved in the safety evaluation of food contact materials (FCM) including plastic FCM, substances used in active and intelligent materials and in processes for the production of recycled plastics. In the area of FCM, the CEP Panel needs to re-evaluate Bisphenol A (BPA) in view of the publication of new toxicological studies and this work is expected to be adopted in September 2020. A new joint mandate with CONTAM was received from the EC to investigate the safety of high-pressure processing (i.e. cold sterilisation/pasteurisation approach). Finally, discussions are ongoing with the EC on a mandate for the re-evaluation of phthalates to be conducted in collaboration with ECHA.

**Nutrition, Novel Foods and Food Allergens (NDA) Panel**

The Chair of the Panel provided an overview on the activities of the NDA Panel in the area of novel food and nutrient sources, health claims, foods for special groups and tolerable upper levels (UL). Claims were received for Art 13(5) (on Bifidobacterium animalis subsp. lactis Bi-07 for improvement of lactose digestion in individuals who have difficulty digesting lactose) and for Art 14 (on Anxiofit-1 that contains Echinacea angustifolia hydro-alcoholic root dry extract that ameliorates sub-threshold and mild anxiety). Five applications were received to assess the safety for children (<3 years) of protein-hydrolysate formula and one application on the efficacy in reducing the risk of developing an allergy. The opinion on dietary sugars (based on the Tolerable UL published in 2016) will go through a public consultation early 2021 to be adopted by the NDA Panel in spring 2021. 56 applications on novel foods are under review by the panel.

Finally, the EC requested EFSA to assess additional scientific evidence in relation to EFSA's Scientific Opinion on the essential composition of total diet replacement for weight control.

**Food Additives and Flavourings (FAF) Panel**

The Chair of the Panel reported to the SC on methodology development and applications of cross cutting issues. The revisions made on the Guidance on (new and renewal of) smoke flavourings included considerations on genotoxicity of mixtures, dietary exposure, uncertainty, environmental risk assessment. The Guidance is expected to be adopted by the FAF Panel in January 2021.

The first cross-cutting issue is the EC mandate for the risk assessment of titanium dioxide (E171) for which data keep coming in. For this work, the Guidance 2018 on nano is applicable and it requires collaboration with the SC WG on nano and WG genotoxicity.

The second cross-cutting issue is the work conducted by the WG genotoxicity on aneugenicity assessment. This work presents methodological challenges with regard to the assessment of flavourings. In addition to the issues reported, two protocols for the assessment of sweeteners were developed using the principles of the PROMETHEUS: one covering hazard identification and characterisation, and the second exposure assessment.

**Plant Health (PLH) Panel**

The Chair of the Panel presented an overview on the activities conducted by the PLH Panel. Pest risk assessment (on bacteria, fungi, mites, insects, phytoplasma, viruses) presents two steps, firstly a pest categorisation and secondly a quantitative assessment. Commodity risk assessments are made for the analysis of high-risk plants for which a dossier is introduced by third countries. Priority pests impact assessments are made on new emerging lineS. The PLH Panel supports also Alpha Unit in preparedness, horizon scanning, plant pest survey and research to reduce uncertainty or to develop methodologies. The Chair reminded that 2020 is the international year of plant health and that observers are welcome to attend the next PLH Plenary that will be opened to observers.

**Additives and Products or Substances used in Animal Feed (FEEDAP) Panel**

The Chair of the Panel provided a summary of the FEEDAP Panel's activities in 2019/2020 with a total of 174 opinions adopted. The activities included a re-evaluation for most categories of additives, the development and update of more than 30 guidance documents, a close collaboration with the EC, the EFSA Panels and EU Agencies (e.g. with EMA on antimicrobial resistance) and stakeholders (e.g. through their participation in scientific events). FEEDAP Panel is cooperating with the BIOHAZ Panel (antimicrobial active substances in non-target feed) with the CONTAM Panel (nitrites and nitrates in feed and risks to animal health) and AHAW (African Swine Fever).

**Plant Protection Products and their Residues (PPR) Panel**

The Chair of the Panel informed the SC on the latest outputs discussed at the last PPR Panel Plenary. The EC requested that a proper methodology is developed to provide guidance to applicants, Member States and EFSA experts on the methodological framework for conducting environmental exposure and risk assessment for transitional metals when used as Plant Protection Products (e.g. copper). Another EC mandate calls for review of all relevant data on *Pseudomonas chlororaphis* MA342 as a fungicide available in the renewal dossier to provide an assessment of the capacity of translocation to edible plant parts. Further consideration of the aneugenicity of the metabolite DDR will be also assessed. A Scientific Opinion is currently being drafted based on IATA (Integrated Approaches to Testing and Assessment) to assess developmental neurotoxicity (DNT) with 2 substances selected as case-studies. Finally, work is

underway to develop a Scientific Opinion on AOPs (Adverse Outcome Pathways) relevant for the identification of substances having endocrine disrupting properties gathering evidence with a systematic review.

**Genetically Modified Organisms (GMO) Panel**

The Chair of the Panel provided the SC with a figure on the current total number of applications under risk assessment by the GMO Panel (i.e. 4 applications for renewal and 25 new applications). Three applications which are new were presented in detail regarding their use and introduced traits. The first is a genetically modified LBFLFK canola submitted under Regulation (EC) No 1829/2003 and consists in a new fatty acid biosynthetic pathway (EPA-DHA) and herbicide tolerance. The second application is a soy Leghemoglobin produced from genetically modified Pichia pastoris submitted under Regulation (EC) No 1829/2003 and is designed for producing a meat analogue ingredient (e.g. for vegetarian burgers). The third is for the GM DP-023211-2 maize submitted under Regulation (EC) No. 1829/2003 created by site-specific integration using I-Cre and flippase to achieve precise genome insertion by recombination. The latter expresses dsRNA and a novel insecticidal protein for control of corn rootworm pests.

The ongoing biotechnology mandates comprise development of scientific opinions on synthetic biology developments in plants, on genetically modified organisms engineered with gene drives (gene drive modified organisms) and their implications for risk assessment methodologies, on in vitro random mutagenesis techniques, on GM plants from new genomic techniques and on plants using type 1 and type 2 Site-Directed Nucleases and oligonucleotide-Directed Mutagenesis.

**Animal Health and Welfare (AHAW) Panel**

The Vice-Chair of the Panel informed the SC about the progress made in the respective areas of animal welfare and health. With regards to animal welfare, the work conducted in rabbit production was completed. The work on "Slaughter of animals" and on the "Killing of animals for other purposes than slaughter" is underway.

The SC was informed with the launching of five new activities in the areas of "Transport of animals", "Protection of laying hens", "Protection of calves", "Protection of broilers" and "Protection of pigs".

With respect to animal health, the Chair mentioned the work on African Swine Fever (which comprises multiple mandates) with the most recent one completed as well as the reception of a new mandate on this issue. The work on the Rift Valley Fever and three other activities conducted in collaboration with the BIOHAZ Panel are still ongoing. They are on the "Categorisation of diseases causing Antimicrobial Resistance (AMR) in Animal Health Law (Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health), "meat inspection" and "AMR in non-target feed". The work on "Lumpy skin disease" was completed.

**Panel on Biological Hazards (BIOHAZ)**

The Chair of the Panel informed the SC about the activities completed over the years 2019 and 2020. These include the publication of 9 Scientific Opinions. The Scientific Opinion on Salmonella control in poultry flocks determine targets, public health impact and risk factors. Two other opinions assessed the public health risks posed by Shiga Toxin producing *E. coli* (STEC) and

*Listeria* in frozen fruits and vegetables. The other opinions were published on *Campylobacter* control in broilers, transport/storage in fishery products, whole genome sequencing (WGS) and metagenomics, qualified presumption of safety (QPS), chronic wasting disease (TSE) and animal by-products (ABP) applications.

**Panel on contaminants (CONTAM)**

The Chair of the Panel informed the SC about the recently finalised opinions and their adoption dates in three areas. In the area of environmental contaminants (risk assessment of chlorinated paraffins in feed and food, in December 2019), in plant toxins (Evaluation of the health risks related to the presence of cyanogenic glycosides in foods other than raw apricot kernels in March 2019; opinion on the risks for animal and human health related to the presence of quinolizidine alkaloids in feed and food, in particular in lupins and lupin-derived products in November 2019) and in the area of mycotoxins (risk assessment of aflatoxins in food in January 2020; risk assessment of ochratoxin A in food in March 2020).

An overview of the ongoing drafting of opinions was also provided. In the area of environmental contaminants and metals (perfluoroalkyl substances in food is foreseen to be published by end 2020; brominated flame retardants (BFRs) in food, Nickel in food), in plant toxins (glycoalkaloids in potatoes), in feed contaminants (nitrates and nitrites in feed), in marine biotoxins (shucking of scallops contaminated with domoic acid or lipophilic toxins exceeding EU limits).

## 5.2 Update on WGs activities

**Cross-Cutting WG Mixtox 2**

The working group had the last teleconference on May 14th and the next one is planned for June 30th. The working group has made progress on the MIXTOX 2 scientific opinion: "Scientific criteria for grouping chemicals into assessment groups for human health risk assessment of combined exposure to multiple chemicals". Schemes for hazard-driven criteria have been finalised and the scheme on prioritisation tools using exposure-driven and risk-based criteria has been drafted, discussed and is being finalised together with relevant examples. The working group will consult DG-SANTE on the relevance of producing a guidance document instead of a scientific opinion (as originally planned) to support the implementation of the methodologies in the work of EFSA panels. The draft document will be presented to the Scientific Committee at the September plenary (16th-17th) for a first reading.

**WG on Non Monotonic Dose Response**

A proposal and a set of generic questions were presented to the SC at the Plenary Meeting in April. The WG is implementing the SC recommendations and continuing with the assessment of the available information. The next WG meeting is planned for July.

**WG on Benchmark Dose**

EFSA is contributing to the update of chapter 5 on dose-response assessment of the WHO IPCS Environmental Health Criteria 240. This work resulted in a consensus among participants on how to perform benchmark dose analysis of dose-response data. The EFSA cross-cutting working group on benchmark dose is now updating the SC guidance on the use of the benchmark dose in risk assessment to reflect this consensus. The main changes will consist in providing further

guidance on how to select the benchmark response, propose a unified set of models to be fitted, independently of the type of data (quantal or continuous) and introduce Bayesian model averaging as the preferred approach for BMD analysis. The EFSA Platform for BMD analysis is being updated in parallel to implement these changes. This work, done in cooperation with other partners (RIVM, US EPA, US NIEHS and Health Canada), aims at developing more harmonised approaches for BMD analysis. It is due by Summer 2021 with a prior public consultation around March-April 2021.
Another task of the cross-cutting working group on benchmark dose is to provide assistance to the EFSA Panels and Units when encountering BMD-related difficulties that are not addressed by the existing guidance document. The latest requests concerned human data and confirmed the need to develop guidance on how to perform benchmark dose analysis of human (epidemiological) dose-response data.

**WG on Synthetic Biology**

Upon endorsement by the SC, the draft opinion on "the evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of micro-organisms obtained through synthetic biology" went into public consultation on 31 March 2020. Due to COVID-19, the deadline was extended until 4 June before closing the public consultation. The comments received are being evaluated by the WG SynBio. Wherever appropriate, these comments are taken into account for the finalisation of the draft Opinion. In total 16 parties (National authority, University/academia, NGO, Private sector, in personal capacity or other) inserted 186 submissions in the online tool (with multiple comments inside). The comments, as well as the responses, shall be published in a Technical Report. The adoption of the Opinion is foreseen in the September SC plenary meeting.

**WG on Genotoxicity**

The public consultation of the draft guidance on aneugenicity assessment closed at the end of May. About 100 comments were received and will be addressed by the WG. Finalisation of the guidance is expected by end of 2020.
The WG is also busy in proving advice to 2 requests received from the FIP unit on styrene and on titanium dioxide.
The SC was also informed that a new colleague, Rositsa Serafimova, has joined the Unit on 1st June. She will take over from Daniela Maurici the coordination of the WG genotoxicity.

**New WG on Emerging Chemical Risk Identification**

A systematic framework for the identification of emerging chemical risks and how data generated under REACH regulation could be used to identify emerging chemicals risks in the food chain was published in 2014[7]. The methodology proposed was further developed and tested on 100 substances registered under REACH (REACH 1[8]). The tested screening procedure was then applied to the 15021 substances registered in REACH (REACH 2[9]). Prioritisation based on the scores assigned and additional data curation steps identified 212 substances that were considered potential emerging risks in the food chain. A follow-up project has been proposed and agreed by the Scientific Committee at its meeting of June 2019 to analyse food samples for occurrence of substances in the priority list. Building on past projects based on horizon scanning, an ad hoc WG on emerging chemical risks identification (ECRI) was set up. The WG has been established in March 2020 for a duration of four years. The objectives of the WG are: (1) to

7 https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2014.EN-547
8 https://www.efsa.europa.eu/en/supporting/pub/en-1050
9 https://www.efsa.europa.eu/en/supporting/pub/en-1597

ensure scientific advice for all activities on emerging chemical risks by supporting the two new projects REACH 3 and JRC TIM (Tool for Innovation Monitoring (TIM) developed by the Joint Research Centre (JRC)) and by reviewing and validating at regular intervals collected data on emerging chemical risks from the various sources (other projects, knowledge networks & international cooperation); (2) to support the dissemination of information on emerging chemical risks in food by supporting the planning and implementation of scientific conference on chemical emerging risk identification. The objective of the project REACH 3 (January 2021 – 2023) will be to analytically screen for newly emerging chemicals in the food chain by suspect screening in food and feed on a selection of 212 emerging chemicals which are registered under the current REACH legislation.

**New WG on Read Across**

Read-across (RAx) is an approach used in chemical risk assessment that allows for the screening, classification, prioritization and hazard assessment of chemicals based on the toxicological data of similar chemicals. It is the most common alternative to animal testing and it provides opportunities for predicting toxicological responses for data-poor chemicals at the organism level. A clear need for developing a framework and guidance on RAx within EFSA was previously identified by the SC. The ToRs are as follows:

- To develop a framework and guidance on the use of RAx in risk assessment.
- To identify the applicability domain (in terms of toxicological endpoints and chemical space) for the use of RAx in food safety.

The deadline of the work to be performed under this mandate is 31 December 2023 and involves the creation of new WG on RAx under the SC. Susanne Hougaard Bennekou has been nominated as chair of the working group.

# 6. Other topics for information and discussion

## 6.1. EFSA collaboration with DG RTD

The SC was provided with an overview of the new framework programme from DG-RTD with a value of 10 billion euros for research projects on food (not only food safety). The framework includes partnerships and one that is relevant for EFSA is "an EU Partnership for the Assessment of Risk from Chemicals – PARC". Further details on the project is provided under 6.2. EFSA works closely with DG-RTD to ensure EFSA's needs are included and covered.

## 6.2. European Partnership for the Assessment of Risk from Chemicals (PARC)

The PARC consortium is the EU partnership for regulatory chemical risk assessment under the upcoming Horizon Europe programme. Its overall objective is to consolidate and strengthen the EU's research and innovation capacity for chemical risk assessment to protect human health and the environment and contribute to a non-toxic environment and a circular economy. The Concept paper for PARC was published early May and was shared with the SC for information. The partnership is expected to involve 25 Member States and will be funded equally by EC and Member States. It is expected that EFSA and other EU agencies (EEA, ECHA) will be involved in various aspects of the project. The project will start in early 2022 and a series of consultations have just started to feed proposals for prioritisation of the first three-year work programme. The project is expected to run until 2028.

### 6.3. Question and answers from/to observers

Time did not allow to answer the questions from the observers and therefore, it was agreed that question and answers would be given in writing in the minutes of the plenary, to be published on the EFSA website.

## 7. Any Other Business

### 7.1. Pre announcement of a workshop on "Artificial intelligence in risk assessment"

The SC was informed about the proposal to organise a workshop (as web conference) with the SC on the use of Artificial Intelligence (AI) covering the whole spectrum of possible evidence streams and its management during risk assessment. EFSA is already developing a project for the use of AI in literature systematic reviews but other data-intensive activities in other theme areas such as chemical and environmental risk assessment are to be considered. The objective of the workshop is to explore other areas where AI can be used to identify and analyse scientific evidence for risk assessment and possible future activities of EFSA. A theme paper will be distributed to the SC for consultation. The date (10 or 12 November 2020) will be confirmed at the next SC Plenary in September. The SC will be consulted for defining the programme and identifying possible speakers.

### 7.2. General matters arising

The Scientific Committee was provided with a document summarising relevant activities that had taken place since the last plenary meeting with focus on the Interagency and International Scientific cooperation and EFSA Stakeholders Meetings.

### 7.3. List of published opinions

The Scientific Committee was provided with a document containing the list of published opinions from 6 April to 4 June 2020, produced by the different panels and units, including those on applications for food contact materials, enzymes, flavourings, GMOs, health claims, novel foods and food additives. The list also includes published conclusions on the peer review of pesticides and ongoing public consultations.

### 7.4. Draft agenda next SC plenary

The SC was presented with an overview of the topics that will be on the agenda of the September meeting. The meeting is scheduled for the 16-17 September via web conference.

100th SC Plenary: 16 Sep (full day) – 17 Sep (9.00-13.00)
101st SC Plenary: 11 Nov (full day) – 12 Nov (9.00-13.00)

END OF THE MEETING

| List of observers attending via web-conference | | | | |
|---|---|---|---|---|
| **Title** | **Name** | **Country** | **Organisation** | **Affiliation** |
| Ms | Aasa Jenny | Sweden | Swedish Food Agency | National authority |
| Ms | Abadjieva Desislava | Bulgaria | Institute of biology and immunology of reproduction, Bulgarian academy of | University/public research |
| Mr | Anselmo Henrique | Netherlands | RB | Private sector |
| Ms | Bonerba Elisabetta | Italy | University of Bari | University/public research institute |
| Mr | Bonovolias Ioannis | Greece | Aristotle University of Thessaloniki | University/public research |
| Mr | Botham Phil | United Kingdom | Syngenta | Private sector |
| Ms | Brasca Milena | Italy | Institute of Sciences of Food Production, National Research Council | University/public research institute |
| Mr | Buck Niel | Switzerland | General Mills Inc | Private sector |
| Ms | Calaco Estefania | Spain | Food Factory | Private sector |
| Mr | Capozzi Vittorio | Italy | Institute of Sciences of Food | University/public research |
| Ms | Cara Magdalena | Albania | Musabelliu | University/public research institute |
| Mr | Cassart Michel | Belgium | PlasticsEurope | International organisation |
| Ms | Castenmiller Jaqueline | Netherlands | Netherlands Food & Consumer Product Safety Authority (NVWA) | EFSA Panel/WG/Network |
| Ms | Cogalniceanu Elena | Belgium | EAS Strategies | Private sector |
| Mr | Dainelli Dario | Belgium | FEC EU FEDERATION OF CUTLERY AND COOKWARE | Private sector |
| Ms | Dammeier Jana | Germany | Chemische Fabrik Budenheim KG | Private sector |
| Ms | Donnarumma Lucia | Italy | CREA DC | University/public research |
| Mr | Eisert Markus | Germany | Bayer AG | Private sector |
| Ms | Gabriel Isabel | Portugal | IASFA, I. P. And PORTUGUESE ARMY/VETERINARY SERVICE | Other |
| Ms | Gârboan Gabriela | Romania | Ministerul Agriculturii și Dezvoltării | National authority |

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| Ms | Geremia Ilaria | Italy | TEAM mastery S.r.l. | Private sector |
| Ms | Giner Marta | Spain | Devreg Consulta | Private sector |
| Ms | Herve Maryse | Belgium | EU Specialty Food Ingredients | Private sector |
| Ms | Hrastelj Nineta | Belgium | European Chemical Society (EuChemS) | Other |
| Ms | Ioannou Kakouri Elmi | Cyprus | European University of Cyprus | University/public research institute |
| Ms | Jankovenko Svetlana | Estonia | Ministry of Rural Affairs | National authority |
| Ms | Jassal Masha | Ireland | Student | University/public research institute |
| Mr | Jozwiak Akos Bernard | Hungary | University of Veterinary Medicine, Budapest | EFSA Panel/WG/Network |
| Mr | Jucan Adrian | Romania | DSVSA SUCEAVA | University/public research |
| Ms | Knazovicka Vladimira | Slovakia | National Agricultural and Food Centre - Research Institute for Animal | University/public research |
| Mr | Lazaro-Mojica Jonas | Belgium | FoodDrinkEurope | International organisation |
| Ms | Levorato Sara | United Kingdom | Unilever | Private sector |
| Ms | Mancini Laura | Italy | Istituto Superiore di sanità | University/public research |
| Mr | Mantovani Alberto | Italy | Istituto Superiore di Sanità | EFSA Panel/WG/Network |
| Ms | Marrocchino Elena | Italy | University of Ferrara | University/public research |
| Ms | Martinez Parrilla Mica | Italy | BASF | Private sector |
| Ms | Martyn Danika | United Kingdom | Intertek | Private sector |
| Mr | Mathew Joash | Belgium | International Platform of Insects for Food and Feed (IPIFF) | Private sector |
| Mr | McElhinney Cormac | Ireland | FSAI | National authority |
| Ms | Melching-Kollmuss | Germany | BASF SE | Private sector |
| Ms | Micu Daniela | Romania | Romanian Sanitary Veterinary Authority - Timis County | National authority |
| Ms | Musaraj Adanela | Albania | Ministry of agriculture | International organisation |

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| Ms | Nardi Tiziana | Italy | CREA - Council for Agricultural Research and Economics - Research | University/public research |
| Ms | Neil Persson Karin | Sweden | Swedish Food Agency | National authority |
| Ms | Nunez Rocio | Canada | GFSS Inc | Private sector |
| Mr | Nurra Gianluca | Belgium | COCERAL aisbl | Private sector |
| Ms | Ono Kaori | France | Ajinomoto Europe | Private sector |
| Ms | Ovesna Jaroslava | Czech | Crop Research Institute - Scientific | Other |
| Ms | Palisi Angelica | Italy | Free researcher in Nutrition | University/public research |
| Mr | Pascale Michelangelo | Italy | National Research Council of Italy | University/public research |
| Ms | Pascual-Linaza Ana | Ireland | European Commission | EU body |
| Ms | Pastiu Anamaria Ioana | Romania | UASMV Cluj | University/public research |
| Ms | Pekan Gulden | Turkey | Hasan Kalyoncu Universitey | University/public research |
| Ms | Pereira Marina | Belgium | Humane Society International | NGO |
| Mr | Phipps Kirt | United Kingdom | Intertek | Private sector |
| Ms | Podevin Nancy | Belgium | Pioneer Overseas Corporation | Private sector |
| Mr | Prieto Arranz Miguel | Belgium | Cefic - the European Chemical Industry | Private sector |
| Mr | Rito Elias | Belgium | Fecc | NGO |
| Mr | Santini Alberto | Italy | | University/public research |
| Ms | Sarubbi Fiorella | Italy | National Research Council | Other |
| Ms | Sberveglieri Veronica | Italy | CNR-IBBR | National authority |
| Ms | Sbrana Cristiana | Italy | National Research Council | University/public research |
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| Ms | Singh Srishti | Portugal | KU Leuven | University/public research |
| Mr | Solà-Oriol David | Spain | Universitat Autònoma de Barcelona | University/public research |

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| Mr | Tomasone Roberto | Italy | CREA | University/public research |
| Ms | Turrini Aida | Italy | Council for Agricultural Research and | EFSA Panel/WG/Network |
| Mr | Vacca Gianluca | Italy | | Press/media |
| Mr | Van Peer Ron | Netherlands | FMC | Private sector |
| Mr | Vanhoof Bart | Netherlands | UPL Europe Ltd | Private sector |
| Ms | Vanova Hrncirik | Netherlands | Meatable | Private sector |
| Ms | Vlachou Angeliki | Belgium | FoodDrinkEurope | Private sector |
| Mr | Vorss Romans | Belgium | FRUCOM | Private sector |

**Questions from observers submitted before the meeting and answers from EFSA**

**Q1.** At the previous observation of Scientific Committee, the possibility was mentioned about the Health Based Guidance Values (HBGV) guidance (or statement) should cover macronutrients, not only micronutrients. Would it be possible to confirm this point?

**A1**. The Statement covers all cases when there is a need for establishing a HBGV for a nutrient used as a regulated product; this may include macronutrients, but a case by case decision will be required for amino acids. In any case, the Statement focuses on the EFSA internal process and the aim is to ensure harmonization; the only specific recommendation for applicants and other interested parties is to ensure that they consider that the substance is a nutrient when compiling the available information or conducing new studies.

**Q2.** "Guidance on appraising and integrating evidence from epidemiological studies". Identifying, using and interpreting biomarkers (exposure/effect/susceptibility) is often a critical aspect for epidemiological studies in humans as well as animals. Will the guidance provide specific attention and/or recommendations on this aspect?

**A2.** The use of biomarkers, e.g. for exposure assessment, is covered at several points in the guidance document. There is no specific section on this however.

**Q3.** Has EFSA any intention to work on harmonization of the risk assessment (and consequent limits) for metals as resulting from DG SANTE and Council of Europe activities?

**A3.** With regards to the specific area of metals articles, the limits from DG SANTE are those listed either in the Plastic EU regulation 10/2011 or in the Ceramics Directive 84/500/EEC currently under revision. When a new or updated health-based guidance value on an element is set notably by an EFSA Panel, it is considered by DG SANTE who may update the limit in the mentioned Regulations. If different limits on the same element coexist in the EU legislation and in the Council of Europe and this is not scientifically justified, the EC may consult EFSA. However, it should be noted that while EFSA is the European Authority for safety assessment, the Council of Europe may have additional or different considerations including management consideration such as the ALARA principle what may explain the setting of a different limit.

**Q4.** What does EFSA, in more general terms, to harmonize risk assessment for food contact materials and articles (e.g. plastics vs. non-plastics)?
**A4.** Plastics materials and articles are EU-regulated under the Regulation 10/2011 while the so-called non-plastics are not specifically regulated at the EU level. As a consequence, EFSA is assessing substances used to manufacture plastics prior to their authorisation, not those used to manufacture non-plastics.
The data needed and the risk assessment methodology applied for plastics are available in the SCF guidelines (2001) and in the EFSA note for guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials (2008 and 2017). These are generally taken into account by national Authorities (e.g. BfR, ISS, ANSES) for the assessment of non-plastic materials and articles that are object of a specific regulation in their Member States. Moreover, in its opinion published in 2016 on recent development in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials, the EFSA CEF Panel highlighted that the proposed scientific reasoning and risk assessment principles can apply to all other migrating substances from all types of FCM.
It should be noted that the EFSA note for guidance and the CEF Panel opinion integrate the related cross-cutting/transversal opinions of the EFSA Scientific Committee (e.g. on genotoxicity, TTC) in order to harmonize the risk assessment methodologies across EFSA where appropriate. In general, the FCM area applies the related cross-cutting/transversal opinions of the EFSA Scientific Committee (e.g. more recently on nano, mixtures).

**Q5.** I am aware that EFSA applies the probabilistic methodology mainly in acute risk assessment. Are there any intentions/plans for this methodology to be extended to cover chronic risk assessment as well?
**A5.** Acute dietary exposure assessments aim at estimating the probability that consumers will be exposed to a high concentration of a chemical within a single day or event. This type of assessment requires the combination of random variables (i.e. food samples and consumption events) and is best addressed by means of probabilistic (or stochastic) modelling. This is the reason why, for the time being, probabilistic exposure assessment is mainly used for acute scenarios.

For chronic assessments, probabilistic modelling is not necessarily of interest. Chronic exposure estimates are calculated over a longer period and are less impacted by fluctuation (or randomness) of the variables. Therefore, deterministic models can already provide good estimates of chronic exposure, and probabilistic modelling would only be used in view of addressing specific uncertainties (e.g. use frequency, co-exposure, sampling uncertainty, etc.).

EFSA recently published the cumulative dietary risk characterisation of pesticides that have chronic effects on the thyroid. This is an example where probabilistic modelling was applied in a chronic exposure assessment.
https://doi.org/10.2903/j.efsa.2020.6088

**Q6.** Have there been any significant scientific developments in assessing historic exposure to environmental chemicals such as pesticides, which could be applied to epidemiology studies looking at possible disease association or causation and would improve their robustness and value in risk assessment?
**A6.** This question does not fall under the Scientific Committee remit, but in the remit of the Panel on Plant Protection Products and their Residues (PPR) and/or Pesticide Units (PREV, PRES). The mandate of the PPR Panel is to provide scientific advice on the risk assessment of pesticides for consumers, operators, workers and the environment. Currently the PPR Panel is working on a Scientific Opinion to develop Integrated Approaches to Testing and Assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment of selected pesticide active substances, in particular deltamethrin. One of the lines of evidences used to this end is human observational studies, particularly birth cohort studies, where exposure was assessed by biomonitoring of urine samples from

pregnant women. However, currently no scientific activity is under way using "historic exposure" to pesticides.

## Questions submitted during the meeting and answers from EFSA

**Q1.** In relation to agenda point 4.3, the question was whether EFSA was aware about the use of beeswax to replace plastic.

**A1.** It was clarified that in the call of data conducted by EFSA for the gathering of more information/evidence on adulterated beeswax, the media (through the JRC media monitoring tool, MedISys) have found indeed an increase trend of use of wrapping paper for food made of beeswax and potential emerging risks that the SCER Unit monitors (further information can be found in the reference list of the published technical report). It was clarified that beeswax adulteration occurs when recycling (old) waxes, which is a current beekeeping practice that is described in section 5 of the report.

**Q2.** Will the epidemiological guidance also be used to take into account epidemiological (observational studies) in EFSA health claims assessments or is it only targeted at risk assessments (eg currently health claims assessments for nutrients/other substances and maybe in future: botanical claims?)

**A2.** Yes, the guidance provides a lot of useful elements not only for risk assessment but also assessing positive effects (such as botanical claims).

**Q3.** Was a guidance on reporting epidemiological study adopted?

**A3.** Given the large variability in designs, it would be difficult to provide a general guidance. Some elements will describe what you need to report, also in the upcoming section on BMD modelling

**Q4.** Yesterday there was discussion on the developing guidance on the use of epidemiological evidence and the appropriateness of using examples which are under active review (e.g. use of epi' in the PFAS draft Opinion). Being mindful of previous situations when recent opinions have had to be updated soon after finalisation due to new methodological guidance being issued (e.g. MCPD and BMD), should EFSA establish a policy to manage these situations? Furthermore, in cases when evidence that is pivotal to an opinion is under methodological review, should the EC be made aware in the summary of an opinion that this introduces an additional uncertainty into the issued opinion?

**A4.1** In the existing process for guidance finalisation, there is always a public consultation before finalisation. This is an opportunity for issues to be raised such as those you highlighted. In addition, we often include a pilot phase of around one year where the guidance is trailed on a few real cases in order to confirm whether the guidance is truly applicable in real cases. These lead to a revision of the guidance before it comes into full force. Furthermore, and following consultation with the European Commission, we also indicate the date from which the guidance is applicable.

**A4.2** The guidance on the identification and assessment of uncertainties in risk assessment is intended to also identify cases such as the one you highlighted.