SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

Scientific Committee

Minutes of the 95th Plenary meeting

Held on 12 September 2019, 09.00 – 18.15h
13 September 2019, 09.00 – 13.00h

EFSA, Parma (Italy)

(Agreed on 4 October 2019)

Participants

- **Scientific Committee Members:**

  Simon More (chair), Diane Benford (vice chair), Susanne Hougard Bennekou (vice chair), Vasileios Bampidis, Claude Bragard, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Kostas Koutsoumanis, Kyriaki Machera, , Søren Saxmose Nielsen (only on day 1), Nils Rostoks, Dieter Schrenk, Josef Schlatter, Vittorio Silano, Dominique Turck, Maged Younes.

- **European Commission:**

  Marina Marini (DG SANTE DDG.2.D1) attending via Video Conference

- **EFSA:**

  - **Executive Directorate:** Bernhard Url, (only for agenda item 9) Marta Hugas (only day 2)
  - **Risk Assessment and Scientific Assistance Department (RASA):** Juliane Kleiner (only day 2)
  - **Scientific Evaluation of Regulated Products Department (REPRO):** Guilhem de Seze (only day 2)
  - **Scientific Committee and Emerging Risks Unit (SCER):** Tobin Robinson (only day 1), Daniela Maurici, Djien Liem, Bernard Bottex, Jean-Lou Dorne, Andrea Gervelmeyer, Angelo Maggiore, Caroline Merten, Reinhilde Schoonjans, Jose Tarazona (only day 1), Agnes Rortais
  - **Assessment and Methodology Support Unit (AMU):** Laura Martino, Elisa Aiassa, (only for agenda item 6), Didier Verloo
  - **Genetically Modified Organisms Unit (GMO):** Michele Ardizzone (only for agenda item 7)
  - **Additives and Products or Substances used in Animal Feed Unit (FEEDAP)** Maria Vittoria Vettori, Orsolya Holczknecht (only for agenda item 12)

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- **Biological Hazards and Contaminants Unit** (**Biocontam**): Marco Binaglia (only for agenda item 5)
- **Animal and Plant Health Unit (ALPHA)**; Nikolaus Kriz, Yves van der Stede (only for agenda item 12)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hanspeter Naegeli, chair of the Genetically Modified Organisms panel (GMO), replaced by Nils Rostoks.

2. Adoption of agenda

The agenda was adopted with the addition of an item (as 9.1) proposed by the chair of the BIOHAZ Panel related to observations about methodologies and common practices currently implemented in chemical risk assessment and divergences with respect to microbiological risk assessment.

3. 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.

4. Guidance on appraising and integrating evidence from epidemiological studies: discussion of the draft chapters "Introduction on epidemiological studies" and "Key concepts of evidence appraisal" (EFSA-Q-2019-00199)

Progress made in drafting the guidance document was presented. The discussions focussed on the sections providing an introduction on epidemiological studies and explaining the key epidemiological concepts relevant for evidence appraisal. The feedback provided by the Scientific Committee members will be used by the Working Group to further develop the document.

The Scientific Committee members were informed that a Plant Health (PLH) panel expert with a background in epidemiology will attend the next physical meeting of the WG (in November 2019), to understand if and how plant health specific issues should be covered in the guidance document. After this, a final decision will be taken by the PLH panel chair and coordinator regarding the need to cover also plant health issues in the guidance document.

The chair of the Scientific Committee reminded the members to reflect on the exact types of question for which epidemiological studies are or could be used in panels' assessments, and to highlight

[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

examples of difficulties panels are experiencing with epidemiological studies. To this end, panel chairs will be asked to complete the information provided during the survey carried out in May 2019, if and where necessary. This evidence will enable the Working Group to adequately address the needs of the different panels in the further sections of the document. An updated version of the draft guidance will be tabled for a second reading probably at the December meeting.

5. Overview of the Panel on Contaminants work programme 2018-2021 (CONTAM)

The Chair of the Panel on Contaminants (CONTAM) provided an overview of the work programme 2018 – 2021. The main areas of activities are: a) Environmental contaminants and metals; b) Mycotoxins; c) Plant toxins and d) Feed contaminants. The Panel is also following two activities related to Emerging Risks: micro and nanoplastics in food and ciguatera food poisoning.

In relation to micro and nanoplastics in food, as a follow-up of the CONTAM Panel Statement published in 2016 (link here), an EFSA Scientific Colloquium will be organised in 2020. The aim is to define priority research questions underpinning the generation of the data necessary to characterise the risks to human health.

In relation to the characterization of the risk of ciguatera food poisoning in Europe, a framework Partnership Agreement is ongoing (called Eurocigua, link here: http://www.aecosan.msssi.gob.es/AECOSAN/web/ciguatera/home/aecosan_home_ciguatera.htm) having the objectives of: a) determining the incidence of ciguatera in Europe and the epidemiological characteristics of cases; b) assessing the presence of ciguatoxin in food and the environment in Europe; c) developing and validating methods for the detection, quantification and confirmation of the presence of ciguatoxin contaminated specimens. The Panel is following, in particular, the third objective (analytical part).

6. Draft framework for protocol development for EFSA's non-application scientific assessments

A Scientific Committee Working Group (WG) started its activity in May with the aim of designing a framework for protocol development for EFSA's non-application scientific assessments (EFSA's assessments for which the entire process from problem formulation to evidence synthesis and integration is performed by EFSA). This protocol will ensure flexibility and enhance harmonisation across EFSA's areas.

The document presents the scientific assessment process at EFSA and the rationale for using protocols. A 4-step approach (1. Problem Formulation and Protocol development; 2. Implementation of Protocol; 3. Verification of compliance between Protocol and actual assessment; 4. Documentation and Reporting) was developed and tested through case-studies. It has already been used in some EFSA assessments (e.g. the protocol for the Scientific Opinion on free sugars from all dietary sources, NDA panel).

The SC provided several comments to the document that will be addressed by the WG. An updated version of the document will be presented at the next SC plenary.

7. Draft technical report "Animal dietary exposure: overview of current approaches used at EFSA" (EFSA-Q-2018-01020)

The SC was presented with the draft Technical Report "Animal dietary exposure: overview of current approaches used at EFSA". The report presents an overview of the current approaches in place at EFSA to assess the risk posed by chemicals in feed and addresses the possibility for a better harmonisation of feed classification and terminology. The animal dietary exposure estimates are undertaken by several Panels/Units to assess the risk of feed contaminants, pesticide residues, genetically modified feed and feed additives. The methodologies used to assess animal dietary exposure vary across risk assessment areas. The report has been presented to the PPR, FEEDAP, GMO and CONTAM Panels. The SC endorsed the report that will be published at the end of the year.

8. Draft guidance on aneugenicity assessment (EFSA-Q-2019-00262)

The SC was presented with a draft of the guidance on aneugenicity assessment. The mandate calls for the development of a guidance on the most appropriate in vivo follow-up for substances that are aneugenic in vitro (often in the absence of metabolic activation) and how risk to human health should be assessed for a substance exhibiting aneugenicity.

The SC made some comments that will be addressed at the next WG meeting. The draft guidance will be hopefully tabled for possible endorsement for public consultation at the December SC plenary. Finalisation of the guidance is expected by mid 2020.

9. Overview of the Biological Hazard (BIOHAZ) Panel work programme 2018-2021

The chair of the BIOHAZ panel described the activities recently completed by the Panel, in particular the "Scientific opinion on salmonella control in poultry flocks and its public health impact" (published here) and the statement on "Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 10: Suitability of taxonomic units notified to EFSA until March 2019" (published here).

The Panel is now involved in the update and review of the scientific opinion published in 2011 on "Campylobacter in broiler meat production: control options and performance objectives and/or targets at different stages of the food chain". This will take into account and, if possible, quantify the expected efficiency in reducing human campylobacteriosis cases.

A "Scientific opinion on the public health risk posed by Listeria monocytogenes in frozen fruit and vegetables including herbs, blanched during processing" (EFSA-Q-2018-01006) is under development. It will assess the main risk factors of contamination and growth of pathogens during all stages and provide recommendations on control options and on routine monitoring. In the context of the evaluation of new processes, a Scientific opinion on the use of the so called "tubs" for transporting and storing fresh fishery products and one on the use of the so called "superchilling technique" for the transport of fresh fishery products are also being drafted.

A new mandate related to food hygiene is asking for the development of a Guidance on date marking and related food information. It aims at assessing a) factors that make certain foods highly perishable and on how those factors should be considered when deciding whether a 'use by' date is required and

setting the shelf-life and the required storage conditions; b) factors that make certain foods become unfit for human consumption (no immediate danger) and on how those factors should be considered by FBO when deciding whether a 'best before' date is required; c) storage conditions and/or time limit for consumption after opening the package in order to avoid increase of food safety risks and d) defrosting frozen foods including good practices, storage conditions and/or time limit for consumption in order to avoid increase of food safety risks.

The panel has received a request for a scientific opinion on the evaluation of public and animal health risks in case of a delayed post-mortem inspection in ungulates.

9.1. Methodologies and common practices currently implemented in chemical and microbiological risk assessment (item added to the draft agenda at the meeting)

Following a request of the Chair of the BIOHAZ Panel (item added on the agenda during the meeting), the Scientific Committee exchanged views on general principles and methods implemented in the area of chemical and microbiological risk assessment. Current methods in chemical and microbiological risk assessment show a high degree of harmonisation in their own domains, but, when compared, appear to show differences in particular in the use of uncertainty factors, the application of probabilistic versus deterministic approaches and the respective roles of risk managers and risk assessors in setting protection goals.

The discussion was well placed in the ongoing development of the EFSA Strategy 2021-2027. Looking at future needs, trends and developments in the area of chemical risk assessment at European and International level, it may be useful to revisit the scientific basis of the use of uncertainty factors and to look at the reduction of animal testing through application of alternative methods. The Scientific Committee will be invited to discuss this further in the December plenary in the context of the preparation of the new EFSA Strategy.

10. Implementation of the guidance on uncertainty in scientific assessment

The SC was reminded of the Implementation plan of the guidance on uncertainty in scientific assessments that was agreed in 2018 after the publication of both, the guidance and its companion opinion detailing the principles and methods behind the guidance (more info available here).

The plans had foreseen the implementation of the guidance in the department of Risk Assessment and Scientific Assistance (RASA) after the renewal of the panels (by mid-2018). The implementation of the guidance in the department of Scientific Evaluation of Regulated Products (REPRO) is foreseen to be rolled out gradually from 2021 onwards, with the exception of some specific outputs per unit.

It was further agreed with the units in the RASA department to start the implementation in autumn 2018 by first providing panel specific tailor-made trainings to the AHAW (last trimester 2018), BIOHAZ (first trimester 2019) and CONTAM panel (last trimester 2019). Hence the implementation is only in its very early phase with very few opinions published so far where the guidance had been applied. Also, the capacity within the panels to apply the guidance without support by the cross cutting WG is highly variable. The PLH, AHAW, BIOHAZ and CONTAM panels reported back to the SC on their current implementation status of the uncertainty guidance and highlighted in which area they would need additional support by the cross cutting WG uncertainty. The benefits of having applied the guidance and related challenges were also discussed.

11. Update on WGs activities

- WG MUST-B and EU Bee Partnership (M-2018-0155)

The MUST-B WG is involved in three different activities related to bee health: (i) the drafting of a scientific opinion on the development of a holistic risk assessment (RA) approach of multiple stressors in honey bee colonies and the monitoring of two outsourcing EFSA projects: (ii) the development of the honey bee colony model APisRAM for the RA of pesticides with other stressors and (iii) the collection of field data to calibrate and validate the model under two EU regulatory zones (Denmark for the North and Portugal for the South). The scientific opinion is due in December 2020 and the two outsourcing projects are due in the beginning of 2021. The latter will be presented to the SC when finalised while the draft opinion will be presented to the SC early 2020, when it is consolidated.

The social science team at EFSA is collaborating with the MUST-B WG (i) to collect the views and perceptions of the beekeepers on the approach and vision developed by the MUST-B WG through a focus research group and survey to be launched in 7-8 EU Member States and (ii) to determine the stakeholders' views on data sharing through semi-interviews with the members of the EU Bee Partnership.

The EU Bee Partnership (link here) will meet again for the 5th time on 15 October 2019. At this meeting, the progress made by stakeholders on the pilot project for data sharing (BeeXML project) will be discussed as well as the synergies with the EU H2020 project B-GOOD and the longer-term sustainability of the Partnership.

- Beeswax WG (M-2019-0061)

An update to the mandate received by the EC on adulterated beeswax was provided. In June 2017, the Commission was informed by the Belgian authorities about contamination of beeswax intended for apiculture use. The adulterated beeswax originated from China and Ukraine. There is a potential risk of adulterated beeswax entering the food chain in the form of honeycombs and a potential risk for honeybee health. The terms of reference (ToR) of the mandate received from the EC on this topic are in 2 folds: ToR 1. in the absence of a specific standard within the EU legislation, the establishment of purity criteria and technical specifications for beeswax when used in apiculture and as a food in honey pots; ToR 2. evaluation of the impact of the migration of stearin and paraffin contained in beeswax intended for apiculture use on bee health, and possible safety concerns for humans due to consumption of honey contaminated with constituents of adulterated beeswax, or direct consumption of honeycombs. For this mandate, an EFSA WG was established and met 2 times (May and July 2019); the next meeting being on 18-19 September. The WG is preparing an EFSA technical report that is due in February 2020, but EFSA requested an extension until April 2020.

- WG Compendium of Botanicals (M-2012-0145)

Composition and toxicity/adverse effects for around 13 plant species are ready to be added to the EFSA Compendium of Botanicals and made available to the public. EFSA is finalising the correction of the various catalogues with the DATA Unit to allow the data transfer by end of 2019 at the latest. A last batch of 900 plant species is pending for review by the Working Group (work planned for 2020 and 2021.

The specific toxicity of the substances identified in the above-mentioned 1300 plant species as of possible concern for human health will be characterised in collaboration with OpenFoodTox. The two contractors are in contact to join resources and avoid duplication of work. A total of four years (end 2019 – end 2023) will be dedicated to characterising the toxicity of the substances listed in the Compendium of Botanicals.

- SC WG Synthetic Biology (M-2018-0205)

The working group had its last meeting on 2-3 September to continue drafting the Scientific Opinion upon request of the European Commission (Mandate nr M-2018-0205). The draft addresses the molecular characterisation as well as environmental risk assessment of GMM developed through synthetic biology. Potential novel developments and novel hazards were discussed, while considering a reasonable timeline for developments that could reach the market in the next decade. The draft opinion will be presented for a first reading to the SC in the December plenary meeting. The public consultation is scheduled for end March 2020.

- Cross-cutting WG Uncertainty

The WG is currently supporting the following activities:
(A) Support to RASA: (1)ad hoc questions from AHAW panel on methodology to address uncertainty e.g. Art. 29 - Slaughter of rabbits for human consumption and killing for other purposes than slaughter (EFSA-Q-2018-00909),; (2) BIOHAZ opinion on Update and review of control options for Campylobacter in broilers at primary production (EFSA-Q-2018-00676), planned to be adopted in early 2020; (3) to develop the case studies for the tailor made training for CONTAM scheduled in 25-26 November 2019;
(B) Support to REPRO: New request received to support PREV WG in their Scientific report on Integrated testing strategy for the evaluation of developmental neurotoxicity with special emphasis to pesticides (EFSA-Q-2019-00100)
(C) Other support: support to EFSA-EBTC (evidence based toxicological collaboration centre) workshop 2-3 October 2019 on "Advancing the application of evidence-based methods to construct mechanistic frameworks for the development and use of non-animal toxicity tests".

Further, the SC was informed that the EFSA/BfR event report on the scientific conference on "Uncertainty in Risk analysis" had been published in August 2019. (https://www.efsa.europa.eu/en/supporting/pub/en-1689). The report emphasises the importance of uncertainty analysis for scientific assessments, the associated implications for decision making, and the need to communicate the most relevant uncertainties to decision makers and to the broad public.

The SC was informed about another recent report revolving around the subject on uncertainty. The Science Advice for Policy by European Academies (SAPEA) published in August 2019 their opinion on "Making sense of science for policy under conditions of complexity and uncertainty". (https://www.sapea.info/topics/making-sense-of-science/)

- Cross-cutting WG Nanotechnologies

The WG had a meeting on 10 September to discuss and progress all its tasks. Regarding the Scientific Guidance for risk assessment of Nanoscience and Nanotechnology in the food and feed chain[3], the pilot phase was very informative to collect feedback from all users, and the guidance is being updated accordingly.

A new mandate from the European Commission is expected soon to prepare a Technical Guidance that shall help Applicants to determine whether a substance contains a fraction of nanoparticles or not, upfront of their submission to EFSA.

[3] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5327

The WG also continues to support various units in the EFSA Department on Scientific Evaluation of regulated Products with expert advice on nanospecific aspects of cases under risk assessment. Furthermore, the WG also provides feedback on new research proposals, such as for nanofibers.

The WG will convene at the Global Summit for Regulatory Science, organised by JRC and FDA (Stresa, Italy, 25-26 September 2019[4]), which is dedicated to Nanotechnology and Nanoplastics (link here).

- Cross-cutting WG Genotoxicity (M-2019-0091)

The WG has finalised the revision of the data package on triazine amine as requested by the PPR panel, following a mandate from DG SANTE. The draft technical report on triazine amine has been sent to the PPR panel secretariat and it will be tabled for discussion at the October PPR plenary meeting.

The WG has also received request for advice from the FEEDAP panel and from the NDA panel that will be discussed in the September meeting.

- Cross cutting WG Benchmark Dose

The EFSA Cross-Cutting Working Group on Benchmark Dose has received a request for assistance from the Chair of the CONTAM Panel in relation to the ongoing assessment of polyfluoroalkyl substances (PFAs) in food. The WG was requested to provide advice on data specific modelling related issues and more generally how to perform dose response modelling in absence of a control group with zero exposure (in all datasets provided, all tested groups show perfluoro-octane-sulfonic acid concentration in serum). The WG agreed on a methodology to be used that will be communicated to the panel, together with the answer to the other questions. The approach agreed in the WG will then be incorporated in the section on modelling of the SC guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments currently under development.

– Cross-cutting WG Mixtox 2

The self-task mandate on "Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals" has been signed by EFSA's Executive Director on 19 July 2019. Christer Hogstrand was nominated chair of the WG. The first meeting has been planned for the 1st and 2nd of October 2019.

- WG Non Monotonic Dose Response (NMDR) (M-2019-0166)

This self-task mandate follows the EFSA external report on NMDR, focusing on the biological plausibility and relevance for risk assessment of the in vivo studies with statistical indications suggesting NMDR. The first WG meeting was held on 11 September 2019. The WG analysed the terms of reference and agreed on the elements to be covered as well as on the general structure of the opinion. A work plan was also prepared including the distribution of tasks among the WG members.

[4] https://ec.europa.eu/jrc/en/event/conference/gsrs19-global-summit-regulatory-science-2019-nanotechnology-and-nanoplastics

- WG Health Based Guidance Values (HBGV) (M-2019-0159)

This cross-cutting self-task will provide recommendation for setting HBGV for nutrients that are also used in regulated products such as additives. The first WG meeting is planned for 7 November. EFSA is preparing a technical report summarising the current methods used by the different Panels and units for setting HBGV, in particular for deriving Upper Limits for nutrients and for proposing ADIs for additives and pesticides.

12. Feedback from Panels

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

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

The Chair of the panel informed the SC about the EFSA's assessment of five phthalates (di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP) and di-isodecylphthalate (DIDP)) used in plastic food contact materials (EFSA-Q-2019-00102).
As stated by EFSA's Scientific Committee in its guidance on the use of the BMD approach for risk assessment, the benchmark dose approach is a scientifically more advanced method compared to the NOAEL approach for deriving a Reference Point (RP). The application of this guidance was therefore initially strongly recommended. Therefore, data were extracted to attempt a BMD fitting of the dose-response curves. However, when extracting the data for the selected critical effects, it was observed that for most of them the data were not reported in a way that would allow data reanalysis for the purpose of BMD modelling. Hence, it was concluded that it was not possible to make use of the BMD approach, and to therefore use again the NOAEL approach for deriving the Point of Departures (PoDs).

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

The Chair of the panel informed the SC that around forty novel food applications were received since the beginning of the year. Few new applications on health claims have also been received.
EFSA has received two requests from the EC for scientific advice on the safety & suitability of infant and/or follow-on formulae manufactured from protein hydrolysates. To address these mandates, the Panel agreed to set a WG on protein hydrolysate-based formula.

Another request regards scientific advice on an application for the exemption from labelling of food ingredients or substances with known allergenic potential listed in Annex II of Regulation (EU) No 1169/2011 or products thereof. To address this mandate, the Panel agreed to set a WG on food allergy.
EFSA will be initiating an internal mandate requesting the Panel to review the scientific basis to derive the uncertainty factor (UF) to establish a health-based guidance value (HBGV) for copper. The Panel accepted this mandate and agreed to set up a WG the UF for the HBGV for copper.

Food Additives and Flavourings (FAF) Panel:

The Chair reported about the Scientific opinion on the proposed amendment of the EU specifications for titanium dioxide (E 171) with respect to the inclusion of additional parameters related to its particle size distribution. The opinion has been published in the EFSA Journal in July 2019 (link here). The Panel considered that the conclusions made, and the uncertainties identified, in the previous EFSA

assessments on E 171 remain valid. The Panel reiterates the need for further research in order to decrease the level of uncertainty and acknowledged that additional studies with characterised E 171 are being carried out by interested business operators.

Two new mandates are going to be received, one on the development of a guidance on smoke flavourings and another on the update of the guidance document on flavourings. The Panel intends to integrate other methodological guidance (Threshold of Toxicological Concern, uncertainty, Weight of Evidence) in this updated guidance.

Plant Health (PLH) Panel

A scientific opinion on the Pest categorisation of Fragaria viruses and viroids (Q-2018-00783) (including a short update on activities of WG plant viruses categorisation) has been adopted by the PLH Panel last 27 June 2019.

The Panel is also involved in high risk plants commodity risk assessment dossiers. Three parallel WGs were established and the chairs were nominated in June.
In the last plenary, the SCER Unit has presented the CLEFSA (Climate change as a driver of emerging risks for Food and feed Safety, plant, animal health and nutritional quality) project, including plant health issues. The Panel discussed the importance of addressing climate change scenarios in plant health risk assessment, particularly with regards to changes in land use and cultivated crops. It was agreed that the coordinator of the CLEFSA project would distribute to interested PLH experts the list of issues identified mainly via a crowdsourcing exercise, with the possible aim of characterising them on the basis of a set of criteria and climate change scenarios.

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

The Chair of the panel described the Feed Additive Consumer Exposure (FACE) calculator (link here). It is a tool for estimating chronic and acute dietary exposure to residues of feed additives and their metabolites present in food of animal origin. It allows users to estimate the exposure for different population groups (e.g., infants, toddlers, adults) in several European countries. This tool implements the exposure methodology recommended by the Guidance on the assessment of the safety of feed additives for the consumer (in particular, section 4.3 - link here). FACE relies on food consumption data collected from Member States which were subsequently disaggregated into raw primary commodities of animal origin (e.g. milk, meat).

There could be cases where the same active principle is assessed simultaneously by EFSA and other assessment bodies that use other methodology to evaluate consumer exposure. In such a case collaboration needs to be implemented in order to explore the possibility to harmonise the tools used to evaluate consumer exposure.

Plant Protection Products and their Residues (PPR) Panel:

At the last Panel meeting a revised draft of the statement on the coverage of bats by the current pesticide risk assessment for birds and mammals (EFSA-Q-2018-00615) was adopted and now published (link here). The main scope of the statement was to investigate whether the current risk assessment for birds and ground dwelling mammals exposed to pesticides covered bats. The Panel concluded that bats are not adequately covered by the current risk assessment approach, and that there is a need to develop a bat-specific risk assessment scheme.

An opinion on the genotoxic potential of triazine amine (metabolite common to several sulfonylurea active substances) (EFSA-Q-2018-00830) is under development. Newly submitted studies by the

applicant are under consideration, in cooperation with the SC cross-cutting WG on Genotoxicity. The outcomes from the assessment will be presented to the Panel for discussion in October 2019. The panel intends to table the draft opinion for possible adoption at the November 2019.

A mandate has been received for developing a framework for conducting environmental exposure and risk assessment for transition metals when used as active substances in PPPs.

Working Groups are under establishment for (a) drafting an EFSA guidance on testing and interpretation of comparative interspecies in-vitro metabolism (EFSA-Q-2018-00444). The final endorsement of the output is foreseen in March 2021; (b) Development of Adverse Outcome Pathways relevant for the identification of substances having endocrine disruptors properties (EFSA-Q-2019-00492).

Finally, an update on the status of the activities of the Working Group drafting the Opinion for developing Integrated Approaches to Testing and Assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment (EFSA-Q-2019-00100) was presented. A presentation on this topic will be scheduled in one of the next meetings.

Genetically Modified Organisms (GMO) Panel:

The vice-chair of the Panel presented the activities of the WG on Synthetic Biology and GMOs engineered with Gene Drives.

In the WG on synthetic biology, EFSA staff/experts are discussing the adequacy of the data requirements for the environmental risk assessment provided in the Guidance on the environmental risk assessment of genetically modified plants (here) for the selected case studies relevant to the mandate on Synbio of the European Commission. The WG is focusing on plant environmental risk assessment. For GMOs engineered with Gene drives, the WG is discussing the suitability of the guidelines established in the EFSA GMO Panel guidance (2012, here and 2013, here) for the molecular characterisation and environmental risk assessment of gene drive modified insects, and reviewed them in light of the respective mandates on genetically modified animals of the European Commission.

A Workshop on the problem formulation for the environmental risk assessment of gene drive modified insects was held in Brussels last 15th May 2019. EFSA met stakeholders and EU Member States to discuss plausible environmental risks associated with the release of gene drive modified insects into the environment. The problem formulation exercise was run for two case studies in two separate discussion groups: (1) self-sustaining gene drives to control disease-spreading mosquitoes (e.g. *Aedes albopictus*), and (2) self-sustaining gene drives to control agricultural pests (e.g. *Drosophila suzukii*).

Animal Health and Welfare (AHAW) Panel:

The EFSA secretariat reported the outcome of the implementation of the guidance on uncertainty in scientific assessment (see item 9). The AHAW Panel has been the first to receive training and is now gaining relevant experience in the implementation of the guidance.

13. Any Other Business

13.1. Draft agenda next SC plenary

The SC was presented with an overview of the topics that will be on the agenda of the December meeting. The meeting is scheduled for the 4-5 December 2019.

13.2. 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 activities of the EFSA Management Board, Advisory Forum (AF), interagency and international scientific cooperation and EFSA Stakeholders Meetings.

13.3. List of published opinions since June 2019

The Scientific Committee was provided with a document containing the list of published opinions from 20 June to 03 September 2019, 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 provides a list of published conclusions on pesticides and ongoing public consultations.

END OF THE MEETING