SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 92nd PLENARY MEETING

Held on 19 February 2019, 14.00 – 18.30h
20 February 2019, 09.00 – 18.30h
21 February 2019, 09.00 – 13.00h

EFSA, Parma (Italy)

(Agreed on 12 April 2019)

Participants

- **Scientific Committee Members:**

  Simon More (Chair), Vasileios Bampidis, Diane Benford (Vice chair), Claude Bragard, Nils Rostoks, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Christer Hogstrand[1], Kostas Koutsoumanis, Søren Saxmose Nielsen, Josef Schlatter, Vittorio Silano, Dominique Turck, Maged Younes.

- **European Commission:**

  Anne Bucher* (Director General DG SANTE),
  Marina Marini, Péter Bokor* and Anastasia Alvizou* (DG SANTE D.D.1)

- **EFSA:**

  - **EXECUTIVE Directorate:** Bernhard Url*, Marta Hugas, Hans Verhagen, Stef Bronzwaer
  - **Risk Assessment and Scientific Assistance Department (RASA):** Juliane Kleiner
  - **Scientific Evaluation of Regulatory Products Department (REPRO)**: Guilhem de Seze
  - **Scientific Committee and Emerging Risks Unit (SCER):** Tobin Robinson, Ana Afonso, Daniela Maurici, Djien Liem, Jean-Lou Dorne, Andrea Gervelmeyer, Raquel Garcia Matas, Angelo Maggiore, Reinhilde Schoonjans, Agnes Rortais
  - **Assessment and Methodology Support Unit (AMU):** Didier Verloo, Marios Georgiadis (only for agenda item 5.1)
  - **Evidence Management Unit (DATA):** Bruno Dujardin, Jane Richardson (only for agenda item 7.3)
  - **Food Ingredientsand Packaging Unit (FIP):** Claudia Roncancio Pena, Anna Castoldi, Camilla Smeraldi, Alessandra Giarola (only of agenda item 6.1.3)
  - **Nutrition Unit (NUTRI)**: Valeriu Curtui, Agnes de Sesmaisons-Lecarre (only for agenda item 6.1.3)

[1] Present on 20th February

European Food Safety Authority
Via Carlo Magno 1A – 43126 Parma, Italy
Tel. +39 0521 036 111
info@efsa.europa.eu | www.efsa.europa.eu

- **Pesticide Peer Review Unit (PREV)**: Luc Mohimont, Federica Crivellente (only for agenda item 7.6)

- **Transformation Services Unit (TS)**: Alexandre Nougadere, Dimitrios Spyropoulos

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Dieter Schrenk, chair of the Contaminants in the Food Chain panel (CONTAM) (replaced by Christer Hogstrand); Hanspeter Naegeli, chair of the Genetically Modified Organisms panel (GMO) (replaced by Nils Rostoks); Susanne Hougaard Bennekou, vice-chair of the Scientific Committee.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Committee/Scientific Panel Members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Scientific topic(s) for discussion and/or possible adoption

4.1. **Draft guidance on chemical mixtures** (EFSA-Q-2017-00595)

The revised version of the guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals "mixtures" was discussed. The Scientific Committee (SC) proposed final editorials changes and adopted the guidance that will be published by the end of March, together with the technical report summarising the comments received during the public consultation.

5. New Mandates

5.1. Draft Terms of Reference self-task activity on epidemiology

Thor Halldorsson, chair of the WG, presented the purpose of this envisaged guidance document.

The terms of reference and three scenarios of the scope of this guidance were discussed and Animal and Plant Health Unit (ALPHA), Biological Hazards and Contaminants (BIOCONTAM), Plant Health (PLH) panels were asked to specify if/in which area they need guidance on epidemiology.

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

The terms of reference were agreed to be: 1) Set the basis for giving guidance on how to appraise and interpret findings from different types of epidemiological evidence and its application in EFSA scientific assessments, 2) Provide guidance on how to appraise and integrate evidence from epidemiological studies of humans or animals for specific scientific assessment questions of the different EFSA panels. Particular emphasis should be given to areas where guidance is lacking, and 3) Provide guidance on how to use evidence from epidemiological studies in EFSA scientific assessments. It was agreed that the scope should be limited to experimental and non-experimental studies of humans and animals (livestock/companion animals), and cover evidence appraisal and integration by study and within evidence stream.

The workplan and the expertise needed for the WG were presented. The mandate will be soon published. First reading of the draft guidance is planned for the SC plenary in December 2019.

5.2. Draft mandate aneugenicity assessment

Aneugenic substances induce numerical chromosomal aberration through the interaction with cellular target other than DNA, such us proteins involved in the segregation of chromosomes during mitosis or meiosis.

The cross-cutting WG on Genotoxicity is requested to provide guidance on how to consider the current limitations in the evaluation of aneugenic substances in the framework of the genotoxicity assessment, particularly in relation to: what is the most appropriate *in vivo* follow-up for substances that show aneugenicity *in vitro*; and how should risk to human health be assessed for a substance exhibiting aneugenicity.

The SC agreed to embark in this activity and approved the Terms of Reference. The aim is to finalise the guidance by spring 2020.

5.3. EFSA Framework for Protocol Development and Problem Formulation

Didier Verloo presented to the SC the proposal for a project on protocol development and problem formulation. The 4 steps approach 1. Problem Formulation (PF) and Protocol development (PD); 2. Conduct of the assessment in compliance with Protocol; 3. Verification of compliance between Protocol and actual assessment; 4. Documentation and Reporting was developed with the PROMETHEUS (PROmoting METHods for Evidence Use in Scientific assessments, link here) approach and tested in several case studies. At the end of the pilot phase, it was agreed that there is a need to adapt the problem formulation process and the content and complexity of the protocol to the different types of mandates.

The SC was presented with a proposal for a framework for protocol development and problem formulation. It was agreed to start a new self-task activity for which a WG will be established. The chair of the WG will be nominated at the next SC plenary.

6. Feedback from the Scientific Committee/Scientific Panels, EFSA, the European Commission

6.1. Scientific Committee and Scientific Panel(s) including their Working Groups

6.1.1. Overview of the activities and of the workplan 2018-2021 of the Panel on Food Additives and Flavourings

Maged Younes, chair of the FAF Panel, presented an overview of the ongoing activities of the new Panel established in July 2018. The Panel covers tasks previously in the remit of the former ANS Panel (evaluation of food additives) and those related to the evaluation of flavouring substances, previously in the remit of the former CEF Panel. The different regulatory framework under which assessments are conducted as well as applicable scientific guidance, main challenges and possible cross-cutting issues from the work-plan of the Panel for the coming years were highlighted.

6.1.2. Overview of the activities and of the workplan 2018-2021 of the Panel on Food Contact Materials, Enzymes and Processing Aids (CEP)

Vittorio Silano, chair of the CEP Panel, gave an overview of the Panel's remit and its expertise for food contact materials, food enzymes and processing aids. Some of the guidance currently in place are in the process of being updated and some evaluated and approved plastic Food Contact Materials (FCM) are requested by the EC to be re-evaluated.

For food enzymes, 260 products still need to be evaluated under a multi-annual workplan until 2023.

6.1.3. Derivation of Health Based Guidance Values for food additives that are also nutrients

Within the framework of Regulation (EC) No 257/2010, the FAF Panel is re-evaluating the safety of food additives, among these a group comprising phosphoric acid, phosphates and polyphosphates. In performing this risk assessment, the FAF panel has considered phosphorus (P) as biologically active moiety, deriving from the metabolisms of the phosphate salts used as additives. In this context, the FAF Panel has sought the advice from the SC on the derivation of health-based guidance values (HBGV) for food additives that are also nutrients.

A presentation was given by Alessandra Giarola, summarising the preliminary conclusions reached by the WG of the FAF Panel tasked with this specific assessment and the more general question on what type of HBGV should be set for substances that are both nutrients and deliberately added to food for non-nutritional purposes. A discussion followed and the SC advised that, for the specific case of phosphates as food additives, in case the data allow the setting of an HBGV, this should be expressed as Acceptable Daily Intake (ADI).

More in general, the SC proposed to develop a statement to clarify how to perform risk assessment for substances that are food additives and nutrients. Further discussion on the possible Terms of reference will take place in one of the next plenary.

6.1.4. Feedback on Panels work programme, with focus on:

- Implementation of SC cross-cutting guidance
- Methodologies development
- Risk assessment with cross-cutting issues

Genetically Modified Organisms (GMO) Panel

The GMO Panel established two new Working Groups (WGs) in response to EC mandates. Synthetic Biology WG was established to provide an opinion on the six existing and potentially additional new sectors in Synthetic Biology (EFSA-M-2018-0205). The focus of this WG is on genetically modified plants deliberately released into the environment.

This WG had its first meeting in January. Gene Drive WG was established (EFSA-M-2018-0138) to provide an opinion on GMOs engineered with gene drives. This WG had its first meeting in February. Both WGs have a rather tight deadline to deliver draft opinions that should be endorsed for public consultation by spring 2020.

Nutrition, Novel Foods and Food Allergens (NDA) Panel

The NDA Panel is working on 2 opinions, one on the Dietary Reference Values (DRV) for sodium and another one on appropriate age of introduction of complementary feeding in infants. These opinions used the PROMETHEUS approach.
Furthermore, the implementation of the guidance on uncertainty has been foreseen for the DRVs with the support of the cross-cutting WG uncertainty.
Overall, the Panel is very busy receiving several novel food applications but less application on health claims.

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

The FEEDAP Panel has adopted 50 opinions in 4 plenaries since the establishment of the new Panel in July 2018. Five guidance documents have been revised. The guidance on environmental risk assessment for feed additives is going to be adopted at the next plenary.
Four new WGs have been established to work horizontally and support the development of opinions in relation to animal nutrition, toxicology, microbiology and the environment risk assessment.

Plant Health (PLH) Panel

The PLH Panel follows a fit for purpose risk assessment approach. 48 pest categorisations, the first step of plant health risk assessment, have been adopted in 2018.
The Panel is now using the guidance on quantitative pest risk assessment (step 2). In this frame, a quantitative pest risk assessment for fall army worm (*Spodoptera frugiperda*) has been recently adopted and the pest risk assessment on Xylella is expected to be discussed in the March plenary meeting.
The second conference on *Xylella fastidiosa* (How research can support solutions) will be organised by EFSA in Corsica, France, in the end of October (https://events.efsa.europa.eu/event/ar/1/xylella-2019).

The guidance for commodity risk assessment for high risk plants is in public consultation. Under PLH law Derogation, three dossiers are currently under examination: one on Citrus Canker host plants and two on Pinus bonsai plants with derogation requests from Japan and China.

A horizon scanning activity has been launched to monitor media for emerging issues, and to have surveillance with the elaboration of pest survey guidelines, along with the organisation of topical workshops with Members States.

Plant Protection Products and their Residues (PPR) Panel

EFSA conclusions on the peer review of the pesticide risk assessment of copper (published in December 2017) indicated that the available guideline on environmental risk assessment does not specifically cover transition metals (e.g., copper) because of their specific characteristics.
The European Commission (EC) requested EFSA to provide a statement outlining an appropriate methodology for the environmental exposure and risk assessment of transition metals used as plant

protection products. This methodology should a) be consistent with the legislative framework 1107/2009 regarding the approval of pesticide active substances; b) identify the key principles of the assessment, and c) how such principles can be implemented for risk assessment.

Another mandate of the PPR Panel with potential cross-cutting implications is the development of Integrated Approaches for Testing and Assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment.
A 2013 Scientific Opinion of the PPR Panel recommended the development of an *integrated in vitro* testing battery complementary to the *in vivo* Test Guideline. This was followed by a systematic literature review on *in vitro* and alternative DNT testing methods (2015), and then by an OECD/EFSA workshop held in Brussels (2016).
EFSA, in collaboration with OECD, is developing a guidance on the application and interpretation of i*n vitro* testing battery for DNT, where other international regulatory agencies (US-EPA, Danish EPA) are also involved. The guidance will include specific case studies dealing with the risk assessment of pesticides to establish whether the *in vitro* testing battery is fit for purpose and can meet regulatory needs.

The third topic addressed with horizontal implications is the EC mandate to assess the genotoxic potential of triazine amine (a degradation product common to several sulfonylurea herbicides – EFSA-M-2018-0207. Given the nature of the topic, the Panel liaised with the SC WG on genotoxicity, which re-assessed the available data and provided a preliminary assessment. The draft report of the WG genotoxicity will be sent to the PPR panel in time for discussion at its April plenary.

Biological hazard (BIOHAZ) Panel

The opinion of the BIOHAZ Panel on Salmonella control in poultry flocks was published last week. New mandates include assessment of *Listeria* in frozen fruits and vegetables, meat inspection and alternative fish storage methodologies.
Cross-cutting activities include the new meat inspection mandate (AHAW, see also below)) and the lactic acid decontamination (CEP).

The current priority of the Panel is the full implementation of the SC guidance on uncertainty. A training course tailor made for the BIOHAZ panel is being organised with the support of the cross-cutting WG on uncertainty in risk assessment on 4-5 March 2019.

Animal Health Animal Welfare (AHAW) Panel

The AHAW Panel has multiple mandates focusing on animal welfare, and these are not cross-cutting. However, AHAW will provide input to the mandate on delayed meat inspection with the BIOHAZ Panel.

Paraphrasing the conclusions in future opinions following the uncertainty guidance is seen as a major opportunity related to the implementation of uncertainty with the formulation of conclusions. However, full implementation of the uncertainty guidance is a lengthy process, and the experiences are still limited. All the quality assurance measures applied to the Panel activities are generally time consuming, but they are also seen as important to assure transparency in the work of the Panel.

6.2. Feedback from EFSA including its Working Groups

- WG genotoxicity(cross-cutting)

The WG is working on a self-task mandate on aneugenicity assessment (see also 5.2). A guidance will be developed that will be published for public consultation before finalisation. The document will be finalised by spring 2020.

The WG is also responding to two requests from the Pesticides unit: the first related to the re-assessment of triazine amine (EC mandate for the PPR panel - EFSA-M-2018-0207); the second one is to review the evidence for genotoxicity of para-chloroaniline (PCA), a potential residue of the pesticide diflubenzuron.

- WG on Benchmark dose BMD (cross-cutting)

A request for assistance was received from the Secretariat of the FAF Panel in relation to the Akaike Information Criteria (AIC), the criteria to compare how two models fit the data. This request for assistance was solved at EFSA Staff level, without the need to address the cross-cutting WG on BMD.

EFSA is part of the JECFA expert group updating chapter 5 (dose-response modelling) of EHC 240. The objective is to ensure that dose response modelling is done in a harmonised/consistent way across the world, and more specifically that there is no divergence between the EFSA approach and the one used by WHO/FAO and other partners (US EPA). The scientific coordinator of the BMD WG will participate in March to the meeting scheduled at WHO in Geneva.

- WG on Uncertainty (cross-cutting)

The WG supports the development of Panel tailor-made trainings on uncertainty:

- ✓ AHAW: finalisation of the case study together with AHAW experts and chair. Final draft will be discussed at AHAW Panel plenary on 21 March;
- ✓ BIOHAZ: development of 2 case studies, one quantitative one and one qualitative for the Panel training scheduled on 5- 6 March;
- ✓ Next steps: development of case study together with CONTAM experts for training scheduled on 23-24 September

The ongoing support to implement the uncertainty guidance to new mandates entails:

- ✓ Support of new Campylobacter mandate of BIOHAZ with deadline early 2020;
- ✓ Support of sodium opinion of NDA: opinion is scheduled for discussion and adoption on 13-15 March.

- WG on Nanotechnology (cross-cutting)

Reinhilde Schoonjans presented the various activities in relation to the WG: info sessions for EFSA; upcoming stakeholders engagement event on 1-2 April that will take place in EFSA. This event will focus on practical cases and technical clarifications for using the guidance document on risk assessment of nanomaterials published in 2018. Possible amendments to the guidance to facilitate its implementation can be proposed upon the collective experience during the pilot phase.

- WG on Compendium of Botanicals

See point 7.4

- WG on Multiple Stressors in Bees – MUST B (EFSA-Q-2016-00358)

Agnes Rortais provided feedback on the objectives of the project and the overview of the different activities: (i) the outsourcing activities (ApisRAM colony model development, the field data collection for calibration and evaluation of the model and the development of DEB models to test binary mixtures on extended periods), (ii) the EC engagement and support from Horizon 2020 on bee health, (iii) the stakeholders engagement with the setup of a EU Bee Partnership with the main representatives on bee health and the European Parliament mandate on bee health which will be presented in details at the next SC Plenary meeting in April.

- WG on Synthetic Biology (EFSA-M-2018-0205)

The EC requests EFSA to determine whether the existing guidelines for risk assessment are adequate and sufficient for current and near future Synthetic Biology (SynBio) developments for agri-food uses, meaning agri/food/feed products falling within the remit of EFSA. The deadline set by the Commission for EFSA scientific opinions is March 2020.

Reinhilde Schoonjans, scientific coordinator of the WG, presented the 3 organism groups, the 5 opinions and the existing guidance that will be subject to this mandate. The SC will be presented with the first draft of the GMM ERA opinion at the December plenary meeting. The draft is to be endorsed by Feb 2020 and online by March 2020 for public consultation.

- WG on Threshold of Toxicological Concern (EFSA-M-2017-0103)

The draft guidance on the use of the TTC approach in food safety assessment was subject of a public consultation between 12 November 2018 and 10 January 2019. One under comments from 23 interested parties (including private citizens) in addition to 3 letters were received. An overview of the comments received was presented to SC committee. The guidance will be tabled for adoption at the April plenary meeting.

6.3.European Commission

Exchange of views with DG SANTE's Director General, Anne Bucher, took place at the beginning of the meeting. The reform of the General Food Law and the increasing responsibilities of EFSA were discussed. A favourable agreement on the proposal for such reform is now achieved, in time before the European Parliament stops its activities in the end of March.

The main elements of the agreement aim at:

- **Ensuring more transparency:** Citizens will have automatic access to all studies and information submitted by industry in the risk assessment process. Stakeholders and the general public will also be consulted on submitted studies. At the same time, the agreement will guarantee confidentiality, in duly justified circumstances, by setting out the type of information that may be considered significantly harmful for commercial interests and therefore cannot be disclosed
- **Increasing the independence of studies:** The European Food Safety Authority will be notified of all commissioned studies to guarantee that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies. The Authority will also provide general advice to applicants, in particular SMEs, prior to the submission of the dossier. Commission may ask the Authority to commission additional studies for verification purposes and may perform fact-finding missions to verify the compliance of laboratories/studies with standards
- **Strengthening the governance and the scientific cooperation:** Member States, civil society and European Parliament will be involved in the governance of the Authority by being

duly represented in its Management Board. Member States will foster the Authority's scientific capacity and engage the best independent experts into its work

- **Developing comprehensive risk communication:** A general plan for risk communication will be adopted and will ensure a coherent risk communication strategy throughout the risk analysis process, combined with open dialogue amongst all interested parties.

The provisional agreement will now have to formally be adopted both the European Parliament and the Council. The Regulation will entry into force on 20th day following publication in the official journal of the EU and will be applied 18 months after its entry into force.

7. Other scientific topics for information and/or discussion

7.1. Horizons for food safety research

Marta Hugas and Stef Bronzwaer provided an overview on research coordination activities that EFSA started to undertake, also contributing to informing the research agenda for Horizon Europe. The aim is to fill gaps from a regulatory perspective, together with other EU agencies that deliver advice to policy makers. An important issue is to stimulate research that is useful for regulatory science and provides impact: science for policy.

Finally, the SC was informed that the Food Safety Research Needs 2030 were formulated based on the input received from the Panels and the staff as well as from contributions during the scientific conference. The SC welcomed the document and provided useful comments, and it will be happy to support the next steps in research coordination.

7.2. Improving the way of working of the Scientific Committee

Daniela Maurici and Tobin Robinson presented some ideas on how to improve efficiency in the way of working of the SC. Some of the ideas that were endorsed are:

- Include case studies when developing new cross-cutting guidance;

- Present guidance under development at plenary of scientific panels without waiting finalisation of the document;

- Reduce length of the documents to the extent possible to make them easy to be read;

- Present table of content of the new document at early stage in SC plenary meetings;

-Foresee pilot phase of newly developed guidance for documents particularly sensitive or difficult (as in the case of the guidance of the risk assessment of nanotechnologies)

-Identify at early stage, the panels for which the guidance will be most relevant, to gather initial feedback. A second reading of the advanced draft is foreseen in plenary meeting before the final reading for endorsement for public consultation.

The proposals were agreed and will be implemented starting from January 2019.

7.3.Data activities - EFSA strategic objectives 2

Jane Richardson provided an update to the SC on the ongoing activities under the objective 2 of the EFSA strategy 2020: widen EFSA's evidence base and optimise access to its data to the public at large.

The knowledge junction (https://zenodo.org/communities/efsa-kj/?page=1&size=20) is a curated, open source community for the exchange of evidence and supporting materials used in food and feed safety risk assessments. It is on the Zenodo platform where anyone can submit data including:

- Evidence – reports, datasets, images, videos, laboratory outputs, etc.
- Supporting materials – software, tools, models, code, protocols, appraisal schemes, FAQs etc.
- Risk assessment – mandates, opinions, statements, guidance documents, annual and strategic plans provided by Member States.

It is accessible to the public though any web browser. The content of this repository can be used by EFSA's panels and WGs and any other interested parties when preparing for new risk assessments.

EFSA will start a proactive data publication process in conjunction with publication of scientific outputs. A further aim is to enhance interoperability of the data, by aligning both technical and semantic specifications. FoodEx2 (https://www.efsa.europa.eu/data/data-standardisation) is a good example of interoperability as it allows foods and products to be described in a way which is useful in a variety of scientific fields.

Another important issue for EFSA is to move towards a structured data submission through the OECD harmonised templates.

The SC welcomed the substantial progress achieved in the Evidence Management Unit in EFSA and endorsed the future vision for a data based on end to end scientific process.

7.4.Overview of the database on Botanicals and the Open Food Tox

Bernard Bottex provided detailed information on the content and the use of the EFSA Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health.

Initiated in 2009, the database contains now a list of 2700 plant species that have been subject to a systematic literature review. Over 2 million citations and abstracts have been collected and searched for relevant information on composition, toxicity and genotoxicity. 900 plants are already accessible via the web-based user interface (http://www.efsa.europa.eu/en/press/news/160705) and an additional 1200 plants are now ready to be added to the EFSA database, following validation of the information retrieved from the literature; the remaining 500 plants will be finalised by end of 2019. The Compendium can be searched by Family names, Plant species names, Chemical groups, and Substances of possible concern.

In 2019, a new outsourced activity will be initiated to characterise the toxicity of 2500 chemical substances listed in the EFSA Compendium as of possible concern for human health because containing a chemical group considered as of concern by default (e.g. epoxide); it is estimated that 10-15% of these substances are already covered by OpenFoodTox. This activity will run until 2023.

Jean Lou Dorne explained the content of the EFSA OpenFoodTox database

Since its creation in 2002, EFSA has produced risk assessments for more than 4,000 substances in over 1,600 scientific opinions, statements and conclusions through the work of its scientists. For individual substances, a summary of human health and – depending on the relevant legislation and intended uses – animal health and ecological hazard assessments has been collected and structured in the OpenFoodTox database. The database provides open source data for the substance characterisation, the links to EFSA's related output, background European legislation, and a summary of the critical toxicological endpoints and reference values. It is a tool and source of information for

scientific advisory bodies and stakeholders with an interest in chemical risk assessment. The summary data sheets for each individual substance can be downloaded in pdf or xls format.

EFSA is also developing "TK Plate", a Toxicokinetic Modelling Platform. This platform would have the potential to reduce to the minimum the animal testing.

7.5. Overview of the activities on emerging risks

Ana Afonso provided a comprehensive overview of all EFSA activities in the emerging risks area and the driving guidelines for future work: foresight and systems analysis, data management and analytics, development of tools and methods for sharing knowledge and optimising resources.

The SC acknowledged the progress made and was interested in how to address the broader impact of some emerging risks e.g. broader than only the food safety aspect of microplastics, but the broader impact on our planet.

7.6. Next steps for testing and implementation of the guidance on risk assessment of chemical mixtures

The SC was presented with a proposal for next steps after publication of the guidance on chemical mixtures, foreseen by the end of March.

The pesticides legislation made a provision in Article 14 of Regulation (EC) No 396/2005 that pesticide Maximum Residues Levels (MRL) setting needs to *"take account of their known cumulative and synergistic effects, when the methods to assess such effects are available*". Methodologies were developed by the PPR panel and were implemented since 2014 in a pilot phase which will be completed in 2019 with the publication of the results of cumulative risk assessment (CRA) of pesticide residues for the nervous system and the thyroid.

It will be a priority in the next years for EFSA to perform the analysis of cumulative chronic and acute risks to the health of consumers from pesticide residues, as part of its legal duty to prepare annual reports on pesticide residues on the basis the results of official control programmes in Member States. For this, EFSA is envisaging a cooperation between 4 units: SCER for methodological development, PREV for Cumulative Assessment Groups of pesticides, DATA for Cumulative exposure assessment and PRES for Cumulative risk characterisation.

A first area of methodological development to be entrusted by the Scientific Committee was presented and discussed: the preparation of a Guidance on criteria to identify effects of chemicals relevant for CRA, and of outputs identifying effects of chemicals relevant for CRA in component-based approach in various organs/systems. Draft Terms of Reference for this self-task activity will be prepared for further discussion at the next plenary, taking particular care of defining the legal and scientific boundaries of the exercise. The increasing complexity of total body exposure to a wider range of chemicals has to go in small steps to be planned with a more flexible timeline. This will be scheduled for the upcoming SC meeting in April.

7.7. Cross-cutting Guidance implementation and post-adoption monitoring

The SC was reminded of the EFSA lifecycle of cross-cutting guidance documents.

The SCER Unit developed a workplan to ensure wider dissemination of cross-cutting guidance documents and to facilitate their implementation. This also involves capacity building through

extensive trainings for experts and EFSA staff on specific aspects of the risk assessment process (e.g. training on benchmark dose approach).

The post adoption monitoring of the implementation of the cross-cutting guidance will be initiated in 2019. A survey for the panel members, WG members and networks will be launched to monitoring how and to which extent the cross-cutting guidance are used. The outcome of the survey will be used to plan revisions of the guidance documents that are either not applied or considered obsolete.

8. Any Other Business

8.1. Report back on issues relevant for the SC

The Scientific Committee was provided with a document summarising the 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.

8.2. Impact of research developments related to the human microbiome for risk assessment

Marta Hugas, EFSA Chief scientist, presented some reflections on the topic of human microbiome.

Currently there is reference on the assessment of adverse effects to microbiome in some EFSA outputs namely: in the 2018 guidance on risk assessment of nanotechnology (specifically for nanomaterials with antibacterial properties such as AgNP); in the opinions on the re-evaluation of food additives (considered as emulsifiers).

In the last four years, there is also an increase in literature mentioning the impact of artificial sweeteners and emulsifiers on the gut microbiome. The microbiome and the impact on food and feed risk assessment is also captured in "Horizon Europe" and there is a proposal for a symposium for EUROTOX 2020 that is aimed at addressing the issue of chemicals and gut microbiota.

Some ideas as follow up steps were presented to the SC: to explore activities on microbiome of international partners and/or agencies (e.g. FDA, EMA, EPA); to invite an expert to introduce to the SC the knowledge around risk assessment for the gut microbiome; to plan a colloquium on the microbiome and its role in food and feed safety risk assessment. The SC was also asked to reflect on what knowledge and expertise EFSA may need at mid- and long-term to address the microbiome in risk assessment.

The SC endorsed to develop further reflections on it and to keep checking the state of the art. The biggest challenge is, given the huge variability, to distinguish normal variation from adverse effects. No efforts into guidance is recommended, but rather holding workshops with relevant experts. All activities were welcomed.

END OF THE MEETING