SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 94th PLENARY MEETING

Held on 25 June 2019, 09.00 – 17.30h
26 June 2019, 09.00 – 15.30h

EFSA, Parma (Italy)

(Agreed on 23 July 2019)

Participants

- **Scientific Committee Members:**

  Simon More (chair), Diane Benford (vice chair), Susanne Hougaard Bennekou (vice chair, day 2), Vasileios Bampidis, Claude Bragard, Thorhallur Halldorsson, Antonio Hernandez-Jerez, Kostas Koutsoumanis, Kyriaki Machera, Hanspeter Naegeli, Søren Saxmose Nielsen (day 1), Josef Schlatter, Vittorio Silano, Dominique Turck, Maged Younes.

- **European Commission:** Marina Marini (DG SANTE DDG.2.D)
- **EFSA:**
  - **Executive Directorate:** Bernhard Url (only for agenda item 1 to 7)
  - **Risk Assessment and Scientific Assistance Department (RASA):** Juliane Kleiner
  - **Scientific Evaluation of Regulated Products Department (REPRO):** Guilhem de Seze
  - **Scientific Committee and Emerging Risks Unit (SCER):** Ana Afonso, Daniela Maurici, Djien Liem, Bernard Bottex, Jean-Lou Dorne, Andrea Gervelmeyer, George Kass, Angelo Maggiore, Caroline Merten, Reinhilde Schoonjans, Justyna Slodek Wahlstrom, Jose Tarazona, Hans Verhagen
  - **Assessment and Methodology Support Unit (AMU):** Didier Verloo and Federica Barrucci (for agenda item 10), Laura Martino (for agenda item 17)
  - **Legal Assurance and Services Unit (LA)**: Simone Gabbi (for agenda item 11)
  - **Transformation Services Unit (TS)**: Claudia Paoletti (for agenda item 19), Alexandre Nougadere
  - **Animal and Plant Health Unit (ALPHA):** Giuseppe Stancanelli (for agenda item 19)
  - **Biological Hazards and Contaminants Unit (BIOCONTAM):** Marco Binaglia (day 1)
  - **Nutrition Unit (NUTRI):** Tilemachos Goumperis (for agenda item 12)
- **Hearing Experts:**

  Jan Oltmanns (Forschungs- und Beratungsinstitut Gefahrstoffe GmbH (FoBiG)) for agenda item 8.

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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 Marco Binaglia).

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[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. Presentation of 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 opened the meeting and welcomed the observers present in the room. He reminded the Scientific Committee (SC) about the amendment of the General Food Law that was recently adopted by the European Council. The new Regulation amending the 178/2002 will be published in September 2019 and will enter into force in March 2021. This will have implications on EFSA's work plan. It is anticipated that EFSA will recruit new staff to implement the new Regulation. The 2020 budget is still uncertain and will depend on the next multiannual financial framework (MFF), the EU's long-term budget.

From the date of the entry into force, EFSA must publish proactively all non-confidential data from the applicant's dossiers. EFSA must check confidentiality claims, publish all study designs upfront, all studies used for each application and set up a register for studies for application. This will require a reprioritisation of EFSA's work to get ready by the strict challenging deadline. Methodology related developmental work, such as guidance development or research, will need to be deprioritized.

It was clarified to the SC that the aim of the public consultations for reauthorizations and first authorisation dossiers is to ensure that all relevant evidence had been considered in the protocol for the risk assessment.

[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

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

5.1. Draft Terms of Reference follow up work on Non-Monotonic Dose Response (NMDR)

The SC was presented with the draft terms of reference for a follow up work on non-monotonic dose response (NMDR). The SC is requested to prepare a scientific opinion on the biological relevance of the *in vivo* non-monotonic dose responses identified in the visual/statistics-based analysis. If biologically relevant non-monotonic dose responses are identified, the SC is requested to address whether there are the links with adverse responses and possible consequences for the human health risk assessments. The WG for this opinion will be set up by July 2019 with the aim of adopting the opinion by end of October 2020.

SC questioned whether the open food tox database (link here) will be enough as a source to retrieve relevant endpoints. It was clarified that the database would be used as one of the screening tools, retrieving all relevant information from the full EFSA assessments as needed.

It was proposed by the SC to start the work first by assessing the biological plausibility and then follow up by assessing the biological relevance. It was concluded that in reality both assessments would probably be done in various iterations. The statistical approach to assess the non-monotonic dose response will need to be clarified. The proposed terms of reference were accepted by the SC. The SC confirmed Maged Younes, chair of the FAF Panel, as chair of the WG as agreed at the 91st plenary meeting.

5.2. Draft self-task mandate on substances that are nutrients and also additives

The SC was presented with a proposal on a new mandate to derive a health-based guidance value (HBGV) for food additives and other regulated products that are also nutrients.

It was proposed that the SC will prepare a statement with specific recommendations. In particular, the SC was requested to provide scientific advice to EFSA Panels and Units, considering risk manager's needs, in line with the following terms of reference (ToR): (1) To assess the background document produced by EFSA, describing current approaches for setting HBGV such as ADI and UL, and to define the general approach on how to estimate the risk to consumers regarding the exposure to additives and other substances in regulated products which are also nutrients. (2) To advise on the terms and definitions that should be used by EFSA in the hazard and risk characterisation in this type of assessments.(3) When setting this general approach, the SC should also consider how to present to risk managers information relevant for their decision making, covering the overall risk for consumers from all exposure sources, as well as the specific contribution to consumer's risk and health concerns from the exposure related to the regulated product, e.g. using the "total" and "added" risk concepts.(4) Where possible, to provide some recommendations for using and combining experimental animal studies and human nutrition information when setting HBGV for regulated substances that are also nutrients, accounting for the differences in background exposure levels between humans and experimental animals, as well as inter-species differences in the physiological roles and homeostatic regulations between species and between nutrients.

It was proposed to have the WG established by September 2019. Antonio Hernandez-Jerez, chair of the PPR Panel, will chair this WG.

The SC advised to use the IPCS approach. It was agreed that it is an opportune moment to tackle this activity horizontally across FAF, PPR and NDA panels with the SC ensuring the coordination between these panels.

It was clarified to the SC that the proposal to develop a statement instead of a guidance document was based on the rationale that once the SC will have issued a statement, then the sector specific guidance documents could be revised as a follow up. The SC agreed with the proposed ToR, indicating

that once the activity is more advanced, the SC will consider if the output should be a guidance document instead of a statement.

To the observers it was clarified that nutrients in this mandate can cover any kind of nutrients, micro- and macronutrients and trace elements.

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 Animal Health and Animal Welfare (AHAW) work programme 2018-2021

An overview on the current 2018-2021 AHAW work programme was presented to the SC. Ongoing and planned mandates on animal health (African swine fever, Avian influenza, Echinococcus multilocularis, Lumpy skin disease) and welfare (slaughter and on farm killing of poultry, slaughter and on farm killing of rabbits and welfare on farm of rabbits production, slaughter of animals, killing of animals for other purposes than slaughter) were presented.

The chair of the AHAW panel reported that they had started implementing the guidance on uncertainty in risk assessment in two ongoing opinions (African Swine Fever, Welfare: slaughter and on farm killing of poultry, slaughter and on farm killing of rabbits and welfare on farm of rabbits). It was found more difficult to do so once the risk assessment process had already started instead of integrating the uncertainty analysis right at the start at the protocol development stage.

The chair also reported some technical issues encountered by the AHAW WG and panel experts when implementing the use of office 365 and Teams.

6.1.2. 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 (Nano, Uncertainty etc); (2) Methodologies development; (3) Risk assessment with cross cutting issues.

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

The CEP panel is currently re-evaluating the safety of Bisphenol A (BPA) by assessing the new evidence available. EFSA published its comprehensive re-evaluation of BPA exposure and toxicity, in January 2015 when it reduced the TDI for BPA from 50 to 4 µg/kg bw/day. The TDI was made temporary and EFSA committed to re-evaluate BPA toxicity again when a two-year study by the U.S. National Toxicology Program will be available.

A Technical meeting with stakeholders on applications for food enzymes was organised in Brussels on 19 -20 June 2019 (https://www.efsa.europa.eu/en/events/event/190619-0). The overall aim of the meeting was to explain the current criteria and to discuss questions on the scientific evaluation of food enzymes, to inform on EFSA's ongoing process of evaluation of the food enzymes that are currently on the market and to get insight on possible applications that might be submitted in the future.

Nutrition, Novel Foods and Food Allergens (NDA) Panel

The chair of the NDA panel informed that three opinions are scheduled at next week's plenary for possible adoption: Dietary reference values for sodium and chloride (2 opinions) and the appropriate age for introduction of complementary feeding of infants (1 opinion) which is an update of the 2009 opinion. All three opinions underwent prior public consultation. It was noticed that the workload in relation to the novel food applications has increased.

A new internal mandate on reviewing the scientific basis to derive the uncertainty factor to establish a health-based guidance value for copper has been accepted (EFSA-Q-2019-00385). In EFSA, an Acceptable Daily Intake (ADI) of 0.15 mg/kg bw per day (corresponding to 10 mg/day for adults) for copper was set by the peer review of the pesticide risk assessments in 2008 and 2018, while the Scientific Committee on Food, in 2003, derived a tolerable upper intake level (UL) of 5 mg/day in adults; this latter reference value has been systematically used in EFSA's food and feed relevant assessments. Although the evidence used in these assessments were similar, different values were derived due to different uncertainty factors applied when deriving the health-based guidance value for copper. The WG will be set up with the aim of having a first meeting in autumn.

Food Additives and Flavourings (FAF) Panel

The FAF Panel envisages an update of the guidance for the assessment of flavouring substances, also in light of the recent publication of the SC guidance on Threshold of Toxicological Concern (TTC) (link here), as well as an update of the guidances for the evaluation of smoke flavourings. This was communicated to interested parties at an *ad hoc* meeting held the day before the SC Plenary.

The FAF Panel has started the evaluation process of sweeteners for which two protocols have been prepared. EFSA had launched public calls for data to offer to interested parties and/or stakeholders the opportunity to submit documented information (published, unpublished or newly generated) relevant to the re-evaluation of sweeteners. The deadline for submission of data on particle size and particle size distribution was launched in June 2019 (Deadline 13 September 2019)[3].

Finally, the FAF Panel is reviewing new data submitted by interested business operators on the specifications of food-grade TiO2, particularly regarding the particle size distribution. Discussion is taking place at the plenary meeting of the FAF panel this week.

Contaminants in the Food Chain (CONTAM) Panel

The CONTAM panel is currently involved in the preparation of the case studies for a tailor-made training to apply the guidance on uncertainty in risk assessment to be held in November 2019. It is foreseen to start the application of the guidance on uncertainty in risk assessment after the summer and to be able to provide feedback on its application in a year's time at the earliest.

Regarding the ongoing assessment on the risks for public health related to the presence of ochratoxin A in food (EFSA-Q-2019-00163), SC WG on genotoxicity was consulted to request an advice. To apply the margin of exposure (MoE) approach for carcinogenic effects was found difficult due to multiple genotoxic modes of actions. It is the intention of the panel chair to ask the SC to consider revisiting the guidance on MOE.

The panel asked for assistance to the cross-cutting WG on Benchmark Dose (BMD) to support the opinion on perfluoroalkyl substances (PFAS).

[3] https://www.efsa.europa.eu/en/consultations/call/190513

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

The chair of the FEEDAP panel informed the SC about a self-task activity for updating the guidance on renewal of feed additives authorisations. It is planned to consider in this update the cross-cutting guidance documents such as the EFSA technical report on animal dietary exposure that will be tabled at the SC plenary in September 2019, the guidance on threshold of toxicological concern (TTC) approach and the one on safety assessment of botanicals.

The FEEDAP panel is involved in cross-panel collaborations with the CONTAM WG on nitrates/nitrites and with the BIOHAZ WG on antimicrobial resistance and growth hormones.

Plant Protection Products and their Residues (PPR) Panel

The PPR panel has adopted a scientific statement on the coverage of bats by the guidance on birds and mammals, which concluded that bats should be subject to specific assessment.

The PPR Panel also endorsed two Scientific Reports evaluating the cumulative effects of exposure to pesticides in food on the human nervous and thyroid systems which are expected to be published by end of September 2019. Furthermore, two additional reports will be published at the same time: (1) Scientific report on establishment of cumulative assessment groups of pesticides regarding their combined effects on the nervous system (EFSA-Q-2017-00434) and (2) Scientific report on establishment of cumulative assessment groups of pesticides regarding their combined effects on the thyroid (EFSA-Q-2017-00436).

In relation to the EC mandate on the genotoxic potential of triazine amine (a common metabolite to several sulfonyl urea active substances) (EFSA -Q-2018-00830) , the Panel requested an advice to the SC WG genotoxicity. The WG is assessing the additional data that have been submitted in spring and will provide a final draft report to the PPR panel for discussion in plenary meeting in autumn.

Biological hazard (BIOHAZ) Panel

The BIOHAZ panel held recently its tailor-made training for the application of the guidance on uncertainty in risk assessment. The first opinion where the guidance on uncertainty will be implemented is the update and review of Campylobacter control options in broilers expected to be adopted by January 2020. The implementation of the guidance remains challenging due to resource and time constraints.

BIOHAZ is involved in the following panel cross cutting opinions: meat inspection with AHAW and CONTAM and antimicrobials in feed with AHAW and FEEDAP. The work on the 2 new mandates will start in the last week of June.

Genetically Modified Organisms (GMO) Panel

The GMO panel started a new WG on gene drive modified organisms with a focus on insects. Gene drives consist of genetic elements that can pass traits among sexually reproducing individuals with higher efficiency than expected under Mendelian inheritance. This WG has been mandated by the European Commission to assess the adequacy of existing risk assessment guidelines for gene drive modified insects.
A workshop was held in Brussels (15 May 2019) with stakeholders and Member States (MS) on the problem formulation for the environmental risk assessment of gene drive modified insects. 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*).The input collected from participants will support EFSA's WG on the environmental risk assessment of gene drive modified organisms to frame its work in the broader societal context.

The WG on GM plants made with synthetic biology will meet the last week of June to discuss case studies to be used for the development of the Opinion. Mandated by the EC, the aim of the WG is to evaluate whether the current GMO EFSA guidance documents are adequate for the risk assessment of such plants, or if there are areas where additional guidance would be needed. The opinion is expected to be finalised by March 2020 (EFSA-Q-2019-00297).

The GMO panel received a mandate from the EC to develop a scientific opinion on plants developed using type 1 and type 2 Site-Directed Nucleases and oligonucleotide directed mutagenesis. In July 2018, the European Court of Justice (Case C-528/16) ruled that organisms obtained by directed mutagenesis techniques are to be regarded as genetically modified organisms within the meaning of Directive 2001/18. The mandate refers to the previous GMO opinion on SDN3 techniques (2012), and specifically requests to advice whether the assessment methodology described in section four of this EFSA scientific opinion may be applicable to plants developed with type 1 and type 2 Site-Directed Nucleases and with oligonucleotide directed mutagenesis. In case the advice is affirmative, the EC further requested to advice whether the conclusions of the EFSA 2012 scientific opinion are valid to plants developed with type 1 and type 2 Site-Directed Nucleases and with oligonucleotide directed mutagenesis.

6.1.3. Overview of the PLH Panel work programme 2018-2021

The SC was presented with an overview of the various activities foreseen in the PLH work programme 2018-2021. Under the new plant heath legislation ((EU) 2016/2031), applicable by end of 2019, EFSA should provide risk-based and preventive measures to protect the Union territory from pests that a plant, plant product or other object originating from a third country might introduce, on the basis of a preliminary assessment of that high risk. A list of those high-risk plants, plant products or other objects should be established and their introduction into the Union territory should be prohibited, pending a risk assessment carried out in accordance with IPPC standards.

The PLH work programme 2018-2021 covers activities to support the implementation of this new legislation such as the categorisation of 133 plant pests with short descriptive reports as a first step of pest risk assessment, quantitative pest risk assessment and commodity risk assessment for high risk plants.

It was clarified to the SC that the potential risk for plant health due to a decreased use of pesticide is not part of the current work programme as this was not requested by the EC.

It was also explained that the tool Medisys, developed by the Joint Research Centre (JRC), was adapted for the first time for EFSA in 2012 in a collaborative project between JRC and the former EFSA Emerging Risk unit. Then, the tool was further adapted for the EFSA plant health team in 2016 to track plant pests in media and scientific literature. Citizen science has potential in gathering data in the plant health area as it is currently piloted in the UK to detect a plant pest. It was added that a close collaboration is ongoing with the European Union Notification System for Plant Health Interceptions (EUROPHYT), in particular, to populate the database. The database is now expanded via surveys to the MS. The system is used for the PLH panel work.

Finally, it was clarified to the observers that the separation between risk assessors and managers is still clear also in the plant health area as the risk assessors work on high priority pests in terms of potential impact in the EU. This work will pave the way for the risk managers to do a better job by deciding on the best possible mitigation measures.

6.1.4. Feedback from new working groups (WGs)

WG Epidemiology (M-2019-0073)

Progress made in drafting the guidance document was presented. The first two sections of the document, in which an introduction on epidemiological studies and the key concepts of evidence appraisal are explained, have been drafted and will be revised by the WG experts at their meeting on 27-28 June 2019. It is planned that these sections will be submitted to the SC for review at its September plenary meeting.

The results of a survey that has been carried out by the WG to capture the experience of the different EFSA panels with using epidemiological studies in their scientific assessments, and their specific needs for guidance, was presented. The needs expressed by the different panels will be addressed in the guidance document.

The SC was informed about two projects by RIVM and BfR that are partly covering the topic of the SC guidance. Hearing experts from both institutions will inform the SC WG to achieve potential synergies and avoid overlaps between the activities.

WG Protocol Development (M-2019-0088)

The motivations of the project were presented. It was explained that the idea of a plan for the scientific assessment (i.e. the protocol) and its advantages were first introduced with the PROMETHEUS project (link here) and tested in a series of case-studies. In this context, the usefulness of the approach emerged along with the need for a standardised template for protocol facilitating its implementation in all assessments that are not arising from applications.

The document is aimed at providing a harmonised template for protocol tailored to the various types of EFSA's mandate covering all steps of the scientific assessment process. To this end, the document will describe the main types of EFSA's questions including the split in sub-questions and their relationship (i.e. problem formulation) and the main methods to address them in the plan for the assessment. It is also in the remit of the project to clarify how level of formality and extensiveness of the methods can vary depending on the time and resources and the required degree of scientific value.

It is planned that a draft of the opinion will be submitted to the SC for first reading and review at its September plenary meeting. The possible adoption is foreseen at the December Plenary meeting. In the meantime the WG will revise the document in light of the comments received by the SC.

Cross -cutting WG Mixtures Risk Assessment – Mixtox 2

The updated self-tasking mandate and terms of reference for the SC cross-cutting WG on mixtures risk assessment was presented to the SC after addressing the changes proposed at the previous plenary (93rd plenary, 24th April 2019). The terms of reference for the first task of the WG is to prepare an opinion on "Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals". The chair of the WG will be Christer Hogstrand. The WG will be set up and work will start in September.

6.1.5. Update on WGs activities

SC WG MUST-B (M-2018-0155)

Simon More, the chair of the MUST-B WG provided an overview of current work within the MUST-B working group in relation to the mandate received from the European Parliament. The EP mandate

asks for a holistic approach to the risk assessment of multiple stressors in honey bees, and builds on a large body of earlier work, by EFSA and others, including (1) an increased understanding of the role of multiples stressors in honey bee colony health, (2) work towards the development of a mechanistic and individual-based model called ApisRAM to assess risks to honey bee colonies exposure to pesticides under different scenarios of combined stressors and factors, (3) harmonised and structured field data collection to assist with model calibration for risk assessment purposes, (4) developments in risk assessment of chemical mixtures, (5) further support from academia by promoting synergies with EFSA with 2 important research projects (PoshBee and BGOOD H2020 projects), and (6) EFSA engagement with stakeholders on data collection and sharing on bee health. The working group is currently seeking to extend current RA approaches using in silico methods, which will assist in accounting for complex exposure patterns, superorganism effects, non-chemical stressors and to extrapolate the RA results to multiple contexts.

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

The GMO SynBio Environmental Risk Assessment WG is developing an opinion to address the molecular characterisation and the environmental risk assessment of Genetically Modified Organisms obtained through Synthetic Biology. The scope of the work, requested by the European Commission, is to focus on the deliberate release of such organisms into the environment through their use in the agri/food/feed chain, e.g. to be used as probiotics, starter cultures, biopesticides, bioremediation, biofertilizers etc. The mandate is to check if existing EFSA guidance document are adequate for the risk assessment in the light of such developments. The opinion is expected to be finalised by end March 2020.

WG Compendium of Botanicals (M-2012-0145)

The WG has finalised the validation of the composition and toxicity information retrieved for 1515 plants. SCER unit is now working with the DATA Unit to add these plants to the 900 that are already publicly available in a database (link here).

The kick-off meeting of the second phase of the project took place on 5 June 2019. The characterisation of the toxicity of the substances of possible concern for human health identified in the above-mentioned 1515 plants has been contracted out. This activity will be done in close cooperation with the Openfoodtox (link here) activity as the two databases will be interconnected.

Cross-cutting WG Uncertainty in safety assessment

The WG has two tasks: (1) to support the development of cases studies for the tailor-made trainings on uncertainty and (2) to support the implementation of the uncertainty GD in the new opinions.

The WG has supported the development of the case studies for the BIOHAZ training on uncertainty which was held in March 2019 and is currently supporting the development of the case studies for the tailor-made training for the CONTAM panel which is scheduled for November 2019.The WG has supported the implementation of uncertainty analysis in the NUTRI scientific opinion on dietary references values (DRVs) for sodium (EFSA-Q-2011-01224 tabled for adoption at the NUTRI plenary in the first week of July. Regarding ongoing mandates, the WG is supporting the mandate on a scientific opinion providing an update and review of control options for Campylobacter in broilers at primary production (EFSA-Q-2018-00676).

EFSA and the German Federal Institute for Risk Assessment (BfR) held jointly an International Conference on Uncertainty in Risk Analysis, "Challenges and Advances in Assessing, Managing and Communicating Uncertainty", in Berlin on 20-22 February 2019. The conference was well attended with 300 participants attending the conference and 1000 registered via the web stream. The event report and the book of manuscript is planned to be published by EFSA by end of July 2019.

Cross-cutting WG Nanotechnologies

Further to the new EC draft mandate as described in point 7.5 below, the cross-cutting WG nano handles more activities as follows.

The draft Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (Part 1, human and animal health - link here), published in July 2018, can now be updated based on the feedback received during one year of pilot phase. It is expected to complete the work in 2020. The timeline for final publication will be synchronised with the publication of the new technical guidance (see point 7.5 below).

The WG also provided support upon request from different EFSA Units/panels in relation to risk assessment of nanomaterials that are part of application dossiers. The WG is currently working on bacterial nanocellulose.

The procurement contract for the Part II guidance on environmental aspects of nanomaterials used in the agri/food/feed chain, was awarded and the first kick-off meeting held on 6 June 2018. The contract has a duration of 18 months.

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

The WG genotoxicity is working on the development of the guidance for the genotoxicity assessment of aneuploidy. Hearing experts from other organisations have been asked to present how the aneugenicity is assessed in their respective fields of activity.

The WG is also finalising the assessment of triazine amine following the request for assistance from the PPR panel as well as the assessment of the para-chloroaniline.

The genotoxicity assessment of ochratoxin A was discussed at the last meeting following a request of assistance from the CONTAM panel.

An additional request has been put forward from the FEEDAP panel on curcumine. This will be discussed at the next meeting in the end of September.

Cross cutting WG Benchmark Dose

The WG received a request for assistance from the CONTAM Panel regarding the modelling of several datasets as part of the ongoing assessment of PFAs (per- and polyfluoroalkyl substances). A meeting will be organised on 5-6 September 2019 to clarify the questions to be answered and agree on a timeframe to deliver the advice to the Panel.

6.2. EFSA

6.2.1. EFSA's progress on independence

The SC was presented with an overview on independence related activities implemented in EFSA, including the screening of declaration of interests (DoIs) of all involved EFSA staff and experts collaborating with EFSA.

Further transparency measures include the publication of a register of activities undertaken by former members of the management board for two years after their term of office has ended, the publication of a list of "Public Institutions" as defined in the EFSA policy of independence (link here), the publication of EFSA middle managers DoIs and the publication of the first annual report on independence activities. Next steps include the finalisation of conflict interest management (CIM) rules

for EFSA staff members, the endorsement of a Declaration of Intent with the Advisory Forum and its signature, and further focus on implementation and enforcement.

6.2.2. Results of the procurement "AQUARIUS" (OC/EFSA/SCER/2015/02)

The SC was presented with an overview on the results of the outsourced project "Applicability of a food chain analysis on aquaculture of Atlantic salmon to identify and monitor vulnerabilities and drivers of change for the identification of emerging risks " (Aquarius, link here).

The objective of Aquarius project was to test the applicability of a food chain analysis approach to identify and monitor vulnerabilities and drivers of change for the identification of emerging risks. This was tested by focusing on the food chain of the Atlantic salmon farmed in Norway. To this end, a literature review was conducted complemented with expert views collected by on-line questionnaires and in-depth interviews.

This review provided an overview of the various stages in the supply chain from farm to consumers and the identification of i) existing and emerging human and animal health hazards, ii) vulnerabilities, iii) control measures, iv) drivers of change, and v) related indicators. Next step in the study was to i) complement the list of vulnerabilities followed by a prioritisation using focus group discussions and Failure Mode and Effect Analysis (FMEA) method and ii) link drivers of change acting upon the (prioritised) vulnerabilities and identification of associated indicators and data sources by means of a Delphi method. Based on the experiences obtained with the different methodologies during this project, literature review, and a direct face-to-face interaction with experts (in-depth interviews, focus group discussions and FMEA in a workshop setting) were found to be as most effective regarding output and effort. In a final step, the methodology to baseline a few key indicators of the selected vulnerabilities was the Bayesian Network (BN) that links data sources for indicators and drivers of change to the prioritised vulnerabilities. This was tested for salmon health in 3 food chain segments. The current BN showed potential to flag an increased exposure of known hazards that may occur due to changes in indicators, but new hazards were not identified. Several recommendations were presented that should be addressed first to improve the methodology for future related work.

The SC agreed that this kind of methodological work on emerging risk identification is needed and should be further developed. It was further advised to focus efforts even more in future work e.g by focusing on one or two food chain segments only, focusing either on human or animal health, and demonstrate success there first.

6.2.3. Overview of the amendment of the General Food Law and impact on EFSA's work

The SC was presented with the program "ART" (EFSA's Architectural Programme) whose aim is to support (1) readiness for implementation of the revised 178 General Food Law and related new requirements; (2) efficiency and efficacy by leaning all EFSA core and enabling processes and (3) digitalisation by lifting risk assessment methods to adapt to an external environment and science that is increasingly digital and social.

The ART programme is composed of five sub-programmes namely: End2End support service, Governance, Organisational Design, End2End science, Engagement and Risk Communication. Timelines are challenging for EFSA to be ready to implement the changes by March 2021. Next year, 2020, will be dedicated to the preparation of the implementation including development of necessary tools. The expected benefits are: re-organised EFSA processes, efficient and effective use of scientific methodologies, improved service delivery supporting quality risk assessment, new way of working and collaborating between external experts and EFSA scientists, open dialogue, transparent procedures for stakeholders' engagement, communication hub focused on food/feed safety addressing stakeholder concerns.

It was clarified to the SC that EFSA will enlarge the pool of staff to support this increased workload. EFSA has foreseen several tools to engage with stakeholders to prepare for the implementation. Following a question made by one of the observers, it was clarified that a systematic consultation of the stakeholders at the problem formulation stage or protocol development steps is not foreseen on routine basis. Stakeholders consultation has been and will be considered in the future on an ad hoc basis, if EFSA identifies the need for such contribution.

6.2.4. Overview of the activities of the Scientific Committee and Emerging Risks (SCER) Unit not already covered under the agenda

The SCER Unit coordinates the work of the Scientific Committee and EFSA activities on Emerging Risks (EmRisk) identification. The Emrisk activities include the coordination of the Emerging Risks Exchange Network (EREN), a network of MS experts nominated by EFSA Advisory Forum and the Stakeholders Discussion Group on Emerging Risks (StaDG-ER) composed by representatives of the various stakeholder categories included in EFSA Stakeholders forum (Industry, farmers, retailers, academia, practitioners, consumers and NGO). The two groups had their first annual meeting in April 2019 where several emerging issues were discussed. EFSA also develops methodologies for the identification of emerging risks in the areas of its remit. The projects DEMETER (Determination and Metrics for Emerging Risks), CIGUATERA (Food borne poisoning in Europe by Ciguatoxin) and CLEFSA (Climate change and Emerging Risks for Food Safety) are currently ongoing in collaboration with Article 36 and international organisations.

A mandate was requested to EFSA by the European Commission on the animal and public health risks of adulteration (fraud) of bees wax with paraffin and stearin (M-2019-0061). An EFSA WG was established to address this mandate. The WG has launched a targeted consultation to relevant organisations to retrieve data and information to support the assessment with the deadline of 10th July 2019.

The available OpenFoodTox database (see also above) was presented to the SC as (1) An open source tool (https://zenodo.org/record/1252752#.XRnEy-gzbD4); (2) A micro-strategy that can be consulted and results can be downloaded (http://www.efsa.europa.eu/en/microstrategy/openfoodtox).

In addition, the ongoing work for the future development of OpenFoodTox 2.0 (2018-2022) was also presented to include new properties in the database (physico-chemical properties, toxicokinetics, summary of exposure estimates, mechanistic data) and linking the database to predictive models such as QSAR models.

7. Other scientific topics for information and/or discussion

7.1. Preliminary results of post adoption monitoring of guidance documents

The SC was presented with an overview of preliminary results of post-adoption monitoring of how cross-cutting guidance documents (GDs) are implemented by the panels after adoption and publication. In particular, citation records were shown for an overview of cross-cutting guidance documents since their publication. The SC was asked to provide feedback on the proposed methodology used, the data sources used and the 5 years' time spam to see a trend in implementation of specific guidance.

The SC was happy with the initial analysis and provided several suggestions on the proposed methodology. To see if panels are implementing GDs consistently where relevant, it was emphasised that key analysis should be focused on actual use of GDs by panels (GD used or not) and then GDs usefulness to EFSA panels (is GD useful). The pilot presented for some GDs should be finalised for all the existing cross-cutting GDs. It was suggested that the time span to analysis the use of the GDs should not be restricted to 5 years but to the entire life of each GD. Then it can be studied qualitatively

if GDs are always used when applicable, thereby making a distinction between conditional and unconditional GDs, and then if the use is done correctly. In addition, the results of a recent customer satisfaction survey, still to be finalised, can be taken on board to further inform the evaluation of the use of cross-cutting GDs.

A report will be published by end of 2019 or beginning of 2020 to present the analysis done and to provide recommendations for future work on post-adoption monitoring of GDs.

7.2. Results of the procurement "Applying a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH - REACH 2"

The SC was presented with the results of an outsourced contract to apply a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH (OC/EFSA/SCER/2016/01-CT1, link to publication here). The selection was limited to substances that (a) were registered with a full registration, (b) met eligibility criteria (e.g. availability of a CAS number and a SMILES notation) and (c) were considered to be inside the applicability domain of the models used in this study (excluding e.g. ionisable compounds and metals). This selection reduced the number of substances from about 15.000 to 2.336 substances that were subsequently assessed in four blocks: environmental releases (based on tonnage and use pattern), biodegradation (using BIOWIN predictions assessed in a battery approach), bioaccumulation in food/feed (using ACC-HUMAN steady modelling) and toxicity (based on classification for carcinogenicity, mutagenicity, reproductive toxicity and repeated dose toxicity). A scoring system was applied with a maximum score of 10 in each of the four blocks. This resulted in the identification of 212 'potential emerging risks' that are considered to (a) be released to the environment and/or poorly biodegraded, (b) bioaccumulate in food/feed and (c) represent a chronic human health hazard. The EFSA external scientific report has been published in March 2019[4] along with supplementary material on the results of all 2.336 substances evaluated and the batch version of ACC-HUMAN steady.

Feedback was sought from the SC on the proposed next research step, to do a qualitative screening on a reduced priority list of potential emerging chemical risks in the food chain. The SC supported the proposed next research step as a sensible way forward and provided several suggestions for its implementation.

7.3. Crowdsourcing: Engaging communities effectively in food and feed risk assessment

The SC was presented with a few examples on different activities at global level involving citizen science. Citizen science is defined as "another method of engaging the public in research is to involve individuals in actual scientific studies, either by providing opportunities for people to serve as research assistants or by enabling them to conduct their own original investigations" (Bonney 1996). Several factors were presented that could make crowdsourcing appealing for EFSA such as engaging the public and stakeholders in the process of scientific assessment, widening the evidence base, promoting data sharing and re-use of data and better use of expertise. In a feasibility study implemented by the Assessment and Methodology Unit (AMU) several areas of activities were identified such as expert identification and systematic literature reviews. Several challenge contests have been launched by EFSA involving crowdsourcing. Next steps will be to explore how platforms could be developed across different EFSA panels to involve citizen science on specific research questions.

[4] https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1597

It was clarified to the SC that citizen science is still in the feasibility consideration phase and has not been used in EFSA risk assessments yet. The SC advised to develop safeguard strategies to ensure the quality of the collected data via crowd sourcing, but also the security of the EFSA data.

7.4. Risk evaluation of chemical contaminants in food in the context of RASFF (Rapid Alert System for Food and Feed) notifications: Rapid Assessment of Contaminant Exposure tool (RACE)

The SC was provided with a presentation on a report published in May2019 (link here) following a mandate to EFSA to develop a tool to harmonise risk evaluation and propose a methodology for a risk-based classification of RASFF notifications on contaminants. The task was divided into three work packages: toxicological parameters, estimating exposure and IT tool. Decision trees were presented to assist the risk assessors and risk managers to evaluate the potential risk if an analytical result showing potential concern or an exceedance of legal limit was detected and notified to the RASFFF members. The IT tool assists in calculating the exposure and comparing the estimate to the established health-based guidance values if they exist.

Clarifications were provided to the SC on the factors used to estimate exposure assessment and assumptions used to go through the decision tree. No background exposure was available for many of the contaminants. The outcome of this tool will provide a more transparent and scientific rationale why certain notifications in the RASFF system will be labelled as "risk" and others not.

Suggestions were provided on the proposed terminology in the tool. It was also clarified that anyone interested in using the tool can register to have access to the tool. The SC suggested to organise trainings for the MSs on how to use the tool and on how to interpret the results, although that task is within the EC 's remit.

7.5. Draft EC mandate for a guidance on technical requirements of regulated food and feed product applications to establish the presence of particles at the nanoscale

An overview on the draft request from the European Commission on a guidance on technical requirements of regulated food and feed product applications to establish the presence of particles at the nanoscale was presented to the SC. Three specific needs were identified: (1) To identify conventional materials that may be of concern: likely consist of, or contain a fraction of, small particles, including particles with external dimensions in the nanoscale; (2) To specify the information that should be included in the application dossiers covering these materials: for characterizing or excluding the presence of nanoparticles; (3) To set the information required for a proper risk assessment when the presence is confirmed in line with the draft guidance document on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (2018). The definitive terms or reference, and final timelines are pending on the reception of a mandate from the European Commission. Pending on the reception of the final mandate from the EC, the SC preliminary agreed with the proposal for allocating the mandate to the cross-cutting Working Group Nano.

8. Questions from and answers to observers

The observers had no additional question to raise under this session. Several observers expressed their gratitude for the opportunity given to follow the discussion of the Scientific Committee and understand how this Committee is working.

9. Any Other Business

9.1. 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 12-13 September.

END OF THE MEETING

ANNEX 1

List of observers attending in person

Title	Name	Country	Organisation	Affiliation
Mr	Beya Noureddine	Italy	Centro Gomme	NGO
Ms	Geiser Stefanie	Belgium	EAS Strategies	EAS Strategies/Private sector
Ms	Liu Yening	Italy	EY	Consulting Company (Supply chain)
Mr	Luetzow Manfred	Switzerland	Saqual GmbH	Private sector
Ms	Martinez Parrilla Maria Del Carmen	Italy	BASF	Private sector
Ms	Menegon Teixeira Detanico Camila	Brazil	Ministry of Agriculture, Livestock and Food Supply	National authority
Ms	Ono Kaori	France	Ajinomoto Europe	Private sector
Ms	Sanderson Jake	United Kingdom	Food Standards Agency	National authority

List of observers attending via web-streaming				
Title	**Name**	**Country**	**Organisation**	**Affiliation**
Mr	Takahiro Narita	Japan	Ajinomoto	Industry
Ms	Maryse Herve	Belgium	EU Specialty Food Ingredients	Industry association
Ms	Stephanie Nadzialek	Belgium	Stephanie Nadzialek	Industry association
Ms	Katarina Rihackova	Czech Republic	Masaryk University	University/public research-EU
Ms	Anna Van der Zalm	United Kingdom	PETA International Science Consortium Ltd.	NGO
Mr	Kacper Wróbel	Poland	Medical University of Lodz	University/public research-EU
Mr	Mamadou Ndiaye	Senegal	FAO	International organization
Mr	Marek Pípal	Czech Republic	RECETOX, Masaryk university	University/public research-EU
Ms	Anna Wittekind	United Kingdom	AW Nutrition	Consultancy
Mr	Stefano Brizzi	Belgium	BASF	Industry
Mr	Ondrej Adamovsky	Czech Republic	Ondrej Adamovsky	University/public research-EU
Ms	Jitka Sosnovcova	Czech Republic	National Institute of Public Health	EFSA Panel/WG/Network
Ms	Catalina Barberi	Colombia	Catalina Barberi	National authority - non-EU
Mr	Hermann Kouassi	France	CIRAD	University/public research-EU
Ms	Simona Radulescu	Romania	National Sanitary Veterinary and Food Safety Authority	National authority - EU
Ms	Anna Jackova	Slovakia	University of Veterinary Medicine and Pharmacy in Kosice	University/public research-EU
Mr	Laurent Oger	Belgium	ECPA	Industry association
Ms	Jacqueline Castenmiller	Netherlands	NVWA	EFSA Panel/WG/Network
Ms	Gabrielle Ventura	France	Synadiet	Industry association
Ms	Dimitra Nikolopoulou	Greece	Dimitra Nikolopoulou	National authority - EU
Mr	Maurizio Ferri	Italy	Ministry of Health - Veterinary Service Pescara	National authority - EU
Ms	Laila Chiadmi Garcia	Spain	Association Foreign Researchers	NGO

Mr	Mohamed Sobhi	Egypt	Food safety observer	Industry
Ms	Stefanie Geiser	Belgium	EAS Strategies	Consultancy
Ms	Anisa Shakirova	Netherlands	CBG-MEB	National authority - EU
Ms	Evangelia Sossidou	Greece	Hellenic Agricultural Organization-Demeter	University/public research-EU
Ms	Johanna Suomi	Finland	Ruokavirasto (Finnish Food Authority)	National authority - EU
Mr	Adam Jonas	Czech Republic	Draslovka	Industry
Ms	Eva Achata	Ireland	UCD	University/public research-EU
Ms	Kaori Ono	France	Ajinomoto Europe	Industry
Mr	Giurgiulescu Liviu	Romania	Technical University of Cluj Napoca	University/public research-EU
Mr	Dave Parker	United Kingdom	Syngenta	Industry
Ms	Jana Dammeier	Germany	Chemische Fabrik Budenheim KG	Industry
Ms	Gauri Deoras	Netherlands	Gauri Deoras	Industry
Mr	Vincenzo Ferrantelli	Italy	Istituto Zooprofilattico Sperimentale della Sicilia	National authority - EU
Mr	Jonas Lazaro Mojica	Belgium	Jonas Lazaro	Industry association
Ms	Leena Seppä-Lassila	Finland	Ruokavirasto - Finnish Food Authority	National authority - EU
Mr	Bizhan Pourkomailian	United Kingdom	McDonald's	Industry association
Ms	Nany Podevin	Belgium	Pioneer Overseas Corporation	Industry
Ms	Maud Perrudin	Belgium	Maud Perrudin	Industry association
Mr	Manfred Lützow	Switzerland	Saqual GmbH	Consultancy
Ms	Fatou Sock	Senegal	FAO	International organization
Ms	Anne-Sophie Garreau	France	United Pharmaceuticals	Industry
Ms	Valmire Havolli	Kosovo	Ministry of Agriculture, Forestry and Rural Development/Kosovo Institute of Agriculture	National authority - non-EU
Ms	Pavla Kovaláková	Czech Republic	AV CR	University/public research-EU
Mr	Jonatan Tomas	Spain	Espa-Diet	Industry

Questions from observers submitted before the meeting and answers from EFSA

None

Questions submitted during the meeting and answers from EFSA

Q1. Maurizio Ferri: It should be interesting to look at past and ongoing experiences as regards to methodology and criteria to assess the data quality and not structured experts from public of start-up that used crowdsourcing to help Japan during the Fukushima nuclear crisis

A1: We are still in feasibility considerations; citizen science has not been used yet for EFSA assessments

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Q2. Maurizio Ferri: Is the guidance on the use of epidemiological studies in risk assessment going to address the current and widespread criticisms of statistical methods, which report excessive use of point estimates with respect to confidence limits based on multiple sampling, and the misuse of the theory and practice of p-value (p-value)('Manipulation', p-hacking)'. This is relevant for corroborating the epi outcome and guarantee effective communication of uncertainty.

A2: The guidance will address some of these aspects, avoiding misuse of these concepts. It should be pointed out that there are different "schools" with regard using or not p-values. In 2014 EFSA published a guidance on how to report statistics - See https://www.efsa.europa.eu/en/efsajournal/pub/3908

Q3. Maurizio Ferri: As regards to problem formulation, is the protocol development document addressing the opportunity of potential involvement of stakeholders in the testing of the framing of question research for risk assessment? Or better what kind (e.g. ad hoc methods and criteria) of extended participation is foreseen?

A3: Engagement of stakeholders (sounding board) to contribute to the implementation of 178 general food law, make comments, raise concern is foreseen on ad hoc basis. With regards to this specific question, it should be said that 90% of the questions posed to EFSA come from the EC and they take into account societal issues. In some cases, consult on draft Terms of Reference has been done and will be done in the future, but this is on a case by case basis.

Q4. Dave Parker: I don't have any questions. I would like to take the opportunity to thank the SC for the opportunity to observe today.

A4: Thank you for the feedback. We also enjoy this opportunity to provide you with an overview of the topics we deal with and how we work

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