Scientific Committee

Minutes of the 100th Plenary meeting

Held on 16-17 September 2020
WEB - conference

(Agreed on 8 October 2020)

Participants

- Panel Members

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

- Hearing Experts[1]:

  Piersandro Cocconcelli (for item 4.2);

  Christer Hogstrand (for item 4.4)

- European Commission and/or Member States representatives:

  DG SANTE Unit D1, Farm to Fork Strategy Alexandra Tuijtelaars (1st day a.m.), Luis Vivas-Alegre (1st day p.m. and 2nd day)

- EFSA:

  Executive Director: Bernhard Url (day 1)

  Executive Directorate: Marta Hugas

  Risk Assessment and Scientific Assistance Department (RASA): Juliane Kleiner

[1] As defined in Article 15 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

Scientific Evaluation of Regulated Products Department (REPRO): Guilhem De Seze

Communication Engagement and Cooperation Department (COMCO):

Scientific Committee and Emerging Risks Unit (SCER): Tobin Robinson, Daniela Maurici, Ana Afonso, Bastaki Maria, Bernard Bottex, Jean Lou Dorne, Raquel Garcia Matas, Georges Kass, Djien Liem, Angelo Maggiore, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans, Rositsa Serafimova, Justyna Slodek–Wahlström, José Tarazona, Hans Verhagen.

Communication Unit (COM): Domagoj Vrbos (for agenda items 4.1 and 7.b), Tony Smith (for agenda item 7.b)

Science Studies and Project Identification & Development Office (SPIDO): Claudia Heppner (for agenda item 7.d)

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Marina Marini (DG SANTE Unit D, Farm to Fork Strategy)

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 Panel 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.

[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

4. Scientific outputs submitted for discussion and/or possible adoption

4.1 A systems-based approach to the environmental risk assessment of multiple stressors in honey bees EFSA-Q-2018-00645.

This agenda item was chaired by Diane Benford.

The Scientific Committee (SC) was presented for the first reading with the draft scientific opinion on a systems-based approach to the environmental risk assessment of multiple stressors in honey bees. The presentation included an overview of the background of the mandate and MUST-B project, the terms of reference (ToR) as requested by the European Parliament and their interpretation by the WG and the table of content of the scientific opinion. Then, more details were provided for each section of the scientific opinion related to the development of the systems-based approach in the context of the EU Green Deal and the EFSA strategy 2027 on Environmental Risk Assessment (ERA). This scientific opinion received the input from the EFSA social science team to include the views of the stakeholders on the proposed systems-based approach as well as on how to better guide the EU Bee Partnership on harmonised data collection and sharing in EU on bee health and beekeeping.

The Executive Director, Bernhard Url, provided an overview on the new challenges that EFSA and the SC will face in the coming years in relation to the new Transparency Regulation (EC 2019/1381), the new data stream methods and ERA. In this respect, the Executive Director noted that the opinion captures the challenges identified by EFSA under the EFSA strategy 2027 on ERA and that the systems-based approach is a model for future developments in ERA. The Executive Director called for "an ecosystem of risk assessors", tightening collaborations between EFSA, sister agencies and Member States.

The members of the SC made specific comments related to the draft opinion that will be addressed in the next WG meeting scheduled on 29-30 September. An implemented version of the opinion will be presented again to the SC in the November Plenary for possible endorsement for public consultation in December 2020 until January 2021.

4.2 Draft opinion "Evaluation of existing guidelines for their adequacy to the microbial characterisation and environmental risk assessment of genetically modified micro-organisms obtained through synthetic biology" EFSA-Q-2018-00921

The chair of the WG on synthetic biology (SynBio GMM ERA) together with EFSA presented the outcome of the public consultation which took place in the period 31 March - 4 June 2020. All the comments have been duly addressed as shown in the Technical Report of the public consultation that will be published together with the opinion. The final draft opinion was reviewed by the Scientific Committee who suggested few adjustments. The revised opinion was adopted and will be prepared for publication after the next WG meeting of 28 September.

A second opinion is to be developed under this mandate, focusing on food and feed aspects of microorganisms developed by Synthetic Biology. The SC reconfirmed Pier Sandro Cocconcelli as the chair of the WG.

4.3 Draft opinion on Non Monotonic Dose Response (NMDR)

EFSA-Q-2019-00530

The draft opinion on biological plausibility of non-monotonic dose responses and their impact on the risk assessment was discussed. It assesses the biological relevance, if any, of the apparent non-monotonic dose responses identified in the external report produced under GP/EFSA/SCER/2014/01, focussing on the *in vivo* datasets fulfilling all checkpoints of the visual/statistics-based analysis. The updated opinion has considered the previous comments from the SC, complementing the assessment of the *in vivo* studies identified in the external report with other cases and two annexes covering studies proposing non-monotonicity for Bisphenol A and phthalates, respectively. During the discussion, the SC acknowledged the progress and provided additional suggestions and recommendations to be considered by the WG. The updated version is expected to be presented for discussion and possible endorsement for public consultation at the next Plenary meeting.

4.4 Draft scientific opinion on "Scientific criteria for grouping chemicals into assessment groups for human risk

assessment of combined exposure to multiple chemicals"
EFSA-Q-2019-00517

The draft scientific opinion under development on "Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals" was introduced to the SC by the Chair of the WG, Vice-Chair of the CONTAM panel, Christer Hogstrand.

The scientific opinion explores harmonised and flexible methodologies to apply scientific criteria for grouping chemicals into assessment groups and prioritisation methods for human risk assessment of combined exposure to multiple chemicals. A framework is proposed to apply hazard-driven criteria for grouping chemicals into assessment groups using mechanistic information on toxicity (mode of action/adverse outcome pathways), when available, or using specific effect on target organs or a common adverse outcome. The use of toxicokinetic data is also discussed as part of the hazard-driven criteria. The application of the hazard-driven criteria is performed using a weight of evidence approach and an example of such application is provided as an annex of the scientific opinion.

A framework for applying prioritisation methods is also provided in the document to identify high priority chemicals and reduce the number of chemicals in an assessment group. These methods include risk-based and exposure-driven approaches and examples are provided in the annex of the document.

The possibility to transform the document into a guidance instead of a scientific opinion was discussed. This option would further support harmonisation of methodologies for grouping chemicals into assessment groups within EFSA panels and internationally. EFSA has consulted DG-SANTE which endorsed the proposal and also the SC members agreed to proceed in this direction. EFSA units will also be consulted to make sure they also endorse this proposal.

The SC members discussed the draft document and provided some comments which will be addressed by the WG in the next version of the document which will be further discussed at the next SC plenary for possible endorsement for public consultation.

5. New Mandates

5.1 New EC mandate on "Risk benefit assessment of fish consumption in relation to the presence of dioxin (PCDD/FS) and dioxin-like PCBs"

EFSA received a new mandate from the European Commission to provide a risk-benefit assessment of fish consumption in relation to the presence of dioxins (PCDD/Fs) and dioxin-like PCBs and to assess the influence of the presence of other contaminants in fish such as methylmercury, brominated flame retardants and perfluoroalkyl substances (PFAS) on the outcome of the risk-benefit assessment. The mandate is still a draft and under negotiation in view of the complexity of the request. EFSA colleagues will participate in meetings of SANTE's working group on Persistent Organic Pollutants in Food with risk managers of the Member States to identify the questions to be addressed by EFSA which would support risk managers of the Commission and the Member States in defining dietary advice for consumers at national level. The intention is to provide more information about the scope and planning of the requested assessment at the next SC plenary meeting.

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

6.1 EFSA including its Working Groups /Task Forces

6.1.1 Cross cutting WG Nanotechnologies

6.1.2 Cross cutting WG Genotoxicity

6.1.3 WG Health Based Guidance Values (HBGV)

6.1.4 WG Uncertainty

Due to time constraints, the points above were not addressed and will be discussed at the next plenary meeting.

7. Other scientific topics for information and/or discussion

a. Biotechnology mandates in the area of GMO

The chair of the GMO Panel gave an overview of the applications under risk assessment (for renewal or new) and the ongoing biotechnology mandates: genome editing, synthetic biology, gene drive.

The mandate on genome editing falls in the context of the judgement of the Court of Justice of the European Union (case C-528/16) of 25 July 2018 and the ruling of the French Conseil d'État of 7 February 2020, as regards the exact list of techniques that will be excluded from the scope of Directive 2001/18/EC. It aims at assessing if the methodology described in the

opinion on SDN-3 is applicable, in whole or in part, to plants developed with SDN-1, SDN-2, and ODM.

The mandate on synthetic biology explores the horizon for SynBio developments and assesses if existing guidance is adequate and sufficient for risk assessment of GMOs obtained by SynBio.

The gene drive mandate assesses the adequacy and sufficiency of existing EFSA guidelines for the molecular characterisation, ERA and post-market environmental monitoring of gene drive modified insects.

b. Provision of technical assistance in the field of risk communication: an update

EFSA received a request for technical assistance from the European Commission in the field of risk communication. A report describing how EFSA is addressing risk communication has been prepared to support EC's implementation of the General Plan for Risk Communication. EFSA's report clarifies a number of definitions and concepts linked to risk communication, and provides guidance for raising awareness and understanding, fostering public understanding of risk analysis, dealing with ambiguity of hazard and risk, as well as on how to fight against false information. The report will be published for public consultation in November-December this year and is due for finalisation and publication around March 2021.

c. Exploring options to re-organise the agenda item "Feedback from the Panels"

The Scientific Committee was consulted on several proposals to improve the usefulness and the interest of the recurrent agenda point "Feedback from the Panels". The objective of this agenda point is to give the opportunity to Panels' Chairs to inform or consult the members of the Scientific Committee on issues of cross-cutting nature, i.e. of interest of more than one Panel and to report back on cross-cutting guidance implementation. The proposals are:

- To have three Panels providing feedback on cross-cutting issues per plenary, in order to allow enough time for more in-depth discussion. An annual planning setting which Panel is reporting at which Plenary meeting will be set in advance so that Panel Chairs can prepare themselves with their supporting EFSA Unit. Some time will be kept for other Panel Chairs to report cross-cutting issues that came up recently, e.g. new mandate of horizontal nature received.

- Implementation of cross cutting documents in the various panels will be discussed in every plenary, focussing on one guidance at the time. The aim is to review the implementation of each guidance, highlighting possible problems and gaps identified during its use. Members of the Scientific Committee were reminded that Panels and Units can ask support to present an overview of the documents and their applicability in Panel plenaries or unit meetings.
- The Scientific Committee was informed that in the future, the plenary meeting will be organised as physical meetings probably twice a year and for the rest as telemeetings.

EFSA has also agreed that virtual meetings (plenary and WG meetings) will have a duration of max 6 hours/day. Longer meetings should be held in 2 days or more. The expert appointed as WG chair may be invited to participate in the role of chair or member in a given WG meeting, based on EFSA's decision whether the agenda topics are sensitive and/or complex.

d. Update on Science Studies and Project Identification & Development (SPIDO)

In order to address the requirements of the Transparency Regulation (EU) 2019/1381 (Art. 32d), EFSA has established a Science Studies and Project Identification & Development Office (SPIDO). It aims at establishing a process to identify scientific themes and develop their roadmaps for action and filling knowledge gaps that can benefit regulatory processes/science. This would ensure preparedness to address divergencies in scientific assessments and for future risk assessment challenges. On the basis of previous EFSA's work and discussions with DG-SANTE, the EFSA's Scientific Committee, EU Agencies and Member States at the EFSA Advisory Forum, a first wave of scientific themes was presented and discussed. Multi-annual, multi-partner and high-value scientific grants and procurements projects are foreseen on these themes.

8. Any other business

a. Feedback received from the 99th SC Open Plenary

The Scientific Committee was provided with a document summarising the feedback received from the observers of the 99th SC open plenary. A positive response on all aspects of the meeting was reported.

b. 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 Advisory Forum (AF), interagency and international scientific cooperation and EFSA Stakeholders Meetings.

c. List of published opinions since June 2020

The Scientific Committee was provided with a document containing the list of published opinions from 4 June 2020 to 1 September 2020 produced by the different panels and units, including those on applications for food contact materials, enzymes, flavourings, GMOs, health claims, novel foods and food additives. The list also provides a list of published conclusions on pesticides and ongoing public consultations.

d. Draft agenda next SC Plenary

The SC was presented with an overview of the topics that will be on the agenda of the November meeting. The meeting is scheduled for the 11-12 November 2020.

e. Celebration 100th SC plenary meeting

The Executive Director, Bernhard Url, congratulated the Scientific Committee for having reached the 100th plenary meeting, seventeen years after its first meeting in Brussels in June/July 2003. The SC met for the first time in Parma on 27th July 2004. Since its inception, the SC was renewed 6 times and the present SC will be in place until 2024. In this period, the SC published 55 outputs which included several guidance documents and methodologies for risk assessment and many opinions on cross-cutting topics of multidisciplinary nature. He expressed a great appreciation for all the work that the SC has been done to ensure that EFSA is conducting state-of-the-art risk assessments which have led to the international reputation as EU risk assessment body that the agency has achieved today.

The Executive Director addressed the various challenges that the agency is facing. He stressed the need to enlarge the pool of experts working with EFSA and the importance of deepening the collaboration with its sister agencies EMA and ECHA in view of the implementation of the new EU chemicals strategy. In this strategy, the European Commission calls for a better use of the EU agencies, to implement a 'one substance – one assessment' approach and to ensure greater transparency when delivering

its scientific advice to the risk managers in the Commission, the Member States and the public at large.

The Chair of the SC thanked EFSA on behalf of all SC members for being given the opportunity to contribute to the protection of the health and safety of the consumers across the EU.