Scientific Committee

Minutes of the 80th Plenary meeting

Held on 14-15 September 2016, EFSA

(Agreed on 21 October 2016)

Participants

- Scientific Committee Members:

  Tony Hardy (Chair), Diane Benford, Thorhallur Halldorsson, Mike Jeger, Helle Katrine Knutsen, Simon More (day 2 only), Alicja Mortensen, Hanspeter Naegli (day 1 only), Hubert Noteborn, Colin Ockleford, Antonia Ricci, Guido Rychen (day 1 only), Josef Schlatter, Vittorio Silano (agenda item 4.3 only), Roland Solecki and Dominique Turck.

- Hearing expert[1]:

  Jan Alexander (agenda item 4.1 only).

- European Commission: Marina Marini

- EFSA:
  - **EXECUTIVE Directorate**: Bernhard Url, Hubert Deluyker, Juliane Kleiner
  - **COMMS Department**: Barbara Gallani, Jeffrey Moon (agenda item 5.3d)
  - **RASA Department:** Hans Verhagen, Elisa Aiassa (5.3f), José Cortiñas (agenda item 5.3h)
  - **REPRO Department:** Guilhem de Seze, Danièle Court Marques (agenda item 5.3c)
  - **RESU Department:** Dirk Detken (agenda item 5.3e), Ilias Papatryfon (agenda item 5.3g)
  - **SCER Unit**: Tobin Robinson, Bernard Bottex, Nikolaos Georgiadis, Andrea Germini, Tilemachos Goumperis, George Kass, Angelo Maggiore, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans.

[1] As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Vittorio Silano (only participating for agenda item 4.3 on day 2) and Simon More (only participating on day 2). The Chair welcomed the new Head of the Department on Communications and External Relations and the new Head of Department on Scientific Evaluation of Regulated Products (REPRO), Barbara Gallani and Guilhem de Seze, respectively. The Scientific Committee (SC) was informed that, from 1st September, Juliane Kleiner has a new role as EFSA Senior Science Coordinator for the Executive Directorate. Juliane will be responsible for ensuring cross-units and cross-panels cooperation activities. She will also make proposals for the development of future sustainable models for providing scientific advice and for increasing attractiveness of EFSA for scientific staff.

2. Adoption of the agenda

The agenda was adopted without changes.

3. Declarations of Interest of Scientific Committee Members

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[2] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[3], EFSA screened the Annual Declaration of Interest and the Specific Declarations of interest filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting were identified during the screening process.

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

4.1 Draft guidance on biological relevance (EFSA-Q-2014-00746): for discussion

The SC was presented with the draft guidance on biological relevance for discussion. The guidance elaborates the concepts about biological relevance: (1) responses of a biological system to exposure; (2) thresholds; (3) critical effects; (4) modelling approaches; (5) biomarkers and indicator species. In addition, the guidance presents a framework for consideration of "relevance". The SC provided some comments in particular pointing out that the guidance is mainly focussing on problem formulation. The AHAW Panel chair provided feedback on the applicability of this guidance in his panel area stating that it will certainly be helpful in its future work. The ANS Panel chair stressed that the currently formulated proposal in the annex is not always in line with the way the ANS Panel is performing risk assessment and therefore needs to be

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[3] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

reconsidered. The SC was reassured that the Terms of References (ToRs) were not intended to cover only the hazard identification step, but also exposure assessment and risk characterisation steps. In addition, it was highlighted that the criteria to assess the relevance were still missing.

Advice was given to align the message from the case studies with the content of the guidance as the correlation was not always clear and the examples do not sufficiently illustrate the substance of the body text because they are partitioned away from the scheme shown in the opinion.

It was agreed that, if more specific criteria are warranted, the opinion will have to be split into different technical areas as one scheme does not fit them all. Alternatively, the examples from the Annex have to be linked to the different specific criteria.

It was concluded that a revised draft will be presented to the SC for discussion before endorsement for the public consultation. This will postpone the timeline for the public consultation initially planned for November 2016 to beginning of 2017.

4.2 Draft guidance on risk assessment of substances present in food intended for infants (EFSA-Q-2015-00591): for preliminary discussion

The SC was presented with the interpretation of the term of references (ToRs) and related challenges on the mandate to develop a guidance on the risk assessment of substances present in food intended for infants. Since it was difficult to precisely define a cut-off age from when health based guidance values (HBGV) for adult age groups apply, it was recommended that for the purpose of this guidance, the term 'infants under the age of 16 weeks' is used to describe the particular infant subpopulations where HBGV have traditionally not been considered applicable. This population includes both term and preterm neonates receiving enteral feeding.

The table of content with a detailed explanation of the different chapters was presented. The WG will meet again soon and a preliminary draft of the guidance will be presented at the November plenary. The plan is to have a draft ready for public consultation in the beginning of 2017 with the possibility to finalise the guidance by the summer.

4.3 Draft opinion on criteria to update and re-open an EFSA scientific assessment (EFSA-Q-2016-00326): for possible adoption

The SC was presented with the advanced draft opinion on motivations, criteria and procedures to update an already published opinion or to re-open assessments already adopted by the panel but not yet published. There are several motivations that justify the timely updating of already published EFSA scientific assessments: (i) availability of new relevant and reliable data, including those on new endpoints, exposure data and/or other variables not considered previously and that may bias the conclusions; (ii) emergence of divergent scientific assessments between EFSA and other organisations carrying out similar tasks due to gaps existing either in the performed scientific assessments or in the different interpretations of the evaluated data; (iii) the adoption, due either to autonomous EFSA decisions or to prescriptions of new Community regulations, of major amendments in assessment methodologies used in the past which may significantly affect the overall outcomes of past assessments and imply the need for updating them. The opinion deals with motivations, criteria and procedures to "update" or "re-open" adopted EFSA's scientific assessments.

The SC commented that the term of references (ToRs) were not entirely met as clear criteria for re-opening an opinion and how to rate additional data provided were not presented yet in this opinion. In some areas (such as dioxins, BPA and nanomaterials) several new studies are published daily. It was questioned whether it is feasible to develop general criteria always applicable or if it is rather better to consider specific criteria for each opinion.

The SC agreed that the draft opinion should be revised considering the comments and the suggestions discussed. The new draft will be presented at the next plenary on 16-17 November for discussion.

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

5.1 Feedback from the Scientific Committee and its Working Groups

- Emerging risks activities:

The SC was presented with an update on all emerging risk-related activities since the 78th plenary in April.
(1) Panel collaboration: The unit engaged with the BIOHAZ and CONTAM Panels by having scheduled a dedicated agenda item at their last respective plenaries in July. The focus of the presentation was on how the collaboration and exchange of information could be improved. The objective should be a "win – win" approach. The identification of emerging risks is a responsibility of all panels and the expertise of the panels is

fundamental for identification and prioritization of emerging issues. EFSA, and in particular the SCER unit, can offer support to ensure a holistic approach. It was agreed to keep this agenda item on emerging risks as a standard item twice a year. The aim is to focus first on the RASA department. To counter the risk that the Panels get used to this standing item and that it becomes static without any emerging issues to be reported by the Panel, some ideas are currently on the table such as to organise focused group discussions with the Panels.

(2) Grants and procurements: the kick-off meeting of the framework partnership agreement on Ciguatera toxin was held in Madrid on 1 June 2016 and first deliverables on case definition, protocol for collection of samples and extraction of toxin were delivered; a thematic grant Lot 2 on development of Emerging Risks identification methodologies was launched and the deadline for applications is 6 October 2016; the procurement on "ERIS - Application of a text mining tool (Natural language processing) for the identification of emerging risks in scientific literature" held its last meeting in September and the final report is expected to be published by November 2016. A follow up procurement on the REACH project (presented at the last plenary) to test a methodology for screening chemicals for the identification of possible emerging risks on food and feed was launched. The objective is to apply the tested framework to the entire REACH chemical substances data base. The deadline for applications is 19 September. The AQUARIUS project on Food chain analysis for the identification of emerging risks is on-going.

(3) Emerging Risks knowledge database: EFSA is now developing a repository of all information gathered on emerging risks that can easily be searched and updated. The repository will be part of OPEN SCAIE (Scientific Advance Information Evidence hub) and the pilot is expected to be finalised by end of 2016.

(4) Stakeholders Discussion group: The last meeting of the Stakeholders discussion group on Emerging Risks was held in Brussels on the 19 May. The group engaged in a brainstorming exercise looking at possible emerging issues linked to new trends in food consumption. A list of issues was identified and will be prioritised for possible follow up activities;

(**5) Standing WG on emerging risks** is planned to be established by October 2016 with the mandate of preparing a report that revises the on-going work and provides recommendations for future activities until the end of the mandate of the present SC (July 2018).

- WG on Benchmark Dose Approach (EFSA-Q-2014-00747)

The public consultation on the guidance is still ongoing and will end on 20 September. Interested Panels were invited to provide feedback also via email. The updated guidance is planned to be adopted at the November plenary meeting.

- WG on Compendium of Botanicals (version 3.0) (EFSA-Q-2012-00486)

Currently the database is being populated further with data collected by the contractor and validated by the WG for 1100 plant species. The colleagues from the NUTRI Unit informed the SC that their guidance documents on Novel Foods and Traditional Foods from Third Countries were updated with the input from the WG on Botanicals.

- WG on Chemical Mixtures (EFSA-Q-2016-00307)

The WG held its kick off meeting in June. The discussion focussed on the draft terms of references (ToRs) to be finalised for public consultation. This is a SC self-task activity. The draft ToRs were also shared with DG Santé who provided many comments that will be considered before finalising the ToR for public consultation. Public consultation of the ToRs of self-task mandates for developing methodologies/guidance is a pilot project in the framework of the Transparency and Engagement in Risk Assessment (TERA) project.

The next WG meeting will finalise the ToRs to be shared with the Panels before launching the public consultation. The timelines of the project will then be re-discussed and agreed, if needed, once the consultation is over.

- WG Multiple Stressors in Bees (MUST-B) (EFSA-Q-2014-00881)

The SC was presented with an update on the progress of the MUST-B WG.

The EFSA technical report on the specifications for the development of a mechanistic model to assess risks to honey bee colonies from exposure to pesticides was published on 28 July. An open call for procurement based on these specifications will be launched in October. The project will last for 4 years.

A session on honey bees was organised on 6 September at the European Parliament to plan the Bee Event for next year on bee health monitoring (EU partnership for harmonised data collection/reporting/analysis on bee health). After that session it was agreed that EFSA will meet again in October with MEPs of the Intergroup on "Climate Change, Biodiversity and Sustainable Development" to receive their views and further discuss the initiative.

The last WG meeting was held on 9 September where the next piece of work was tackled: the drafting of a second technical report specifying the requirement for the data collection to calibrate and evaluate the model developed with the first outsourcing. This report should be finalised by end of January 2017.

On 13 September, the AHAW Panel adopted the scientific opinion on health of honey bee colonies, a toolbox designed to facilitate harmonised data collection.

- WG on Nanotechnologies (EFSA-Q-2016-00281)

The WG held its first meeting on 29 June and the next meeting is scheduled for the end of September. So far the WG has revisited the former guidance document and identified areas prone to be updated. The work plan foresees updating the 2011 guidance and to have a draft ready to be published for public consultation by the end of 2017. The finalisation of the guidance is expected in 2018.

- WG on Weight of Evidence (WoE) (EFSA-Q-2015-00007)

The SC was presented with an update on the on-going work. The draft guidance is expected to be presented at the November plenary for preliminary discussion. The next step will be to develop a framework to evaluate the WoE approach. This proposal on a draft framework will be sent to the Panels to identify cases where the WoE approach had already been used and to evaluate any differences with the proposed framework. These examples will then be annexed to the guidance. Finalisation of the project is expected in 2018.

- WG on Threshold of Toxicological Concern (TTC)

The SC was informed that the process of establishing the WG and drafting the specific ToRs is ongoing. The kick off meeting will be probably held by the end of the year.

- WG on uncertainty in risk assessment (EFSA-Q-2013-00738)

The WG will meet mid-September. The main focus of the WG is at present to support the testing of the draft guidance with case studies across the different Panels. The support provided is monitored and the first lessons learnt are already gathered. Furthermore, during its next meeting, the WG will discuss the draft questionnaire to evaluate the impact of the implementation of the guidance in terms of resource needs and applicability to support the risk assessors and risk managers.

The SC was informed about the organisation of an additional training session on the uncertainty guidance organised in EFSA. Representatives of other agencies and from the German Federal Institute for Risk Assessment and from the French Agency for Food, Environmental and Occupational Health & Safety will attend the training session.

5.2 Feedback from the chairs of the Scientific Panels

5.2a Activities in the area of the GMO panel

The SC was presented with 3 examples of the overall work of the GMO Panel which covers applications for market authorisation, guidance documents for risk assessment and recurrent requests on specific mandates from EC/DG SANTE.

First example: Draft guidance on allergenicity guidelines. Three areas are

covered in this guidance: Non-IgE mediated immune adverse reactions to foods, in vitro protein digestibility and endogenous allergenicity. This guidance might be of interest to other panels as well. The guidance document is currently under public consultation until 25 September and the finalisation of the guidance is expected by spring 2017.

Second example: Mandate on possible derogation of existing requirements for applications of GM foods and feeds at low levels submitted under regulation (EC) 1829/2003. The threshold of a low level presence (LLP) GMO (i.e. GM plant and derived products) at a level of maximum 0.9% per ingredient in any food and/or feed containing that very same ingredient, due to its adventitious or technically unavoidable presence. A first draft of this guidance document will go for consultation with the MSs by autumn 2016 and a revised draft will be published for public consultation by end 2017. The applicants will need an authorisation to market LLP GMO up to a 0.9 % per ingredient but the exact amount to be authorised will depend on a risk assessment.

Third example: A strategy document on risk assessment of sub-combinations in stacks applications expected to be discussed in September 2016 by the GMO panel. A stack is synthesized from multiple genetic events which have been combined to develop commercial stacks. A precondition for a stack to be assessed is that each individual event was previously risk assessed concluding that the individual event is of no concern. One example of an opinion was presented.

The SC acknowledged the increasing number of events per stack developed over the last years and the challenges to communicate on this very technical subject.

5.2b Feedback from the Scientific Panels and other scientific activities

AHAW and CEF Panels : No feedback was reported due to apologies from the chair and vice chairs.

ANS Panel

The panel chair informed the SC that the ANS panel had finalised the re-evaluation process of the food colours according to the planned work plan by having adopted the last two opinions on food colours to be revaluated at their last plenary before the summer break: the one on titanium dioxide and the one on annatto extracts. Likewise several opinions on gum had been evaluated and the first gum opinion is expected to be adopted at the next plenary.

The next plenary will be an open plenary that is scheduled on 27-28 September.

BIOHAZ Panel

The panel held its last plenary in the week preceding this SC plenary and it was an open one. Overall the open plenary was a positive experience with 10 observers having attended and with a very good interaction. Questions were allowed to be asked after each session. Observers suggested to attempt to ease the technical language of the BIOHAZ opinions. No opinion was adopted at that last plenary.

Regarding the joint Antimicrobial Resistance (AMR) opinion on measures to reduce the need for antibiotics in animal husbandry in the European Union and the resulting impacts on food safety in collaboration with the European Medicines Agency (EMA) it was finally decided to publish it in the EFSA format. The plan is that EMA will endorse the adoption by the BIOHAZ panel planned by end of 2016. Both, the AHAW and FEEDAP panel were collaborating as well on this joint opinion.

The opinion on the risk for the development of AMR due to feeding calves with milk containing residues of antibiotics is planned for adoption at the next plenary and was chosen as well to trial the uncertainty guidance document. The other opinion, used to test the guidance document, is the one on *listeria monocytogenes* contamination of ready-to-eat foods and the risk for human health in the EU which is still in its infancy steps.

At the July plenary the opinion on the evaluation of the safety and efficacy of Listex P 100 for reduction of pathogens on different ready to eat (RTE) food was adopted. This opinion was chosen to test the Prometheus approach developed by EFSA. The panel recognised that it was important to accurately draw the lessons learnt from this pilot along with the unit, to provide feedback and ensure this feedback is taken up.

CONTAM Panel

The CONTAM panel will meet in the week after this SC plenary. It is planned to discuss the guidance on the benchmark dose (BMD). A new mandate was discussed at the last plenary in July for a scientific opinion on the evaluation of the toxicity of Tetrodotoxins (TTX) and TTX-analogues in bivalve molluscs and marine gastropods (EFSA-Q-2016-00399). The new WG will be set up by end of September and it was proposed to extend the deadline to end of May 2017.

FEEDAP Panel

The Panel held its last plenary in Brussels on 12-13 July in an open session with 16 observers.

Nine opinions were adopted at this last plenary and the revision of the opinion on maximum copper content in feed was discussed and adopted.

After the plenary session an EFSA Info session on Applications – Feed Additives – Technical meeting with Stakeholders was organised. EFSA met with stakeholders to present and collect feedback on the statement

"Analysis of the need for an update of the guidance documents" issued by the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). Over 110 participants, including applicants, representatives of industry associations, consultants, representatives of national competent authorities and academics met with EFSA experts from the FEEDAP Panel, EFSA staff and representatives of the European Commission. Attendants participated actively in the discussions and considered the meeting as an important opportunity to enhance constructive dialogue and increase engagement with EFSA.

It was planned that the standing WG of the FEEDAP Panel will revise the existing guidance documents by June 2018.

NDA Panel

The Panel will meet in the week after the SC plenary. It is planned to discuss the outcome of the public consultation for two guidance documents: the one for the preparation and presentation of a notification of traditional foods from third countries and the one on preparation and presentation of an application for authorisation of Novel Foods.

A new WG on infant nutrition was launched after 2 new requests had been received by DG Santé. The objective is to update the EFSA opinion from 2009 on the appropriate age for introducing complementary feeding for infants and to draft a scientific opinion on scientific and technical guidance for the assessment of formulae manufactured from protein hydrolysates.

PLH Panel

The chair reported on the publication in August of the Statement on the diversity of *Xylella fastidiosa* subsp. *pauca* in Apulia. Six opinions are expected to be adopted at the next plenary in September.

PPR Panel

The next plenary will be held in the week after this SC plenary. The guidance document on the establishment of the residue definition for dietary risk assessment was discussed at the last meeting and additional changes were brought in by including case studies. The adoption will now occur by written procedure. An information session on this guidance is planned for 26-27 September in Parma with a wide audience expected to attend.

The work of the Panel and unit will be presented at the next EFSA Advisory Forum meeting. In particular, the work of the WG on experimental toxicology data of pesticides and their potential link to Parkinson's disease and childhood leukaemia and its opinion still under public consultation and the work of the WG on epidemiological studies in pesticide risk assessment will be presented. Work is ongoing to develop guidance for risk assessment of pesticides for amphibians and reptiles (terrestrial toxicology).

5.3 Feedback from EFSA

5.3a Report back on issues relevant for the Scientific Committee

The SC was presented with a note on several updates on meetings organised since the last Scientific Committee Plenary (6-7 July) with a focus on international collaboration meetings.

Particular interest was raised in the meeting with the Food Standards Australia New Zealand (FSANZ) at the 25th Anniversary Symposium in Canberra, Australia. FSANZ is not engaged in developing new guidance documents. On the other hand the agency is well aware of EFSA' s work, follow it with great interest and seems interested in testing the EFSA guidance on Prometheus approach and uncertainty in scientific assessment and they may be invited to attend the EFSA training on these guidance documents.

5.3b Overview of activities in the Communications Department

The SC was given an overview of the different key on-going communication activities in EFSA's communications & external relations department (COMMS). New developments such as the EFSA Journal referenced by Wiley and the newly designed website were described in more details. New dynamic communication tools e.g. science videos, flash interviews, infographics, blogs and interactive scrollers were presented. On-going efforts in institutional relations were briefly outlined. Media and stakeholders engagement is planned to be reinforced, including training opportunities for relevant EFSA staff to be offered in 2017. International cooperation will continue to focus on supporting the European Commission on the Codex priorities and on exploring opportunities for knowledge exchange. Future planned work with the SC and the other panels was presented such as the project for harmonisation of risk assessment terminology.

Further the SC was updated on a target audience research project (2015-2016) coordinated by COMMS and testing the Clear Communication Index (CCI) on communicating uncertainty. Five focus groups, each with a different target audience (political decision-makers, technical policy-makers, NGOs and civil society groups, industry representatives, informed members of the public) were involved with this project.

The SC raised the challenges they experienced in finding a specific guidance on the newly designed website. Current efforts to improve the user-friendliness of the website and the online library are ongoing.

5.3c Update ongoing work in the Pesticides Unit

- Criteria for the assessment of endocrine disrupting potential in the Pesticides Unit

The SC was presented with an update on the ongoing work in the Pesticides Unit, in particular, on the criteria for the assessment of endocrine disrupting (ED) potential. The SC was reminded of the process of the pesticides peer review, before elaborating further on the content of the EC regulation 1107/2009 concerning the placing of Plant Protection Products (PPP) on the market. In particular, it was highlighted that the Regulation establishes hazard-based interim criteria for the identification of EDs until scientific criteria are implemented[4].

Since 2014 EFSA's pesticides unit (PRAS) has peer reviewed around 70 outputs (conclusions and technical reports on pesticides) with considerations of the ED potential according to the interim criteria. A scientific assessment is presented in parallel in the outputs assessing the adverse effects that could potentially result from endocrine-mediated modes of action and identifying missing data to complete the ED assessment.

In June 2016 the EC published draft criteria based on the 2002 WHO definition for endocrine disruptors and 2009 WHO definition of adverse effects as endorsed by EFSA in its scientific opinion on hazard assessment of endocrine disruptors[5] (2013). The approval criteria have not changed in this new proposal, whereas the derogation has changed from negligible "exposure" to negligible "risk" (which would align the PPP criteria with the ones established in the biocide Regulation[6]).

The EC draft criteria will be voted by a group of experts of Member States at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee on Plant Protection Products – Legislation) and will be presented to the European Parliament and the Council for them to exercise their functions.

The SC concluded that it is important to avoid duplication of efforts and suggested to make sure that the view of ECHA and EFSA is aligned.

[4] Substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties. In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.

[5] http://www.efsa.europa.eu/en/efsajournal/pub/3132

[6] Regulation (EU) No 528/2012 of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1-123.

5.3d The EU risk assessment agenda

The SC was presented with an update on the EU risk assessment agenda which was developed in collaboration with the Discussion Group of the Advisory Forum (AFDG) by implementing a Delphi study across the MSs involving over 200 independent experts from countries across the EU. The experts were asked to identify food safety priorities and to rate them according to a number of criteria, including their potential for saving resources, the mid to long-term nature of projects, their added value to support risk assessment activities and their potential to improve harmonisation of risk assessment. The resulting list derived from the study grouped topics into four domains – chemical, microbiological and environmental risk assessment and nutrition – plus a further category of generic topics that were more cross-cutting. The identified priorities will be tackled collaboratively with interested MSs in joint research projects by using the funding mechanism of thematic grants. MSs were asked on which topics they would like to lead a specific topic.

The SC took note of the list of identified topics and questions were raised about possible plans to complement this list of priorities with existing in house knowledge and map out already existing projects at European level on the same topic. To this end the European Cooperation in Science and Technology (COST) action may provide insight into on-going research at MSs level to ensure complementarity without duplicating efforts.

5.3e Independence policy review

The SC was presented with a plan to review the EFSA 2011 policy on independence. The proposed process and main subjects were outlined. According to feedback from the Management Board meeting (June 2016) the current policy as it stands does not need major revisions of the current approach. It was decided to deliver a proposal to be developed by a Working Group of the Board. The revised draft policy should undergo public consultation after adoption of the draft by the Management Board to be concluded by April 2017 with the aim of implementing the act by September 2017. No major changes are expected to occur.

The SC suggested aligning the policy with other EU agencies. It was clarified that this alignment is already on-going with the exchange of information for example with ECHA and EMA. In addition, DG SANTE has a task force on this subject meeting yearly by bringing the different agencies to the same table.

5.3f Draft technical report on Prometheus deliverable 2: for endorsement (EFSA-Q-2015-00106)

The SC was presented with the draft technical report on Prometheus deliverable 2 for possible endorsement for publication. The objective of this report was to identify the EFSA methodological needs to foster the principles and implement the process for evidence use in scientific

assessments. These needs were gathered with a survey carried out from Dec 2015 – March 2016.

The SC reviewed the summary of the technical report and provided suggestions for revisions. The possible obstacles for the uptake by all panels of cross-cutting guidance documents developed by the SC was also discussed. A dissemination plan, together with an implementation plan, will be discussed by the standing WG on Guidance Review and a proposal will be presented to the Committee in order to increase awareness of the methodological cross cutting guidance.

In addition, it was cautioned not to over-generalize as some cross-cutting guidances are not applicable to all the Panels. The lesson learnt to be drawn is that the general induction training given when Panel are renewed may not be enough to raise awareness on the cross-cutting guidance documents and that more efforts from the EFSA units will be needed to raise the awareness of the new Panel members on these documents. It was further recommended to properly gather feedback on the ongoing trial phase of the draft uncertainty guidance document for which a better buy in may be reached thanks to the testing phase.

The SC endorsed the report for publication and agreed to continue to support PROMETHEUS in its next steps (i.e. testing of the approach).

5.3g Preliminary work-programme for grants and procurement 2017 and 2018

The SC was presented with an overview of the activities related to EFSA's scientific work which may be outsourced by EFSA in 2017 and 2018. The activities and outsourcing tools are only indicative. In comparison with last years' procedure, the plan presented covers two years to be aligned with the biannual implementation plan of the EFSA strategy and these activities were retained instrumental by EFSA towards the implementation of the new EFSA Strategy 2020. As in previous years, EFSA's Advisory Forum and the three EU agencies having complementary remits with EFSA (i.e. ECDC, ECHA and EMA) are asked to provide comments on EFSA's indicative activities to be included in its 2017 and 2018 annual Work Programmes for grants and procurement in science, in particular with respect to their content and appropriateness, while identifying activities of common interest and thereby avoiding duplication of activities. The feedback received from these consultations will be used in fine tuning the list of indicative activities and in the prioritization that will be carried out by EFSA before the final draft 2017 and preliminary draft 2018 work programmes are presented for the attention of the EFSA Management Board in December 2016. In summary, 70 calls are included in the indicative planning.

The SC welcomed this consultation process and was requested to send possible comments to the SC secretariat.

5.3h Overview of modelling tools available and used in EFSA

The SC was presented with an inventory of the existing modelling tools applied in the different scientific areas across EFSA. In total 49 modelling tools are currently used in EFSA. Further, eight projects linked to data and modelling were briefly presented.

The SC raised particular interest for the project called "OpenScAIE" whose main objective is to create a collaborative environment in which digital objects could be stored, accessible to everyone and citable, and for a project in collaboration with the German Federal Institute for Risk Assessment to create a platform in which models could be developed and evaluated by the user for a specific purpose. The aim is to put all the current 49 models used in EFSA in this platform.

The SC welcomed the initiative to share these models with the broader scientific community. It was agreed that this project can help in avoid duplicating efforts. The SC also suggested integrating in this platform a user interface where feedback can be shared and user experiences exchanged with the aim of providing impetus to stimulate further research.

In the end, the possible need for a workshop bringing experts together to share the Panel's respective experiences with the different modelling tools and to evaluate the lessons learnt from past and on-going modelling tools used in EFSA was discussed and agreed. A joint EFSA/EPPO workshop will be held on 12-15 December 2016 linked to this topic. The SC agreed that the most appropriate timing to organise an EFSA internal workshop side to side with this joint EFSA/EPPO workshop was probably after the joint event. The aim of this internal workshop would be to assess how to adapt these generic models to the specific cases at hands across the different units.

6. Any other business

- **Priority Topics for Horizon 2020**

The SC was informed that possible topics for Horizon 2020 EU research and innovation programme were collected over the summer from EFSA staff and experts. These topics will be compiled in a technical report to be sent to DG Research and Innovation by early October 2016. The SC was encouraged to send any pending research idea to the SC secretariat by 28 September.

- **Guideline for observers for open plenary meetings**

The SC was reminded about the next upcoming open plenary (two full days) on 16-17 November in Brussels. The SC was reminded the rules to be followed during the meetings open to observers.

- **Final confirmation 2017 meeting dates for SC plenary**

Five meeting dates were confirmed for 2017:

- 82nd plenary: 13 – 14 February
- 83rd plenary: 26- 27 April
- 84th plenary: 12 -13 July
- 85th plenary: 13 – 14 September
- 86th plenary: 15 – 16 November
- 87th plenary (TBC): 7 December

- **Experts survey:**

The SC was informed about the intention to launch a survey across the EFSA expert employers. The aim is to investigate about possible consequences brought to the experts' organisation, in particular, regarding the financial impact. The plan is to inform the expert's employers about the intent before launching the survey. The survey is going to focus on panel experts only. The outcome of this survey will provide a basis for discussion with the EC and European Parliament.

- **Follow up on the results of the procurement on non-monotonic dose response:**

In relation to the recommendations from the last SC plenary where possible follow up on procurement on non-monotonic dose responses of substances for human risk assessment were discussed, the SC was informed that some additional work was done in evaluating further the quantal in vivo data sets reported in the published report. The next step would be to tackle substances for which evidence on non-monotonicity was claimed, fulfilling at least five of the checkpoints and to look for biological plausibility. The report from the procurement has been published[7] in May 2016. The proposal from EFSA would be to extract those datasets, circulate them amongst volunteers from the SC to assess their biological relevance.
The SC discussed whether to start looking into the papers describing organ effects as opposed to behavioural effects, blood pressure, enzyme activity, or mRNA expression. Prioritising which effect to consider was recognised important, but it was cautioned not to limit the work to these endpoints only.

[7] https://www.efsa.europa.eu/en/press/news/160503

The SC agreed to the proposed approach, but as this additional task was not foreseen in the initial work plan of the SC, the timeline and process under which to perform the task remains to be clarified.

End of the meeting