Scientific Committee

Minutes of the 78th Plenary meeting

Held on 20-21 April 2016, EFSA

(Agreed on 30 June 2016)

Participants

- Scientific Committee Members:

  Tony Hardy (Chair), Diane Benford, Achim Gathmann, Thorhallur Halldorsson, Mike Jeger, Helle Knutsen, Kostas Koutsoumanis, Simon More, Alicja Mortensen, Androniki Naska (agenda item 5.2b only), Hubert Noteborn, Colin Ockleford, Maria Saarela, Josef Schlatter, Vittorio Silano and Roland Solecki.

- Members of scientific Panels:

  Theo Brock (via telecon for agenda item 4.1)

- Hearing experts :

  Jan Alexander (via telecon for agenda item 4.4 only), Robert Luttik (via telecon for agenda item 4.1 only).

- European Commission:

  Takis Daskaleros

- EFSA:
  - **EXECUTIVE Directorate**: Bernhard Url, Hubert Deluyker
  - **COMMS Department**: Alberto Spagnolli, Djien Liem, Simon Terry (5.2e only), Arthur Healy (5.2c only)
  - **RASA Department:** Hans Verhagen, Elisa Aiassa (5.2a only), Andrea Bau (5.1a only), Davide Arcella and Jose Angel Gomez Ruiz (5.2d only)
  - **REPRO Department:** Juliane Kleiner
  - **SCER Unit**: Tobin Robinson, Ana Afonso, Bernard Bottex, Jean-Lou Dorne, Nikolaos Georgiadis, Andrea Germini, Tilemachos Goumperis, George Kass, Daniela Maurici, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hanspeter Naegeli (chair of the GMO panel) who was replaced by Achim Gathmann; Guido Rychen (chair of the FEEDAP panel) who was replaced by Maria Saarela; Dominique Turck (chair of the NDA panel) who was replaced by Androniki Naska

(for agenda item 5.2 b only) and Antonia Ricci (chair of the BIOHAZ panel) who was replaced by Kostas Koutsoumanis.

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[1] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interest[2], 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. For further details on the outcome of the Oral Declaration of Interests made at the beginning of the meeting, please refer to Annex I.

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

4.1 Draft guidance on Biodiversity and ecosystem services to define protection goals for environmental risk assessment (EFSA-Q-2013-00289)

The Scientific Committee (SC) was presented with the draft Guidance to define specific protection goal options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. As agreed during the previous SC plenary meetings, the comments received by DG SANTE were addressed in this version now tabled for final adoption.

The opinion was adopted and will be published on EFSA's website together with the technical report of the outcome of the public consultation on the draft guidance. The SC congratulated the WG for the preparatory work and the drafting of the guidance.

DG SANTE expressed its appreciation for the document and addressed the importance of a sustained dialogue between risk assessors and risk managers (also including MS).

4.2 Draft opinion on priority topics for the development of RA guidance by EFSA's Scientific Committee in 2016-2018 (EFSA-Q-2016-00129)

The SC discussed the draft of the scientific opinion on "Priorities for SC guidance development in 2016-2018" that was prepared by the Standing Working Group on Guidance Review. The comments received will be incorporated into a new version that will then be shared for adoption by written procedure.

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

4.3 Draft statement on non-monotonic dose responses of substances for human risk assessment (NMDR) (EFSA-Q-2013-00611)

Following the presentation of the results of the grant on "Review of non-monotonic dose responses of substances for human risk assessment (NMDR)" during the 77th SC Plenary, the SC was presented with a draft statement to contextualise the outcome of the project in terms of scope, strengths and limitations, as well as to describe the next steps to further analyse the results.
The SC expressed its satisfaction regarding the final version of the report and identified a number of follow-up activities that will be needed to confirm or refute the possible evidence for non-monotonic responses retrieved by this project.
The SC decided that at this stage a statement is not necessary and opted instead for a web story, to be published together with the report to contextualise it. The web-story will explain the views of the SC on the work done and summarise the proposals for follow-up activities.

- **Feedback from the BfR meeting on endocrine disruptors**

The SC was provided with feedback on an Expert meeting to reach scientific consensus on endocrine disruptors, organised by Germany's Federal Institute for Risk Assessment (BfR) in Berlin on 11 April 2016, and in which EFSA was invited to participate as Observer.
The participants signed a consensus statement on "Scientific principles for the determination of endocrine disrupting properties of chemicals". The statement and related documents are available on the BfR website (http://www.bfr.bund.de/en/international_expert_meeting_on_endocrine_disruptors-197246.html).
The Statement is submitted as a contribution for the consideration of the European Commission who is currently developing scientific criteria for identifying the hazard potential of harmful endocrine substances.

4.4 Draft opinion on biological relevance (EFSA-Q-2014-00746)

EFSA has requested its SC to prepare a guidance document providing generic issues and criteria to consider when deciding on whether an observed effect is of biological relevance, i.e. is adverse (or shows a positive health effect) or not.

The SC was presented with an update on the development of the guidance.

The SC welcomed the document and raised comments to improve the draft. More specifically, although the issue of how to decide on the relevance of the data to be used for the assessment is well covered, there is a need to set specific decision criteria on whether an effect is biologically relevant.

Regarding the examples presented with annexes, the SC suggested to focus more on the relevance issues, and not just on the description of previous

assessments. The examples are an essential part of the guidance and they should be treated as such.

A revised draft will be prepared and tabled at the September SC plenary for possible endorsement for Public Consultation (PC). Finalisation of the guidance is foreseen by the beginning of 2017.

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

5.1a Scientific Committee and their Working Groups

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

  The SC was presented with a draft report that will allow interested parties to search the Compendium database directly from the EFSA Website. This report will therefore replace the former Excel version of the Compendium, allowing the users to search the database by families, species or substances / chemical groups of interest. This new version of the Compendium is still under development (900 plant species have been uploaded so far) and will be finalised by early 2017. The final version will contain around 2000 plant species, and propose an additional feature to search the database by toxicity / adverse effect of interest.

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

  EFSA requested the SC to develop a guidance document on the use of the WoE approach in scientific assessments for use in all areas under EFSA's remit.

  The SC was presented with an update on the ongoing work. The WG has developed the table of contents and is working on the contextualisation of the guidance following the on-going work of the WGs on Biological Relevance and Uncertainty.

- **WG on Benchmark Dose approach (BMD)** (EFSA-Q-2014-00747)

  The last meeting of the WG to further develop and update the guidance document on the use of the benchmark dose approach in risk assessment had to be postponed to 21-22 April 2016. The WG will submit the draft guidance for possible endorsement for public consultation at the next Plenary of the Scientific Committee (6-7 July 2016): the intention is to finalise the guidance by the end of 2016.

- **WG on MUST-B** (EFSA-Q-2014-00881)

  A report on both the activities of the MUST-B project (Multiple Stressors in Bees) and the progress of the MUST-B WG were provided. The information is also collected and explained in the dedicated microsite (https://www.efsa.europa.eu/en/topics/topic/beehealth).

  MUST-B activities in 2016 included a meeting with NGOs in February; the publication of the bee microsite on the EFSA website in March; the organisation of a workshop in March by EFSA/SCER and DG-AGRI to prioritise research topics under H2020 on bee health and sustainable pollination; a workshop organised by EFSA (ALPHA Unit) with stakeholders

to discuss the ongoing work for the development of the opinion on HEALTHY-Bees, to be finalised in September; the publication of the scientific report on the statistical analysis of the EPILOBEE dataset in April (http://ec.europa.eu/food/animals/live_animals/bees/study_on_mortality/index_en.htm); the foreseen publication of the scientific report on toxicity data (mixtures) and DEB models (Dynamic Energy Budget model) for bees; the publication of the first technical report and Tender Specifications for the model development in July; the publication of the scientific opinion on HEALTHY-B in September and the technical report on the specification for the field of "data collection for the model validation" in December.

The report of the progress made by the MUST-B WG included a presentation of the overall purpose and broad concepts of the model development focusing on the risk assessment of single pesticides on single colonies in the context of multiple stressors and in a realistic landscape. More details were provided on each of the modules comprising the model (core "colony" module with "foraging" and "in-hive products" submodules; "pesticides" module; "resource providing unit and external drivers" module; disease infection and infestation module; beekeeping management module).

- **WG on Risk Assessment for Infants and Young Children** (EFSA-Q-2015-00591)

  No meetings of the WG have been held since the last 77th SC plenary meeting.

- **WG on nanotechnologies**

  The Terms of Reference for a new SC working group on nanomaterials in agri/food/feed were amended as suggested by the SC during its 77th plenary meeting to include stakeholder's involvement and life cycle analysis of products. EFSA accepted this self-tasking mandate to update the 2011 guidance document for assessing "nano" applications in food and feed and to develop *de novo* a guidance document for environmental risk assessment of nanomaterials in agri/food/feed. Both activities will be complemented by procurement contracts to collect reviews of best practices and test results with nanomaterials used in agri/food/feed applications.

  The expertise needed for this working group will be mapped and the WG will be established with the aim of holding the first meeting by the end of June.

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

  The SC was presented with an update of the ongoing activities. Following the endorsement of the revised draft version of the guidance, that took place during the last SC plenary meeting, the methodology is now being tested on selected opinions by the different EFSA Panels for one year. Training sessions to support the trial phase have been organised in April and May for both EFSA Panel members and EFSA staff. The WG will continue holding regular meetings during the trial phase to discuss the status of the activities and provide support to the testing.

- **Follow up on Threshold of Toxicological Concern (TTC)**

  EFSA agreed to mandate the SC with a self-task to establish a WG to update the Scientific Opinion on "Exploring options for providing advice about possible human health risks based on the concept of Threshold of Toxicological Concern (TTC)" published in 2012 and recommended to take into account the outcome of the WHO/EFSA expert workshop on TTC held in December 2014, for which an event report was published in March 2016 together with the outcome of the public consultation held on the recommendations of the workshop.

5.1b Follow up on Emerging risks brainstorming during last plenary meeting

The SC was updated on the follow up of the actions agreed during the last plenary meeting brainstorming session on emerging risks. The proposed AHAW-BIOHAZ panels' joint session on emerging risks was discussed with the secretariat of the respective units and a proposal on agenda will be prepared for the next common plenary in 2017. The SC was requested to consider the interests of different panels on organising such events with SCER support and the need to include emerging risks identification in the agenda of the panels.

The Terms of reference of the Standing WG on emerging risks were proposed and agreed: 1) the dissemination of information and coordination between panels and 2) to foster innovation and technologies as well as the usefulness of data collection and generation in the area of emerging risks. The Scientific Committee agreed for the WG to be chaired by Dr. Hub Noteborn, vice chair of the SC.

The SC was informed of the signature on a new framework partnership agreement on "Risk characterization of Ciguatera food poisoning in Europe" and the launch of a thematic grant on "Methodology development in risk assessment" (https://www.efsa.europa.eu/en/art36grants/article36/gpefsaafsco201601), and where one of the lots is related to "Methods and systems for the identification of emerging food risks".

The SC was also informed about the outcome of the 15th Emerging Risks Exchange Network meeting held on 14-15 April in Parma.

5.1c Feedback on crisis exercise and future plans

The SC was updated on the workshop on "Crisis preparedness" for the Baltic countries that took place in Riga, Latvia, on 15-17 March 2016, facilitated by EFSA.

The training session aimed to improve collaboration between EFSA and Member States as well as EU sister agencies. The 40 participants from Latvia, Lithuania, Estonia, Germany, Poland, the European Commission, and European Centre for Disease Prevention and Control (ECDC) learnt about tracing methodologies, rapid assessment and crisis communications, using a fictitious scenario of a

multi-country foodborne outbreak. A report capturing the outcomes of the workshop will be published on the EFSA website in June 2016.

EFSA's recently published the new crisis communication guidelines (https://www.efsa.europa.eu/en/press/news/160315), proved to be a crucial supporting tool as the training incorporated urgent media and social media activities. Participants agreed that the workshop helped to improve preparedness and collaboration between MSs.

5.2 EFSA

5.2a Update on Prometheus deliverable 2

The SC was presented with an update on Prometheus deliverable 2 which reflects the overall picture of the future needs of EFSA and enhances openness and transparency.

The first objective is to illustrate the EFSA methodological needs for evidence use, along with their priority, risks, benefits, desirable characteristics and/or possible mitigation actions.

The second objective is to provide recommendations for implementing new methods or approaches in EFSA, thereby covering any needs identified. It is expected that these recommendations will serve the purpose of providing further input to EFSA projects that have already started and triggering the development of new ones.

The SC members highlighted the need for supporting mechanisms to better implement the existing and newly developed guidance documents.

The SC suggested revising the content of the draft report, focusing more on the identification of guidance to be developed. More assistance is needed from EFSA in relation to guidance implementation. The final version of the document will be presented at the SC plenary in September.

5.2b Feedback from the Scientific Panels and other scientific activities

(Report back on issues of common interest for the Scientific Committee)
Panel chairs were invited to report back on issues of common interest for the SC.

GMO Panel:

The Panel plans to develop two new guidance documents. The first one will aim at providing supplementary guidelines for the allergenicity assessment of GM plants to incorporate new developments. A pilot group composed of Member States Representatives and Representatives from the EFSA Stakeholder Platform has been given the opportunity to provide input at an early stage of the development of the guidance.

The second guidance document will address possible derogations of existing requirements for applications of GM food and feed at low levels submitted under Regulation (EC) 1829/2003 on GM food and feed. The deadline for finalising these two guidance documents is mid-2017.

PLH Panel:

The Commission has recently been confronted with a number of statements which are questioning the overall EU control strategy against *Xylella fastidiosa* and some relevant legal provisions laid down under Decision (EU) 2015/7893.

The Commission requested EFSA's scientific advice and the Panel published a Scientific opinion on four statements questioning the EU control strategy against *Xylella fastidiosa*. The Panel considers removal of infected plants, in a system-based approach, as the only option to prevent further spread of the pathogen to new areas.

CONTAM Panel:

The Panel adopted three opinions in March. The Panel finalised a scientific opinion on risks for human health related to the presence of 3- and 2-monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food.

The next plenary meeting, planned in May, will be open to observers.

BIOHAZ Panel:

Work is in progress on 10 opinions. The Panel received 2 new mandates. A plenary meeting has been planned together with the AHAW Panel next month. The panel selected the opinion on increased trend for *Listeriosis* as an example to test the draft guidance on how to address uncertainty in risk assessment.

AHAW Panel:

A plenary meeting has been planned with the BIOHAZ Panel next month.

The Commission asked for the revision of 39 vector-borne diseases. Given the broader interest in the subject, and the many ways in which these 39 diseases differ, the Panel plans to communicate the results of this work to the general public in a simple way using story boards. A number of other opinions are currently in preparation within the Panel, on a diverse range of issues relating to animal health and animal welfare.

ANS Panel:

The ANS Panel discussed the different parts of the risk assessment and adopted the opinion on the revaluation of Benzoates as food additives.

The ANS Panel discussed the different parts of the opinion on the safety of the proposed use of potassium polyaspartate (A-5D K/SD) as a stabiliser in wine and adopted it. The Panel acknowledged that it was the first case of a dossier for a new food additive being submitted and evaluated according to the current 'Guidance for submission for food additive evaluations' (EFSA, 2012).

The Panel held a plenary meeting together with the FEEDAP Panel and positive feedback was received by both Panels.

FEEDAP Panel:

Sixteen opinions were adopted during the last plenary (re-evaluation of feed additives).

A plenary meeting with ANS took place and positive feedback was received by both Panels.

A Panel statement about the "Analysis of the need for an update of the guidance documents" has been published. More specifically, the Panel adopted a series of guidance documents which complement the Regulations governing the authorisation of feed additives. These are intended to help applicants in their preparation of technical dossiers. Although most guidance documents prepared by the Panel have been updated at some point, experience has shown that some elements need a technical update. The FEEDAP Panel addressed this by considering the experience gained since the last major revision of the individual guidance documents.

CEF Panel:

A working group of international experts is going to established to evaluate new scientific evidence on the potential effects of bisphenol A (BPA) on the immune system. The review will be conducted following publication of a report that raises concerns about the effects of BPA on the immune system of fetuses and young children. The report by the Dutch National Institute for Public Health and the Environment (RIVM), critically examines two studies describing pre- and perinatal effects of BPA on the immune system by Menard et al. (2014) that were unpublished when EFSA reviewed the available scientific literature for its 2014 risk assessment of BPA. EFSA accepted a request from the Dutch Ministry of Health to examine the results of the RIVM report and specifically will review the toxicity of BPA on the immune system in light of this new evidence. EFSA's experts from the CEF Panel aim to issue a statement in the next few months.

A public consultation on the draft Statement on exposure assessment of food enzymes was launched at the beginning of the year and closed at the end of March. The statement proposed a strategy to refine the exposure estimation by following a tiered approach as a self-tasking mandate of the CEF Panel. This strategy was presented to stakeholders during an Info Session on food enzymes on 3 February 2016. This document is intended to be annexed to the CEF guidance on food enzymes. The statement is now being revised and will be published soon together with a report summarising the outcome of the public consultation.

PPR Panel:

A scientific opinion addressing the findings of the external scientific report on 'Literature review on epidemiological studies linking exposure to pesticides and health effects' (University of Ioannina Medical School, 2013), will probably be finalised by the end of the year.

With regards to the opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms, the opinion will soon be published for public consultation.

NDA Panel:

During the last plenary meeting, the draft opinion on dietary reference value for Vitamin D was endorsed for public consultation. The UK Scientific Advisory Committee on Nutrition is also preparing an opinion on the same topic and the Panel is in close contact with them.

The Panel is working on two guidance documents: one on the preparation and presentation of a notification of traditional foods from third countries and one for the preparation and presentation of an application for authorisation of Novel Foods. They are both in progress and more updates will be given during the next SC plenaries.

5.2c EFSA Journal – Revised guidelines for authorship of scientific outputs

The SC was presented with a proposal for the revision of the authorship policy for EFSA scientific outputs. While legal responsibility for opinions remains as it is at present, i.e. with the EFSA Scientific Panels/Scientific Committee, EFSA is proposing to implement a joint authorship model where both corporate and personal authorship are recognised. Personal authors can be Panel members, WG members, EFSA staff and trainees depending on their contribution to the opinion. The proposal was highly welcomed and endorsed by the SC.

5.2d Exposure Assessment: draft scientific report on non-dietary exposure and reflection paper on exposure assessment

The Exposure assessment team of the EFSA DATA Unit informed the SC on the process that led to the preparation of a draft scientific report on non-dietary exposure assessment and provided an overview of a reflection paper on human dietary exposure assessment. The SC commented on the issue of aggregating dietary and non-dietary exposure data. The SC also highlighted the importance of collaborating with the EChA Agency, particularly in the area of development of tools that could serve both organisations.
The SC agreed with the proposal of setting up a Standing WG on Dietary exposure assessment led by the Exposure assessment team and under the umbrella of the SC. More discussion on the possible Terms of Reference will be held at the next plenary meeting in July.

5.2e Report back on issues relevant for the Scientific Committee

- The Communications Department presented some highlights of their current activities to the members of the SC. The new webpage for the EFSA4Bees project is now available on the EFSA website.

- The SC was informed that EFSA highlighted to DG SANTE the need to adjust the mandates of its current ANS, CEF and NDA Panels to better balance their workload. EFSA also suggested taking this opportunity to align the terms of the ANS and CEF Panels to those of the other Panels and Scientific Committee. The European Commission confirmed its willingness to amend the names of EFSA's Panels in the Founding Regulation as requested by EFSA.
- The inaugural meeting of the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) took place on 28-29 April in Luxembourg. EFSA's Scientific Adviser participated at the meeting and received expressions of interest for further collaboration with EFSA.

6. Any other business

- EFSA and RIVM will co-organize a symposium on the future of risk assessment and toxicity testing for chemical mixtures. The symposium will take place in Utrecht on 18-19 May 2016.
- EFSA's Scientific Colloquium on "Epigenetics and Risk Assessment: Where do we stand?" will take place in Valencia on 14-15 June 2016.
- The SC was provided with an update of the roll-out measures for the TERA Project (Transparency and Engagement in Risk Assessment).
- The SC was informed that the November SC plenary meeting will be an open plenary taking place in Brussels.

End of the meeting