Scientific Committee

Minutes of the 73rd Plenary meeting

Held on 8-10 June 2015, Parma

(Agreed on 21 July 2015)

Participants

- Scientific Committee Members:

  Tony Hardy (Chair) Jan Alexander, Diane Benford, Qasim Chaudhry, John Griffin, Michael John Jeger, Alicja Mortensen[1], Robert Luttik, Ambroise Martin[2], Simon More, Birgit Nørrung[3], Bernadette Ossendorp, Joe Perry (via teleconference), Josef Schlatter, Kristen Sejrsen, Vittorio Silano[4] .

- Hearing experts:

  Theo Brock (agenda item 5.1, via teleconference), Andy Hart (agenda item 5.2)

- European Commission:

  Michael Walsh (DG Sante)

- EFSA:
  - **COMMS Department**: Alberto Spagnolli[5]
  - **RASA Department:** Marta Hugas
  - **REPRO Department:** Juliane Kleiner
  - **SCISTRAT Department**: Tobin Robinson, Djien Liem
  - **SCER Unit**: Andrea Altieri, Bernard Bottex, Jean-Lou Dorne, Andrea Germini, Tilemachos Goumperis, Angelo Maggiore, Daniela Maurici, Caroline Merten, Agnes Rortais, Reinhilde Schoonjans.

[1] Present on 9-10 June
[2] Present on 8-9 June
[3] Present on 9-10 June
[4] Not present on 9 June a.m.
[5] Present on 8 June

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Bernhard Url, EFSA Executive Director, and Hubert Deluyker, EFSA scientific adviser.

2. Adoption of the agenda

The agenda was adopted after adding an additional item under any other business, namely the feedback from the grant contract on "Review of non-monotonic dose-response of substances for human risk assessment."

3. Declarations of Interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes[6] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[7], 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. Agreement on the minutes of the 72nd Plenary meeting held on 22-23 April 2015

Minutes were agreed without changes.

5. Scientific outputs submitted for discussion and possible endorsement for public consultation

5.1 Draft documents on Environmental Risk Assessment

The Scientific Committee was presented with the 3 draft opinions on Environmental Risk Assessment, to be discussed and endorsed for public consultation. In particular:

Draft opinion on coverage of endangered species in environmental risk assessments at EFSA(EFSA-Q-2013-00901).

Without making a judgement where, when or for how long endangered species have to be protected, the present draft opinion reviews the characteristics that can be used to determine which of those endangered species can suffer more than non-endangered species from assessed potential stressors in an agricultural context.

Draft guidance to define protection goals for environmental risk assessment in relation to biodiversity and ecosystem services (EFSA-Q-2013-00289).

This draft document presents a conceptual framework which accounts for biodiversity and ecosystem services, to make policy protection goals operational for use in EFSA's ERA.

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

Draft opinion on the temporal and spatial ecological recovery of non-target organisms for environmental risk assessments (EFSA-Q-2013-00902).

This draft opinion presents an integrative approach based on well-defined specific protection goals, scientific knowledge derived by means of experimentation, modelling and monitoring, and the selection of focal taxa, communities, processes and landscapes to develop environmental scenarios to allow the assessment of recovery of organisms and ecological processes at relevant spatial and temporal scales.

These draft documents were submitted for panel consultation in March-April and the comments received from the relevant Panels (PPR, GMO, PLH and FEEDAP) were considered for the revision of the documents.

The SC welcomed the three drafts and provided comments or suggestions for amendments. The use of the term "stressor" and possible alternatives was discussed in detail. For communication purposes, this widely used scientific term will be changed into "potential stressor", implying that the risk assessment outcome is still not yet known. The SC endorsed the three documents for public consultation to be launched in the second half of June. It also advised to extend the deadline until mid-September so that submitters have sufficient time during non-holiday months.

The Chairs of the Panels are invited to promote the consultation with their Panels and to disseminate the version of the public consultation as feedback to the Panel members who had provided comments. The EU/international organisations that have being sitting as observers during the preparation of these opinions (EMA, ECHA, EEA, JRC, non-food committees of DG Sante, OECD, US-EPA and WHO) will be invited to participate in the consultation. The comments received during the public consultation will be considered and a revised version of the documents will be prepared to be tabled at the November SC plenary for possible adoption.

5.2 Draft guidance on Uncertainty in scientific assessment (EFSA-Q-2013-00738)

The Rapporteur of the Working Group, Andy Hart, presented the layout of the document and the key concepts. This draft guidance offers a flexible framework and toolbox for EFSA Panels to report on uncertainties in their scientific assessment in a clear and unambiguous way. The approach proposed is scalable to the needs of the assessment and aims at supporting risk managers during the decision making process.

The SC discussed and reviewed the draft guidance and endorsed it for public consultation. The consultation will start in June and last until September. After addressing the public comments, a revised version of the opinion will be presented to the SC plenary in November. The procedure described in the document will then be tested by each EFSA Panel for a period on about one year before the guidance is finalised.

5.3 Draft opinion on Production and consumption of insects as food and feed (EFSA-Q-2014-00578)

The draft opinion on production and consumption of insects as food and feed was presented to the SC for a first reading and discussion. The Chair of the WG, Birgit Nørrung, explained chapter per chapter the principle information and concepts for the assessment. The SC welcomed the document and provided some comments that will be considered for the preparation of the final draft to be tabled for possible adoption at the SC plenary in September.

6. New mandates

None.

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

7.1 Discussion on the work programme of the Scientific Committee to be proposed for continuation to the new SC (2015-2018)

As this is the last meeting of the SC 2012-2015, the following discussion aims at reviewing ongoing activities and forecasting new activities for the next SC 2015-2018.

Ongoing work:

a. **Compendium of botanicals (version 3.0):** The SC Working Group on Compendium had an interim meeting in May 2015 with the contractor in charge of transforming and expanding the information in the compendium. By July 2015, the botanicals species of version 2 of the Compendium will be transferred to the EFSA data warehouse. Version 3 of the compendium will then be released shortly after. In parallel, the contractor is performing an extensive literature review for the plant species that have been added to version 2 of the Compendium, or that require further information on substances of concern and adverse effects. As soon as the new data have been validated, the plant species will be added to version 3 of the Compendium. This activity will run until end of 2016.

   In view of the timeframe of the above-mentioned procurement, the SC agreed to align the mandate (initially foreseen to expire by end of June 2015), with the deadline for the procurement (December 2016). The terms of reference will be updated after the new SC had discussed its 2015-2018 work programme related to the assessment of botanicals and botanical preparations.

b. **WG Weight of Evidence in scientific assessments**:

   The WG held its first meeting on 19-20th March 2015 and substantial amounts of information on available weight of evidence approaches in areas under EFSA's remit (e.g. chemical and biological hazards, nutrition etc…) were collected. The linkage with the work on biological relevance and the uncertainty guidance documents is apparent and will be discussed during the upcoming WG meeting, taking place in June 2015. Case studies to support the Panels' work will be developed to illustrate the practical use of weight of

evidence approaches. The working plan is to publish the draft guidance on the use of the Weight of Evidence Approach in Scientific Assessments for public consultation in 2016 and to finalise it by summer 2017.

c. **WG Biological Relevance in toxicology**:

The WG held its 2nd meeting end of May 2015. The participants drafted a detailed outline of the guidance document aiming at identifying criteria and concepts to decide on the biological relevance of an effect for an assessment. The guidance document will be organised according to the risk assessment paradigm, with an additional section discussing the uncertainties related to decision on biological relevance. Case studies will illustrate how to apply the proposed guidance to the various EFSA areas of activity. The SC suggested to make the link with the activity on weight of evidence by using the same case studies, where possible.

The detailed outline as well as concepts and definitions related to biological relevance will be discussed during the workshop on increasing robustness, transparency and openness of EFSA's assessments next 29-30 June in Brussels. The outcome of the discussion will then be considered by the working group for further developing the guidance document.

A public consultation will then be organised in April 2016 before adoption of the guidance foreseen in October 2016.

d. **WG on Benchmark Dose (BMD) approach**:

The WG held its 2nd meeting end of May 2015. The mandate is to update the 2009 guidance document on the use of the BMD approach in risk assessment, clarifying issues/difficulties reported by the Panels and EFSA Experts when applying the BMD approach during these last 6 years, and reviewing the latest developments in dose-response modelling.

The updated guidance document will be published for public consultation early 2016 and should be adopted by April 2016. A series of trainings will be organised as from second half of 2015 for a better implementation of the guidance by EFSA Experts and Staff on this issue.

e. **WG on Bees**:

The chair of the WG MUST-B (MUltiple STressors in honeyBees), Simon More, reported that the impact of multiple stressors such as pests and pathogens, pesticides and environmental change and pollution, on honeybee colony health has been discussed during the 2 meetings in March and May. One task of the WG is to seek a model to include landscape properties, population dynamics and multiple stressors on honeybee colonies. The second is to calibrate the model with field data from defined and representative sampling sites in EU.

The work of PPR Panel on Good Modelling practices and their assessment of the BEEHAVE model have helped a lot regarding colony dynamics. There is also good collaboration with the Healthy-Bee WG of the AHAW Panel, focussing on indicators, criteria and methods for measuring the health of a

honeybee colony. Also the EPILOBEE project, led by the European Reference Laboratory on honeybee Health (EURL at ANSES), gives useful insights in the strengths and weaknesses of the design for monitoring infectious agents, pests and viruses. Close contacts with DG AGRI, EURL and Member States will be maintained during the work of the MUST-B WG.

Proposal for new self-task activities to be initiated:

The SC was presented with a list of possible new activities to be initiated under the new SC as from September 2015. The list comprises activities that could be undertaken as self-task for development of SC guidance documents. Brief discussions on most, but not all, proposals took place during the meeting. New items were also added to the list during the meeting, as raised *ad hoc* by the SC members. In order to present to the new SC at the inaugural meeting that will take place on 23rd July, a tentative priority list, the SC was asked to indicate possible topics where activity should be initiated by end of 2015-beginning of 2016. More in depth discussion will also take place in September in order to finalise the SC work programme 2015-2018 for self-tasks activities.

7.2 Feedback from the Scientific Panels

- **AHAW Panel**:
  During the last plenary, the AWAH Panel discussions included the opinion on African swine fever and the opinion on small hive beetle (*Aethina tumida*). For the African swine fever, the definitions of the model parameters were discussed. The Panel agreed to provide a tabulation of the model outcomes, comparing the combinations of the different management options with their different efficacy of implementation, so the risk managers would be presented with a range of combinations out of which they could choose the most suitable combination.
  A feedback session on the AHAW Panel period 2012-2015 will be held at the last plenary meeting in June.

- **ANS Panel**:
  At the last plenary meeting, several opinions on food additives re-evaluations were adopted.
  Following a request from the EC, a refined exposure assessment was carried out based on the maximum permitted levels authorised for extracts of rosemary (E 392) and the extension of its use in fat-based spreads. The Panel recommended to decrease the existing uncertainties arising from its conservative estimates based on current maximum permitted levels.
  Seven new mandates were received since the last plenary.

- **CEF Panel:**
  The Panel is working on amendments of the Food Contact Materials guidance. Two documents will be produced: the first will present the main amendments to the existing guidance and the rationale for the update. This doc will be discussed and presented to the relevant stakeholders. The

second document will be the actual revised guidance and will aim at clarifying steps for more transparent decisions making.
The Panel is also working on safety assessment of enzymes. A conservative technique such as the "budget method" has been used to assess potential dietary exposure for adult, but the possibility to use a different approach is being tested.

- **BIOHAZ Panel:**
  At the plenary last week, various issues were discussed, including the transport of meat, storage of fish products in the supermarket, and disposal of waste. The Panel compiled its legacy document with useful self-mandates, but prioritisation by the new BIOHAZ Panel will be necessary.
  During the last plenary, the Panel was presented with the SC work on Emerging Risks and on Uncertainty in risk assessment. Both activities received full support from the Panel members. The selection of examples for the pilot phase on uncertainty guidance (see also item 5.2), to be initiated in 2016 after the closure of the public consultation, were discussed.

- **CONTAM Panel**:
  The adopted opinion on chlorate will be published soon. The clarification of diverging views with BfR is still ongoing. At the last plenary, also the opinions on nitrofurans and tetrahydrocannabinol in food were adopted. The latter was previously assessed by the FEEDAP Panel using different exposure scenarios.
  The opinion on acrylamide in food has been published, together with the technical report of the public consultation and non-technical summary of the scientific opinion for easy understanding of the lay audience. EU wide advice to reduce exposure to acrylamide from baked food is expected: the EC will be considering maximum limits in foods together with the Member States as well as possible advice to consumers. The opinion is also on the agenda of the Advisory Forum taking place in Riga this week.

- **FEEDAP Panel:**
  The work on feed additives applications is ongoing. A stakeholders meeting in Barcelona took place in May, convening 130 participants from industry and research institutes to an open exchange of views on the renewal process, on flavouring and on botanicals. Participants gave very positive feedback on EFSA's initiatives to open up more and increase their communication with stakeholders.

- **GMO Panel:**
  At the last plenary in April, the Panel adopted 4 opinions on import and processing applications, and 2 guidances on agro-phenotypical characterisation and on renewal of applications. Both draft guidances were published before for public consultations and were discussed at the network meeting with MS delegates.
  The uncertainty analysis in the scientific assessment of the GMO Panel for the impact on GM plants on butterflies was performed.

Two opinions on stacked events are probably going to be adopted at the last plenary meeting in June.
The chair pointed out that the Panel has been renewed but unfortunately it will have again less than 21 members.

- **NDA Panel:**
  The latest NDA plenary meeting was open to external observers, particularly interested in the opinion on safety of caffeine. Some apparent discrepancies between the ANSES, BfR and EFSA opinion needed to be clarified. The meeting was a good opportunity to clarify the terms of references and other scientific issues. The third scientific opinion on iron intake comprises new modelling results elaborated from the Assessment and Methodological Support Unit.
  New guidances on novel foods and foods for specific medical purposes will be produced.
  The updated guidance on the scientific requirements for health claims related to gut and immune function will be finalised by December when it is expected that the Panel will also adopt the Guidance on the general principles for health claims evaluation.

- **PLH Panel**:
  The plant pathogenic bacterium X*ylella fastidiosa* was found in 2013 on olive trees in Apulia. This bacterial species originates from the Americas and is a quarantine organism in the EU. It has a very broad host range (the range of plant species reported as hosts of *X. fastidiosa* comprises plants in 68 botanical families, 187 genera and more than 300 plant species) and can be transmitted by insects feeding on xylem sap fluid. The Apulian strain of *X. fastidiosa*, since its discovery in October 2013, has been found affecting 18 plant species including olive, almond, cherry, rosemary, Spanish broom and many ornamentals. The EFSA PLH panel pest risk assessment has concluded that *X. fastidiosa* poses a major risk for the EU agriculture and recommended the continuation and intensification of research on biology, epidemiology and control of the Apulian strain of *X. fastidiosa*. Following the pest risk assessment made by the EFSA Plant Health Panel in January 2015 and the EFSA rapid responses to EU Commission urgent requests in March and April 2015, new EU emergency measures on *X. fastidiosa* have been adopted/promulgated. The risk of *X. fastidiosa* has been discussed by European Parliament that recommended strengthening of measures to prevent introduction and research funding on this plant pathogen. The Plant Health Panel has further discussed the risk of the Apulian strain of *X. fastidiosa* at its last plenary and recommended to organise a workshop to identify knowledge gaps and research needs as well as the need work on a broader mandate to conduct a specific and detailed assessment of the risk of establishment, spread and impact of the Apulian strain of *X. fastidiosa*, keeping into account data and results from ongoing research.

- **PPR Panel**:
  At the May plenary meeting, the Panel discussed the following points of overarching interest: (1) A statement on the BEEHAVE model was adopted. The model was considered overall to be in line with the

requirements explained in the Opinion on good modelling practice, but it needs some amendments before it can be used in regulatory risk assessment. E.g. a pesticide exposure and effect module is missing. The overarching SC WG MUST-B was informed of the findings. (2) There are 2 ongoing mandates on epidemiological studies linking exposure to pesticides to health effects in Plant Protection Products peer review: one is reporting – from the toxicological point of view on progressing and developing Adverse Outcome Pathways (which is linked to biological relevance ongoing work of the SC). The other mandate focuses on the epidemiological data interpretation and is also progressing. (3) A guidance on the residue definition for dietary risk assessment and relevance of metabolites (incl. isomers) is being developed by the Panel. In addition, the Pesticides Steering Network submitted a draft mandate for EFSA to the EC for providing technical guidance for risk assessment of isomers and expects feedback for EFSA by autumn. Since dealing with isomers is an overarching issue, the draft ToR will be circulated among the Panel Chairs in order for them to assess whether there would be interest to join this activity. (4) Priorities of future activities for the PPR panel were discussed. (5) A joint EFSA/FAO/WHO stakeholder meeting and workshop is planned on 7-9 September to revisit the international estimate of short-term intake (IESTI).

7.3 Feedback from EFSA:

a. Report back on issues relevant for the Scientific Committee

None.

8. Other scientific topics for information and/or discussion

8.1 Thematic grants: proposing topics

EFSA defined broad thematic areas to co-finance large innovative networking projects with Article 36 organisations. Kerstin Gross-Helmert from the AFSCO Unit, presented the results of the pilot project launched in 2014 that closed in April 2015. 6 applications were received from 37 organisations from 15 countries. The Scientific Committee is asked to provide feedback on the possible thematic areas to be considered for future grants or to make further suggestions, take into account possible interests and needs in 2016.

8.2 Human biomonitoring (HBM) for chemical substances: possible involvement of EFSA in EU human biomonitoring intiative (EHBMI) and self task activities

EFSA outsourced in 2013-2014 a research project to provide an overview on HBM and possible application to human risk assessment, an inventory of different HBM surveillance programmes and a review of results to identify emerging chemicals, vulnerable population groups and validated biomarkers. The EFSA CONTAM and CEF Panels already assessed HBM data in some opinions. Recently, an EU Human Biomonitoring Initiative is launched with the objective to bring together relevant national and EU-level (EHBMI) research to address the exposure of European citizens to chemicals. EFSA involvement in the EHBMI was

discussed. EFSA is expected to provide technical inputs to the draft project proposal to be launched by autumn 2015 and to the project itself planned to start by end of 2016. Currently the SCER Unit in collaboration with colleagues from Pesticides and Biocontam units has developed a first priority list of chemicals for EFSA to be monitored by the program. The next step is to match this list with the criteria for the priority setting defined by the EHBMI. It was agreed to keep the SC updated on the development of this priority list and the status of this initiative. Additionally, the subject is also to be considered in the proposals for future activities of the Scientific Committee during the 2015-2018 mandate (see item 7.1).

8.3 EFSA's chemical hazards database

A brief description of the content and application of EFSA's chemical hazards database (OpenFoodTox) was presented to the Scientific Committee. A practical demonstration illustrated examples of the type of data that would be possible to retrieve form the EFSA's data warehouse as from October 2015. The hazard database has being updated on a monthly basis with the data from EFSA's incoming mandates and published opinions using a framework contract. The Scientific Committee welcomed the presentation and considered the data warehouse that will be accessible as from autumn very helpful for EFSA's activities.

8.4 Scientific data warehouse: open data today

An overview of the on-going activities for data collection and storage in an open scientific data warehouse was presented to the SC. The open scientific data warehouse is expected to be publicly available for free information download from the EFSA's website in autumn.

Any other business

- Update on the EXPO Conference "Shaping the future of food safety, together": all information is available on the website and panel members will receive the official invitation in the coming week.
- Update on the public consultation on TTC: The public consultation on conclusions and recommendation resulting from the EFSA-WHO workshop held in Brussels in December 2014 are currently being addressed. An event report will be probably published in autumn.
- Update on the Nanonetwork: the 5th meeting of the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed will take place on 7-8 July 2015 in Parma. The draft agenda was presented to the SC and approved.
- Ongoing grant on "Review of non-monotonic dose-response of substances for human risk assessment": the SC was presented with an update of the project and its preliminary results concerning the literature search and the review of publications claiming non-monotonicity.

Annex I

Interests and actions resulting from the oral declarations of interests done at the beginning of the meeting

a) With regard to this meeting, Bernadette Ossendorp as employee of RIVM, declared an interest with respect to the grant on "Review of non-monotonic dose response", since RIVM is part of the consortium involved in the grant. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes and the Decision of the Executive Director on Declarations of Interests, and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest for the expert concerned. Bernadette Ossendorp was therefore asked to abstain from expressing any view or making any comments.