# Scientific Committee

# Minutes of the 81st Plenary meeting

**Held on 16-17 November 2016, Brussels**

**(Meeting open to Observers)**

**(Agreed on 15 December 2016)**

## Participants

- Scientific Committee Members:

  Tony Hardy (Chair), Thorhallur Halldorsson, Mike Jeger, Simon More, Alicja Mortensen, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford, Antonia Ricci, Maria Saarela, Josef Schlatter, Vittorio Silano, Roland Solecki, Dominique Turck, Christiane Vleminckx.

- Hearing experts[1]:

  Maged Younes (agenda item 6.1), Jan Alexander (via teleconference, agenda item 6.2)

- European Commission:

  Marina Marini, Luis Vivas-Alegre, Diana Herold

- EFSA:
  - **EXECUTIVE Directorate**: Hubert Deluyker, Juliane Kleiner
  - **RASA Department:** Hans Verhagen, Marta Hugas (day 2)
  - **REPRO Department:** Guilhem De Seze, Andrea Terron
  - **RESU Department:** Dirk Detken (by teleconference, agenda item 7.3c)
  - **SCER Unit**: Tobin Robinson, Bernard Bottex, Jean-Lou Dorne, Nikolaos Georgiadis, Tilemachos Goumperis, George Kass, Daniela Maurici.

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Helle Katrine Knutsen (substituted by Christiane Vleminckx), Hanspeter Naegeli (substituted by Josep Casacuberta), Guido Rychen (substituted by Maria Saarela) and Diane Benford.

[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.

## 2. Brief introduction of Scientific Committee members and observers

A tour de table was organised for the participants and observers to introduce themselves.

## 3. Adoption of the agenda

The agenda was adopted without changes.

## 4. 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. For further details on the outcome of the Oral Declaration of Interests made at the beginning of the meeting, please refer to Annex I.

## 5. Presentation of the *EFSA Guidelines for Observers*

The observers were reminded about the code of conduct before, during and after the meeting.

The chair suggested opening the floor for discussion with the observers anytime during the course of the meeting.

## 6. Scientific outputs submitted for discussion and possible adoption

### 6.1 Draft Guidance Document on the Weight of Evidence approach (for preliminary discussion) (EFSA-Q-2015-00007)

The Chair of the Working Group on the Weight of Evidence approach introduced the draft guidance document. The purpose of this guidance document is to formalise the way weight of evidence assessment is conducted and documented in EFSA. This document complements other EFSA activities related to the use of evidence in risk assessment: the Prometheus Project (PROmoting METHods for Evidence Use in Scientific Assessment), the development of guidance documents on Biological Relevance and on Uncertainty in scientific assessment.

The Scientific Committee welcomed the draft and recommended mentioning the level of obligation to follow (conditional / unconditional) of the guidance document, and to ensure that the content of the document is aligned with the views of other institutions with whom EFSA may collaborate. It was clarified that such links have already been established (e.g. with the non-food Committee of the DG Santé, SCHEER).

The comments from the Scientific Committee will be conveyed to the working group for further developing the guidance document.

The guidance will be presented again to the Scientific Committee in February 2017. The objective is to launch public consultation on the guidance document on Weight of Evidence and the one on Biological Relevance at the same time.

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

An editorial will be prepared by the Secretariat and the Chair of the Scientific Committee to position the two documents also in relation to the Uncertainty guidance and the PROMETHEUS project.

Questions from the observers:

The Representative of Monsanto asked whether history of safe use would be considered in a weight of evidence approach and how it would be taken into consideration for assessing products. The Scientific Committee clarified that history of safe use is part of the data that can be collected or submitted for a risk assessment, just like other types of data. All the information available to answer the assessment question should be looked at but it is not part of this document to discuss the strengths of the different types of data.

The Representative of R.I.S.K. Consultancy underlined the importance of considering the sensitivity and specificity of the data for an assessment and asked how these aspects would be evaluated. The Scientific Committee confirmed the importance of issues such as the specificity of data or the power of a study. It was clarified that the guidance document on weight of evidence aims at providing a methodology for considering different and integrated types of evidence together. It is not the purpose of this document to provide a list of "relevant" evidence.

### 6.2 Draft Guidance Document on Biological Relevance (for discussion) (EFSA-Q-2014-00746)

The Chair of the Working Group on Biological Relevance presented the terms of reference and the content of the draft guidance document.

The Scientific Committee took note of the improvement of the draft guidance and reiterated its recommendation made in the previous sections of these minutes to draft an editorial which will be prepared by the Secretariat and the Chair of the Scientific Committee to position the two documents also in relation to the guidance on Uncertainty in scientific assessment and the PROMETHEUS document.

As for all horizontal guidances, it is not expected that all the content of the guidance document will be applicable to all panels. That is the reason why examples covering the various EFSA Panels' areas of work have been annexed to the document, to illustrate various possible implementations of the proposed framework depending on the EFSA area of activity considered.

A proposal was made to be more precise on what type of "biologically relevant" effects are meant in the various EFSA areas. In order to strengthen the document, it was suggested to ask for further documentation of the rationale why a data set was considered as non-relevant. As stressed by one of the observers, the sensitivity and power of a study, i.e. the ability of a study to detect an effect, is an issue that will be further expanded in the guidance document.

The comments from the Scientific Committee will be conveyed to the working group on Biological Relevance who will further develop the document. The guidance document will be presented again to the Scientific Committee in

February 2017. The objective is to bring the guidance document on weight of evidence and the one on biological relevance to public consultation at the same time.

Questions from the observers:

The Representative from Nestlé stressed the importance of this guidance document, not only for transparency and harmonisation considerations, but also for educational purposes, and asked whether EFSA was considering organising training workshops for younger scientists after the document is finalised. She also asked about the usefulness of these types of documents for generating relevant experimental data.

The Scientific Committee confirmed the importance and relevance of the concepts described in this guidance document when developing experimental study designs. It was clarified to the participants that, as for all horizontal guidance documents, trainings are organised for EFSA Experts and Staff. Experts from Member States who are part of the EFSA networks are also offered the possibility to attend. EFSA will explore the possibility of widening the access to the trainings, e.g. through the development of videos or other training materials.

### 6.3 Draft opinion on the Benchmark Dose (BMD) approach (for discussion and possible adoption) (EFSA-Q-2014-00747)

The Chair of the Working Group on Benchmark Dose, introduced the BMD concept. He then summarised the outcome of the public consultation and highlighted the changes made to the guidance document as a result of the comments received during the public consultation. The Scientific Committee adopted the guidance document with a couple of minor modifications to be taken into consideration by the Secretariat and the Working Group.

The guidance document and the report of the public consultation will be published on the EFSA website early in 2017. A workshop will then be organised around the beginning of 2017 to disseminate the content of the guidance to EFSA Partners (relevant European Agencies, European Commission Scientific Committees, Member States' Competent Authorities and relevant international organisations).

### 6.4 Draft opinion on scientific criteria to update and reopen an EFSA scientific assessment (for discussion) (EFSA-Q-2016-00326)

The Rapporteur of the Working Group on criteria to update and reopen an EFSA scientific assessment presented the content of the document.

The purpose of this opinion is to provide scientific criteria to consider whether or not to update an EFSA assessment. It was noted that in some areas, existing legislation is already setting the need and frequency for updating assessments.

The Scientific Committee recommended that the document further describes what is currently in place to decide for a possible update of an opinion or guidance document. Recommendation was also made to focus the document on the circumstances that would require updating an assessment from a scientific point of view and better explain this in the introductory section.

The Secretariat and the Rapporteur will amend the document according to the comments made by the Scientific Committee. The document will then be sent

again to the Scientific Committee and EFSA for a last review before it is proposed for endorsement for public consultation by written procedure.

Questions from the Observers:

The Representative from Monsanto asked who can decide to update an assessment and whether such a decision could be challenged by third parties. EFSA clarified that the updating of an assessment follows the same rules as for mandating EFSA to perform a safety assessment: only the European Commission, the European Parliament or Member States' Competent Authorities can send a mandate, or EFSA can initiate the process as a self-task. Other parties cannot initiate the process.

The EU Food Policy questioned the complexity of the considerations described in the draft opinion when, fundamentally, the availability of new significant data should trigger the immediate updating of an assessment as a self-task. EFSA clarified that this is exactly what is being done; the purpose of this opinion is to clarify what is "significant data".

The Representative from Nestlé asked about the impact of all these methodological guidance documents currently under development on on-going assessments. EFSA clarified that the application of the concepts described in the draft guidance are considered on a case-by-case basis, depending on the type of assessment.

### 6.5 Draft Guidance on Risk Assessment for infants and young children (for discussion) (EFSA-Q-2016-00489)

The Chair of the Working Group on Risk Assessment for infants and young children presented the mandate received from the European Commission and the first draft of the guidance document. The Scientific Committee noted that a chapter listing the pros and cons of the various animal models to extrapolate results in relation to scientific assessment of infants and young children is missing.

The working group will further elaborate the draft guidance document, taking into account the comments made by the Scientific Committee. The document will be submitted again to the Scientific Committee for discussion and possible endorsement for public consultation in February 2017.

Questions from the Observers:

The Representative from Nestlé asked whether the guidance document will provide a recommendation on the type of data that will be needed to assess substances for infant formulas. The Chair explained that the working group is still considering whether it is possible to extrapolate data from existing studies, e.g. developmental, sub-chronic or chronic studies, to the group of interest, eventually by applying additional uncertainty factors to compensate for the lack of data in the group of interest. The working group is also aware of animal models (e.g. neonatal pigs) but considers that it is still premature to recommend this as a standard test. The use of such animal models need to be justified based on the pharmacodynamics and –kinetics of the substance in question.

The Representative from Nestlé also underlined that a lot of work has been done by the UK authorities on soy formula and suggested better reflecting this work in the guidance document. EFSA reassured her that the working group will access these data and consider them for the guidance.

The Representative from the International Special Dietary Food Industries asked how to deal with the absence of suitable exposure data. It was noted that some Member States have exposure data starting from 2-3 months of age but there is no real information on exposure between 0 and 3 months of age.

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

### 7.1 Feedback on the work-programme of the Scientific Committee Working Groups

a) WG on Compendium of Botanicals (ver. 3.0) (EFSA-Q-2012-00486)

The working group is busy validating the data retrieved from an extensive literature search as a result of a procurement procedure. Additional 450 plant species will be loaded, around February 2017, in the EFSA database that currently contains 900 plant species. At the end of this project (July 2018), the Compendium will provide data on naturally occurring substances of possible concern for human health and report possible adverse effect for around 2600 plant species. The Chair of the Working Group underlined the enormous work done by the contractor and the working group and its usefulness to perform the risk assessment of plant-based products.

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

This activity aims to develop a guidance document for human and ecological risk assessment of combined exposure to multiple chemicals. Considering the high interest from various parties on this topic, the terms of reference for the working group was published for public consultation from 25 October to 30 November 2016. The WG will discuss the comments received and, if deemed necessary, amend the Terms of Reference of the mandate.

c) WG on Multiple Stressors in Bees (MUST-B) (EFSA-Q-2016-00358)

The working group has completed the first phase of its work, i.e. the release of the specifications for the computer model for pesticide risk assessment in the context of multiple stressors. The next step consists of specifications for field data collection to support model evaluation. The above-mentioned data collection will be outsourced. The objective is to finalise this work early next year.

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

The working group is updating the EFSA 2011 guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. More information has become available on the definition and physico-chemical characterisation of nanomaterial, on absorption, distribution, metabolism, and excretion (ADME), and the working group should e.g. consider whether the new tiered approach for the submission of food additives can also be applied in this area.

Environmental aspects will be addressed in a second phase of this activity.

e) WG on Uncertainty in Risk Assessment (EFSA-Q-2013-00738)

Following the public consultation held in summer 2015, the draft guidance on uncertainty has been published on the EFSA website and is subject to a trial phase across the panels who were asked to develop case studies.

The working group is monitoring progress and providing support to the panels in this exercise. The trial phase will close in April 2017. A workshop will be organised mid-summer 2017 to bring key-experts from the panels together and build further on their experience.

f) Standing WG on Genotoxicity

The standing working group received two requests for advice from the CONTAM Panel. Advice is requested on the maximum sensitivity of the in vitro and in vivo genotoxicity tests to identify genotoxic components present at low levels in a complex substance, and how to develop approaches for the risk assessment of germ cell mutagens. The group will meet next week to address these questions.

### 7.2 Feedback from the Scientific Panels

a) Report back on issues of common interest for the Scientific Committee and on guidance documents under public consultation

**AHAW Panel**

The Panel endorsed sections prepared by AHAW of the joint EFSA/EMA scientific opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union and the resulting impacts on food safety. The discussion mainly focussed on the section on alternative production systems and related conclusions and recommendations. The opinion will then go for possible adoption by the EFSA BIOHAZ Panel and EMA's Committee for Medicinal Products for Veterinary Use.

The Panel received a question from the European Commission on Bluetongue disease in sheep. Two opinions will be produced to answer the question.

The Panel is working on the risk of introduction and transmission in Europe of African Swine Fever and Lumpy Skin Disease. The Panel is also preparing an opinion on the use of low atmosphere pressure for stunning poultry, and another opinion on animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals.

**ANS Panel**

The Panel adopted its first re-evaluation of a gum (Karaya gum – E 416) during its Open plenary in September.

The Panel is working on the re-evaluations of potassium and sodium nitrites and nitrates (E 249, E 250, E 251 and E 252). The Scientific Committee noted that nitrates/nitrites were also assessed as contaminants and recommended that the CONTAM Panel is kept informed on the ANS discussion.

**BIOHAZ**

The Panel adopted the update of the Qualified Presumption of Safety (QPS) list. An extensive literature search was carried out for the update of the list to be as

robust as possible. The meaning of the QPS status was also further clarified.

The opinion on the risk for the development of antimicrobial resistance due to feeding calves with milk was selected to test the SC draft guidance on uncertainty in scientific assessment. The exercise was judged as quite heavy and the experience and lessons learnt will be sent back to the SC Working Group on Uncertainty.

The Panel still has to adopt the BIOHAZ-related sections of the Joint EFSA (BIOHAZ-AHAW-FEEDAP) / EMA opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union and the resulting impacts on food safety. The deadline to adopt the opinion is December 2016. The Panel received from the European Commission a new mandate for a joint ECDC, EFSA and EMA scientific opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals.

**CEF Panel**

The Panel adopted its statement on the exposure assessment of food enzymes. A flow chart, data requirements and methodologies for exposure assessment of food enzymes are described in the document.

The Panel reached a consensus on two opinions related to enzymes (beta-amylase from barley and wheat). The Panel is now ready to proceed with the re-evaluation of the 300 dossiers of enzymes.

**CONTAM Panel**

The Panel adopted an opinion on the risks to human and animal health related to the presence of erucic acid in feed and food.

The Panel is evaluating four new substances as acceptable previous cargoes for edible fats and oils. The Panel was also asked by the European Commission about the appropriateness to set a group health-based-guidance-value for the mycotoxins T2 and HT2. An opinion on the risk for animal health of the presence of zearalenone in feed is also being prepared.

The Panel decided to use the opinion on dioxins in food and feed to test the Prometheus principles.

**FEEDAP Panel**

The Panel adopted the feed-related sections of the Joint EFSA (BIOHAZ-AHAW-FEEDAP) / EMA opinion to reduce the need for antimicrobial resistance in husbandry.

The Panel has initiated an update of all its guidance documents. Some of them will be subject to multiple endorsements because of their impact on other Panels.

**GMO Panel**

Two scientific opinions and a Statement were approved during the last GMO Plenary meeting. The later concerns the risk assessment of new sequencing data on GM maize event 59122. The Panel received a request from the European Commission to review new data showing differences in the sequence of this event with respect to the sequence initially reported. The Panel found out that

differences in sequences were due to errors in the sequencing of the original material. The Panel assessed the new information and concluded that the original risk assessment of event 59122 as a single and as a part of stacked events remains valid.
At the recent GMO Panel Open Plenary meeting, the European Commission informed on ongoing activities in the area of New Breeding Techniques for which a decision on whether or not these would lead to a GMO is pending (see: minutes of the 110th plenary meeting of the GMO Panel)
The Panel is still working on its guidelines on possible derogation of existing requirements for applications of GM food and feed at low levels submitted under Regulation (EC) No 1829/2003.

**NDA Panel**

The Panel endorsed for public consultation a draft opinion on Dietary Reference Values for vitamin K.

The Panel adopted an opinion on the energy conversion factor of D-tagatose for labelling purpose.

The Panel received a request from the European Commission for an update of the scientific opinion on the appropriate age for the introduction of complementary feeding of infants. This request has been assigned to the SWG on Infant Nutrition. The Panel is also preparing an opinion on the safety and suitability for use by infants of a follow-on formula with a protein content of at least 1.61 g/100 kcal, and on a draft scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates.

**PPR Panel**

The Panel held a public consultation on its scientific opinion investigating experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukaemia. About 100 comments were received, mostly from various industries.

The Panel is preparing an opinion addressing the state of the science on in-soil risk assessment.

The Panel is also preparing an opinion addressing the state of the science on risk assessment of pesticides for amphibians and reptiles. Existing tests can detect adverse effects in growth but no standard test exists to detect impaired reproduction or adverse effects on fertility.

b) Activities in the area of the Plant Health Panel

The Chair of the Plant Health Panel provided the participants with an overview of the recent and on-going activities of the Panel: the two-step pests risk assessments for inserting pests in the annexes of the Regulation, the new methodology for pest risk assessment, and the work on Citrus Black Spot and *Xylella*.

The Panel is also involved in media monitoring activity, particularly on the *Xylella* issue, as well a crisis preparedness exercise with the European Commission. Finally, the Panel is looking at potential threats and opportunities that could impact its work, such as climate change or temporal trends of movements of

goods.

### 7.3 Feedback from EFSA

a) General matters arising

The Scientific Committee was provided with a written report back of the 70th meeting of the EFSA Management Board, of the 61st meeting of the Advisory Forum and of the on-going international scientific cooperation activities.

The participants were also updated on the status of the renewal of the ANS and CEF Panels. The ANS and CEF Panels will be appointed only for one year as there will be a renewal of all 10 Panels and the Scientific Committee in 2018.

On 14 November 2016, EFSA obtained the ISO 14001:2004 certificate. This represents a step towards the EMAS registration (EC 1221/2009), planned for next year. EFSA has also received the final Stage 2 ISO 9001:2015 audit report that recommends that EFSA is awarded the certification. The auditors did not find any major/minor non conformities but made some suggestions on how to improve the quality management system. These suggestions for improvement will be assessed and reviewed in the surveillance audit next autumn.

b) The EFSA's Chemical hazard database: Development of open source tools for chemical risk assessment at EFSA (EFSA-Q-2015-00170)

EFSA has developed a chemical hazard database that compiles EFSA's chemical toxicity data since its creation, and more specifically chemical information, document descriptors, toxicity endpoints, critical studies demonstrating genotoxicity status and information for health-based guidance values. The database will ease the retrievability of already public information. Over 1500 scientific outputs were considered, comprising 4000 substances and over 10000 toxicological endpoint inserted in the database. The database is planned to be released in the beginning of 2017.

Toxicokinetics (TK) and dynamic energy budget (DEB) tools are also being developed. Their application will be illustrated in different contexts (e.g. data poor /data rich situations, mixtures of substances). Ten case studies with mixtures relevant to food/feed safety will be produced in 2017.

Questions from the Observers:

The EU Food Policy asked whether the database provides all the data and endpoints related to the assessment of a given substance or just only some of it. It was clarified that the database provides primarily the critical data on which the assessment is based but it also offers the possibility to access the data used in a given opinion.

The Representative from Nestlé asked which information is provided when no heath-based guidance value could be established for a given substance because of insufficient data. EFSA explained that in such a case, intermediate parameters such as the TTC or the NOAELs/BMDLs will be provided.

c) State of play of independence policy

The Head of the Legal and Regulatory Affairs Unit updated the Scientific Committee on the on-going review of the EFSA Independence Policy to be implemented in September 2017.

A working group of the EFSA Management Board was created to review the policy. The resulting draft policy will go for public consultation in March 2017. Before this consultation, EFSA experts will be consulted by means of an online survey to be launched before early December 2016 and that will close mid-January 2017. A number of Panel Chairs confirmed the interest of their Panels to contribute to this survey. The Scientific Committee agreed with the proposal of an online survey going to all EFSA Experts and asked for the outcome of the survey to be discussed at the next Plenary meeting of the Scientific Committee in February 2017.

## 8. Answers to questions from Observers (in application of the *EFSA Guidelines for Observers*)

The following questions, that were submitted prior to the Plenary meeting but that could not be addressed during the specific agenda points, were answered at the end of the meeting

– The Representative from Firmenich S.A. asked whether EFSA would accept QSAR or in silico data as supporting evidence, in the context of using alternative methods to animal testing.

It was explained that EFSA has been exploring alternative methodologies, such as in vitro, in silico, read across, to support its assessments for a number of years. The Scientific Committee confirmed the usefulness of these tools, particularly in case of absence of in vivo data but the Committee also underlined that a number of gaps were identified that limit the applicability of these approaches for regulatory risk assessment. Recommendations were made for further improvement before a regulatory risk assessment can be based on these methods. A lot of activities are ongoing and are being monitored by EFSA.

- The Representative from Firmenich S.A. reported that there is an increasing body of literature showing thresholds for genotoxicity and asked whether EFSA would reconsider its position that genotoxicity is a non-thresholded effect.

The participants were reminded that in 2005, the Scientific Committee published an opinion on a harmonised approach for the risk assessment of substances that are both genotoxic and carcinogenic. In this opinion, EFSA indicated that genotoxicity should be considered as a non-thresholded effect and recommended the use of the margin of exposure approach to characterise the level of concern of a substance that is genotoxic. When answering the question, the Scientific Committee also underlined the complexity of the concept of threshold, as it implies that it is able to demonstrate the absence of an effect, which is not possible scientifically. Rather than the idea of a threshold, the issue of genotoxicity is more about the number of mutations compared to the ones occurring in the background.

- The Representative from Monsanto pointed out that the GMO Panel considers that the methodologies to assess protein allergenicity are insufficient. She asked whether other Panels were experiencing the same difficulty and whether this topic had been listed in the list of priority topics for further research activities under Horizon 2020. EFSA acknowledged that this is an issue for the GMO Panel activity and explained that there is an EU COST action project currently ongoing that is being monitored.

- The Representative from Monsanto then asked how the Scientific Committee was monitoring the development of guidance documents with a possible horizontal application by specific Panels. The Chair explained that it is done by inviting the Panel chairs to report back on any of their activities, that could be of relevance for the other Panels, during each plenary meeting. If an activity is confirmed to be of relevance for more than one Panel, mechanisms are in place to ensure that interested Panels can contribute to the development of the guidance.

The Chair of the Scientific Committee ended this session of the meeting by asking the Observers for some feedback on what they thought of this open Plenary and whether they would have some suggestions for improvement.

There was a general feeling of appreciation on how the Scientific Committee and the Panels are working together, and also a better understanding on how an opinion is built. The opportunities for interaction at the end of each agenda point were also appreciated.

The Chair thanked the participants and the observers for the meeting and the fruitful discussion.

## 9. Any other business

### 9.1 Possible upcoming workshop on environmental protection goals

In 2016, the Scientific Committee adopted its guidance to develop specific protection goal options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. In this document a method was provided for risk assessors to specify options, but it was underlined that the choice of specific protection goals is a Risk Managers' decision. Ideally, a dialogue between Risk Assessors and Risk Managers should take place to discuss scientific considerations and environmental consequences of each option. For this reason, EFSA and DG Santé are planning an event to map the needs from risk assessors and risk managers in the diverse scientific areas. The Scientific Committee will be updated when more detailed information is available.

### 9.2 Feedback on OECD-EFSA workshop on "Developmental neurotoxicity (DNT): the use of non-animal test methods for regulatory purposes", 18-19 October 2016

The Scientific Committee was presented with the outcome of the OECD-EFSA Workshop on developmental neurotoxicity (DNT). The current DNT guidelines are entirely based on in-vivo animal experiments. There is a quite important data gap on the DNT potential of chemicals, the in vivo testing is time consuming and costly, and the relevance of these studies for predicting human health effects have often been challenged. The participants of the workshop discussed a proposal for using an in vitro testing battery able to assess the impact of chemicals on cellular processes critical to normal brain development. Such a proposed battery could be used immediately for the screening and prioritisation of chemicals but additional work is needed for use of these in vivo methods for regulatory purposes in chemical specific risk assessments. The task now is to establish performance standards and a testing strategy guidance for the whole

DNT testing battery. Therefore, funding is urgently needed. Collaboration has been set up between EFSA, ECHA, OECD and US EPA to come to a final consensus on the testing battery procedures and the compound lists to be tested.

The Scientific Committee agreed to consider DNT is a cross-cutting issue for EFSA, and as such goes beyond the area of pesticides. The Scientific Committee asked that this topic be put back on its agenda after the report of the workshop has been published.

### 9.3 Priority Topics for Horizon 2020

The Scientific Committee was provided with an overview of the topics collected and submitted by EFSA for the final round of the programme (2018-2020). Additional research needs were collected from the Advisory Forum, EFSA Panels and Units. Proposals were screened against the criteria of the programme, innovation criteria and EFSA's strategy. 12 potential areas were selected that will be submitted to DG Research at end November 2016. The call for research proposals will be launched by DG Research in summer 2017.

### 9.4 Survey of employers of EFSA Panel Members

The Scientific Committee was updated on the survey prepared for employers of EFSA Panel members. Five institutions that are also members of the EFSA Advisory Forum volunteered to participate in a pilot and feedback from those institutions will help to finalise the survey template. The survey will be launched early December 2016 and will concern 50 institutions. Panels Chairs were invited to motivate their Panel members to contribute to the survey. The Scientific Committee will be kept informed on the outcome of the survey.

### 9.5 The new "EFSA Methods" social media account

The Scientific Committee was informed about the launch of a twitter account on risk assessment methodologies. A Linked-in group will also be created for EFSA experts and peers to interact. The objectives are to encourage knowledge sharing, build a network and give more visibility to EFSA Scientists and their work. The members of the Scientific Committee were invited to join these new ways of interacting and to advertise them.

**End of the meeting**

ANNEX I

## List of observers

| Last Name | First Name | Title | Company | Country |
|---|---|---|---|---|
| Bertho | Lieselot | Ms | Monsanto Europe S.A./N.V. | United Kingdom |
| Bucci | Giulio | Mr | FEFANA | Belgium |
| Constable | Anne | Dr | Nestlé Research Centre | Belgium |
| Coppens | Patrick | Mr | Food Supplements Europe | Switzerland |
| Etter | Sylvain | Dr | Firmenich S.A. | Belgium |
| Fernández | Rebeca | Dr | FoodDrinkEurope | Spain |
| Fernandez | Sandra | Mrs | European Federation of Associations of Health Product Manufacturers | Austria |
| Geiser | Stefanie | Ms | EAS Strategies | Belgium |
| Gentiluomo | Ignacio | Mr | SAFE Food Advocacy Europe | Belgium |
| Hartwig | Markus | Mr | Red Bull GmbH | Belgium |
| Korhonen | Jari | Mr | Specialised Nutrition Europe | Switzerland |
| Kostolaniova | Petra | Ms | EuropaBio | Belgium |
| Lazidu | Sasha | Ms | Danone/Specialised Nutrition Europe | Belgium |
| Leiponen-Syyrakki | Hanna | Mrs | Fur Europe | Kosovo |
| Mellema | Monique | Ms | Mead Johnson Nutrition/ Specialised Nutrition Europe | Belgium |
| Meunier | Leo | Mr | International Special Dietary Foods Industries | Belgium |
| Perrudin | Maud | Ms | AESGP - Association of the European Self-Medication Industry | Belgium |
| Podevin | Nancy | Dr | Pioneer | Belgium |
| Trollope | Kate | Ms | EU Food Policy | Belgium |
| Tweedale | Anthony | Mr | R.I.S.K. Consultancy | Belgium |