Scientific Committee

Minutes of the 76th Plenary meeting

Held on 11-12 November 2015, Brussels

(Agreed on 22 January 2016)

Participants

- Scientific Committee Members:

  Tony Hardy (Chair), Diane Benford, Theo Brock, Josep Casacuberta, Thorhallur Halldorsson, Mike Jeger[1], Helle Knutsen, Simon More, Alicja Mortensen, Hubert Noteborn, Antonia Ricci, Guido Rychen, Josef Schlatter, Vittorio Silano, Roland Solecki.

- Hearing experts :

  Robert Luttik (for agenda item 7.1 only)

- European Commission:

  Takis Daskaleros and Marina Marini[2]

- EFSA:
  - **COMMS Department**: Simon Terry[1]
  - **RASA Department:** Hans Verhagen
  - **REPRO Department:** Juliane Kleiner
  - **SCER Unit**: Tobin Robinson, Bernard Bottex, Jean-Lou Dorne, Lesley Koschel[3], Angelo Maggiore, Daniela Maurici, Agnes Rortais, Reinhilde Schoonjans.

Observers (in application of the guidance for observers): see Annex I.

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 the Vice-Chair, Josep Casacuberta; Colin Ockleford (chair of the PPR panel) who was replaced by the Vice-Chair Theo Brock; and Dominique Turck, chair of the NDA panel.

[1] Present on Day 1 only
[2] Present on the morning session of Day 2 only
[3] Present on Day 2 only

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

The Chair welcomed the observers and invited the members of the Scientific Committee and EFSA Staff to briefly introduce themselves. The Observers were then also invited to present 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[4] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[5], 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 Interest related to the issues discussed in this meeting were identified during the screening process.

5. Presentation of the EFSA Guidelines for Observers

Tobin Robinson, Head of the Scientific Committee and Emerging Risks Unit, presented the code of conduct to be followed by the Observers before, during and after the open Plenary meeting. He underlined that these rules should not however prevent the Observers from raising any questions they may have for the Scientific Committee.

6. Agreement of the minutes of the 75th Plenary meeting held on 15 September 2015

The minutes were agreed by written procedure.

7. Scientific outputs submitted for discussion and possible adoption

7.1 Draft opinions on environmental risk assessment

Robert Luttik, Chair (until July 2015) of the working group on overarching elements for environmental risk assessment (ERA), introduced the full mandate given in 2013 to the Scientific Committee to develop guidance and opinions on the following three topics in ERA. He explained the underlying need for harmonisation that was identified by the previous SC and described the working process and timelines of the working group, including consultations with the EFSA panels, consultations with the observing international organisations and the online public consultations.

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

a) Endangered species as non-target organisms in single-stressor environmental risk assessments at EFSA (EFSA-Q-2013-00901)

Robert Luttik presented the draft opinion on coverage of endangered species in environmental risk assessments at EFSA.

The Scientific Committee reviewed the draft opinion section by section, made a number of terminology suggestions, and requested some modifications to clarify certain parts of the opinion. The Scientific Committee congratulated the working group who prepared the opinion for this state-of-the-art paper that brings all the currently existing knowledge in a single place and will serve as a good basis for future guidance.

The Scientific Committee adopted the opinion, subject to the editorials and incorporation of the suggested clarifications/modifications. The Scientific Committee also took note of the EFSA technical report of the public consultation that summarises the comments received from interested parties and how they have been considered for the finalisation of this opinion. Both documents will be published early 2016.

b) Temporal and spatial recovery of non-target organisms for environmental risk assessments (EFSA-Q-2013-00902)

Theo Brock, Chair (from July 2015) of the Environmental Risk Assessment Overarching Group and chair for the subgroup on recovery, presented the draft opinion on recovery in environmental risk assessments at EFSA.

The Scientific Committee reviewed the draft opinion section by section and made a number of editorial suggestions and requests for clarifications.

The Scientific Committee adopted the opinion, subject to the incorporation of the above-mentioned editorials and suggestions for clarifications/modifications. The Committee also took note of the EFSA technical report of the public consultation. Both documents will be published early 2016.

c) Biodiversity and ecosystem services to define protection goals for environmental risk assessment (EFSA-Q-2013-00289)

Robert Luttik presented the on-going work to develop guidance for defining protection goals for environmental risk assessments at EFSA, in relation to biodiversity and ecosystem services. A number of outstanding issues were identified during the public consultation process and prevented the document from being ready for adoption during this Plenary meeting:

- Inclusion of habitat and ecosystem among the options for ecological entities to be protected;
- Inclusion of stability of ecosystem properties and habitat structure among the options for the attribute to be protected;
- Inclusion of generation and rotation among the options for the temporal scale of the tolerable effect.

The working group will meet in January to address these pending issues and the draft guidance will be submitted to the Scientific Committee for possible adoption at the next Plenary meeting (16-18 February 2016).

7.2 Draft revised guidance document on the use of benchmark dose in risk assessment (EFSA-Q-2014-00747)

Josef Schlatter, Chair of the Working Group on Benchmark Dose, updated the participants on the progress of the update of the 2009 SC Guidance on the use of the benchmark dose in risk assessment. He explained that the relatively simple and rapid update requested in the mandate turned out to be a major redrafting of the 2009 guidance because of new methodological tools:

- a new criterion for measuring the goodness-of-fit of the mathematical models will be recommended
- The model averaging approach to be used by default when doing a BMD analysis will be introduced, in line with the US EPA Technical Report on Benchmark Dose.

As a consequence, the Scientific Committee was informed about the need to postpone the deadlines for the public consultation and the adoption of the updated guidance to May-June 2016 and October 2016, respectively.

The Scientific Committee identified the need for an integrated web-based software allowing for single-models and model averaging BMD analysis, and the need for a standing working group on benchmark dose (same model as the one currently existing for genotoxicity) to assist EFSA Scientific Panels and Units in case of problematic datasets. The Scientific Committee repeated the urgent need to provide guidance on the use of the BMD approach with human data.

8. New mandates (if any)

None

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

9.1 Update on the activities of the Scientific Committee Working Groups

a) WG Compendium of Botanicals (ver. 3.0)

The participants were informed about the upload of around 900 plant species from the EFSA Compendium of Botanicals reported to contain naturally occurring substances of possible concern for human health in the EFSA data warehouse. Access to the data should be given to the public, together with access to the EFSA chemical hazard database, early 2016.
The 2nd phase of the project, that consists in an extensive literature review for botanical species for which the Compendium currently lacks information, has started and will run until end of 2016. At the end of the project, around 3000

species should have been reviewed for possible substances of concern or reported adverse effects.

Vittorio Silano, Chair of the Working Group on Botanicals, underlined the need for further clarification of the previous guidance/opinions prepared by the SC. Further guidance should be provided, for example, on how to use the information on history of safe use for the assessment of botanical and botanical preparations, and on what is meant by an "appropriate" characterisation of the botanical preparation subject to the assessment.

b) WG on Weight of Evidence (WoE)

The Fourth meeting of the SC Working Group on "The Use of the Weight of Evidence Approach in Scientific Assessments" was held in Parma on 20-21 October 2015. The members of the working group reviewed weight of evidence approaches in their respective disciplines and presented their contribution to the working group. The presentations included weight of evidence approaches in human and environmental risk assessment of chemicals, computational toxicology (i.e. *in silico* tools), microbiological risk assessment and nutrition. The working group also discussed a harmonised framework to be developed for the next meeting (February 2016) and illustrated specific examples to test its applicability in different areas of EFSA 's remit.

c) WG Biological Relevance

The working group has not had a meeting since the last SC Plenary meeting. Case-studies covering the whole remit of activity of EFSA are currently being developed to identify all concepts used by the Scientific Panels and Units to decide on the (non) relevance of a dataset or information for their assessment. The working group will meet on 30 November and 1 December to review these examples and start drafting the main text of the guidance document.

d) WG on Bees

The group is working on a two-step approach: (i) the development and validation (with high quality field data) of the full model incorporating the biological core module, the various modulators (i.e, weather, landscape, beekeeping practices), and the stressors (i.e. pesticides, biological stressors, etc.) and (ii) the use of the model as a tool for pesticide risk assessment, in the context of multiple stressors.
A first technical report describing the specifications for the model will be developed by mid-2016. A second technical report describing the field data collection and sites for the model validation will be developed by end-2016.
The activity is done in collaboration with parallel research activities such as Healthy-B, DEB-Tox models for bees and Epilobee.

e) WG on Risk Assessment for Infants and Young Children

EFSA received a mandate from the European Commission for developing horizontal guidance on the requirements for the risk assessment of substances in foods for infants below 12 weeks of age. The deadline is end of December 2016. The ANS Panel will then use this guidance to re-evaluate the 33 food additives,

for which this issue emerged, by the end of 2018. The working group in charge of developing the guidance will contain specialists in nutrition of very small infants and have its first meeting on 25 November 2015; a representative from WHO-JECFA will also be invited to present information on how this population group was considered in the evaluation of a number of emulsifying agents used in infant formula, such as carrageenan.

f) WG on Uncertainty in Risk Assessment

Tony Hardy, Chair of the Working Group on Uncertainty, reported back on the outcome of the public consultation of the draft guidance document for characterising uncertainty in scientific assessments. A total of 370 comments were received from interested parties and are under review by the working group for finalising the document. The working group will respond to the various comments in the technical report of the public consultation. The aim is to get the revised opinion to the February 2016 SC Plenary meeting for endorsement for the testing phase. A trial period for the EFSA Scientific Panels and Units to choose examples and apply the guidance/toolbox will then be launched. Expertise/assistance will be provided by the working group to the panels, if needed during this testing phase.

g) Standing WG on Guidance Review

The SC was provided with an overview of the documents produced by the former working group on guidance review and the recommendations they made for further work. A preliminary draft of Terms of Reference for the continuation of the working group's activities for the period 2015-2018 was presented.
The Scientific Committee agreed to re-establish the working group on guidance review and nominated Prof. Tony Hardy as Chair. The Panel Chairs were invited to nominate Representatives of their Panels for the working group.

h) Standing WG on genotoxicity

Participants were reminded that the purpose of this group is to serve as a platform for advice on possible issues related to genotoxicity data interpretation and to provide support to the Panel who requested the working group's assistance on possible diverging interpretation of these data. The Scientific Committee agreed to re-establish this standing working group with the same Terms of Reference as before and took note that Riccardo Crebelli (from the ANS Panel) has been selected as chair of this WG. A kick off meeting was held in November to discuss questions submitted to the WG by the Nutrition Unit and by the Pesticides Unit.

9.2 Feedback from the Scientific Panels and other scientific activities

9.2a-b Report back from Scientific Panels and Programme on Panel activities 2015-2018

Panel Representatives were invited to report back on issues of common interest for the Scientific Committee, including self-tasks, guidance documents and upcoming mandates for the period 2015-2018.

AHAW
The Panel will start a two-year activity on practical means of reducing the use of antimicrobials in farms. A thorough assessment of factors influencing animal health, such as management, housing systems, husbandry, genetics and immune response will be done.

The Panel received a mandate from four European Member States on animal welfare aspects in respect of the slaughter or killing of pregnant livestock animals (cattle, pigs, sheep, goats, horses). The Chair reported that very limited information is available.

ANS
The Panel is busy with the re-evaluation of food additives. A new guidance for the evaluation of nutrient sources will be developed to replace the 2001 one developed by the former European Commission Scientific Committee on Food currently in use.

The Chair of the Panel informed the participants that the Panel has changed its way of working, creating smaller working groups but meeting more often in order to gain in efficiency.

The Panel is also looking at the issue of nanoparticles in some of the food additives. Even if they are not engineered as such, their safety should be addressed. The Panel is currently gathering information on this issue.

BIOHAZ
The Chair informed the Scientific Committee about the following self-tasks and mandates:

- The gathering of prevalence data of *Listeria monocytogenes* in various food sectors has been outsourced. This information will then be used to update the 2014 opinion.
- The Panel will initiate a self-task looking at the application and use of whole genome sequencing for risk assessment. The purpose is to provide guidance on how to use this type of information in risk assessment.
- The update of the 2010 opinion on *Campylobacter* is postponed as the European Commission is currently working on a new piece of legislation.
- The Panel is in the process of updating the QPS list of biological agents intentionally added to food or feed.

The following opinions will be discussed during the next Plenary meeting (2-3 December 2015):

- Draft opinion concerning the risks for public health related to the presence of *Bacillus cereus* and other *Bacillus spp*., including *Bacillus thuringiensis* in foodstuffs,
- Joint EFSA and 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,
- Scientific Opinion on hazard analysis approaches for certain small retail enterprises in view of the application of HACCP principles.

Finally, the Chair informed the participants about a new request for an EFSA scientific opinion on the risk for the development of Antimicrobial Resistance (AMR) due to feeding calves with milk. The Opinion will be prepared in cooperation with the FEEDAP Panel.

CEF

The Panel is currently reviewing the methodologies for its assessments. A first opinion explaining the rationale for updating the guidance document for the safety assessment of substances used in food contact materials is currently published for public consultation and should be finalised by February 2016, after which the update of the guidance will then start.

The Panel is now reviewing its 2009 guidance on the submission of a dossier on food enzymes for safety evaluation to improve the currently proposed methodology to assess exposure to enzymes. A document with the proposed approach will be discussed in Brussels with stakeholders on 24 November 2015, with the aim of finalising the methodology by February 2016.
Finally, the Panel will review the methodology for the assessment of flavourings; the existing methods had been proposed by the former Scientific Committee on Food and need to be updated to take account of the development of science in the meantime. The new guidance is expected in two-years time.

CONTAM

The Chair reported that the Panel has no capacity to initiate self-tasks before 2017. The two top priorities for self-tasking in the Panel are cadmium, looking at adverse effects at low dose, and arsenic in food: newly generated data could allow for bridging the gaps identified in the Panel's previous opinions.

The Scientific Committee suggested the Panel reconsiders the priority level of brominated and mixed halogenated dioxins and furans. The Chair clarified that this issue was ranked lower because of on-going work on dioxins that will only be finalised in 2017.

FEEDAP

The Chair informed the Scientific Committee that one expert resigned from the FEEDAP Panel for personal reasons. The replacement process should be finalised in the following weeks.
The Chair reported that 20 guidance documents have been produced by the Panel so far. Fourteen of them are planned for revision during the three coming years. The timetable for the revisions will be discussed during the next Plenary meeting in December 2015. The development of a new guidance document on the assessment of feed additives produced from GM organisms will also be discussed.

GMO

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.

NDA

In the absence of the chair of the NDA panel, a feedback on the Panel's activities was provided by Juliane Kleiner, Head of the EFSA Scientific Evaluation of Regulated Products (REPRO) Department.

The Panel plans to update stepwise its remaining guidance documents on health claims taking into account the information gathered from the grant for collection of data in relation to claimed effects, outcome variables and methods of measurement in the context of the scientific substantiation of health claims (GP/EFSA/NUTRI/2014/01).

The draft guidance on novel foods is planned for endorsement by the Panel in December 2015 or February 2016 for public consultation. The document will also be shared with the Scientific Committee.

The Panel adopted a scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. A new activity aimed at developing scientific and technical guidance on the evaluation of the safety, suitability and properties to reduce risk of developing allergy to milk proteins for formulae manufactured from protein hydrolysates will start in 2016.

PLH

On 12 November 2015 the Panel, in cooperation with DG Research and Innovation, held a workshop in Brussels to discuss knowledge gaps and research priorities for the EU on *Xylella fastidiosa*. The workshop will be followed up with a research call from DG Research and Innovation.

Disagreement expressed by some countries on the EFSA opinions on Citrus black spot have now been brought to the International Plant Protection Convention for further discussion.

The Panel will develop a new guidance document on quantitative pathway analysis of plant pest introduction with commodities. This two-year mandate was considered by the Scientific Committee of broader relevance than just for the PLH Panel. The Chair of the AHAW Panel expressed some interest on this topic.

PPR

The Vice-Chair reported that, in addition to the endorsed recommendations on possible future activities for risk assessment of PPPs (see annex to minutes of 75th Plenary meeting of the PPR Panel), the new PPR Panel identified three additional topics for guidance development:

- immunotoxicity assessment
- risk assessment for residents
- assessment of aged soil sorption studies

The Panel endorsed an EFSA scientific report on the quality and scientific relevance of dermal absorption studies submitted by industry to EFSA in view of the revision of the guidance on dermal absorption.

Within the context of preparing guidance on the establishment of residue definition to be used for dietary risk assessment, a technical hearing was organised with the EMA Committee for Medicinal Products for Veterinary Use.

The PPR Panel wished to inform the Scientific Committee that, during its next Plenary meeting in February 2016, discussions will take place regarding an on-going activity on pesticide epidemiology and, more particularly, the development of Adverse Outcome Pathways for Parkinson's disease and childhood leukemia.

The Panel has started working on a scientific opinion on the state of the science on ERA for amphibians and reptiles.

The Vice-Chair finally reported that the Panel discussed the draft SC Guidance on uncertainty characterisation in risk assessment but highlighted the difficulty to select an example to test the proposed approach, since the PPR Panel is not doing any risk assessment. The task of testing the draft SC guidance, foreseen to start in Spring 2016, was therefore transferred to the EFSA Pesticides Unit.

9.2c Finalisation of the work programme for the SC 2015-2018

The Head of the SCER Unit presented the six topics that were prioritised by the Scientific Committee during the brainstorming meeting held last 16 September 2015 in Parma, as well as the next six topics considered as of lower priority. The Scientific Committee was invited to identify the two subjects that, based on the resources available, could already be initiated in 2016, the other topics being postponed for the 2017-2018 work programme. He also indicated that the current list of topics is a living list and can therefore be amended during the course of the mandate of the Scientific Committee.

After some discussion on the various topics listed, the Scientific Committee decided to start working on how to consider inter-individual variability in risk assessment, as a direct follow up of the guidance on uncertainty characterisation in risk assessment. The second topic proposed is to review the use of the Threshold of Toxicological Concern approach in risk assessment, making use of the experience gained on applying this approach these last years, and of the synergy that has been created with FAO/WHO (see http://www.efsa.europa.eu/en/events/event/150907).

Draft Terms of Reference, as well as proposals for the most adequate format (e.g. setting up working groups, outsourcing) to start these two activities will be tabled for further discussion at the next Plenary meeting in February 2016.

Aside from these two activities, the important role of the Scientific Committee in the area of emerging risks identification was highlighted. A thorough discussion is planned during the next Plenary meeting to agree on the strategy on emerging risks identification and characterisation for the next 3 years.

9.3 Feedback from EFSA and EC

a) Highlights from the Communications and External Relations Department

The Scientific Committee was shown the communication tools that were used for the publication of the SC opinion on the risk profile related to production and consumption of insects as food and feed. This opinion and associated news story, viewed over 5000 times, generated a lot of activity on social media and were covered by various science magazines.

The Scientific Committee was then provided with an overview of the outcome of the EXPO 2015 conference "Shaping the future, together" held from 14-16 October 2015 in Milan, and of the social media coverage (news, video highlights of the event, number of visits on the dedicated micro-website). Participants were informed that all conference presentations and their video recordings are available on the micro-website. An event report is also under preparation and will be presented to the SC at the February 2016 plenary meeting.

b) Quality Assurance System (QAS) for Science

The Scientific Committee was presented with the outcome of the 2015 customer feedback exercise carried out with EFSA's main customer, i.e. the European Commission DG SANTE. A number of specific areas for improvement were identified with regard to fitness for purpose, clarity, coherence and consistency. In 2016, the Quality Assurance System for Science will need to be implemented in order to move away from a system based mainly on quality control. The system foresees a step of a formal Quality Review of the output before the adoption.
The Scientific Committee agreed to the need to move to quality assurance but questioned the EFSA proposal that the step of formal quality review could be performed by one panel member supported by the EFSA Secretariat. This is mainly due to workload considerations and the fact that a panel member, in charge of adopting an opinion, cannot be responsible for certifying its quality as well. The Scientific Committee was of the idea that fundamentally, the quality review should not be done by anybody involved in the adoption of the opinion. The Committee also recommended that the quality assurance system to be put in place should not be too rigid.
EFSA was invited to come back to a future Plenary meeting with a proposal on how concretely quality assurance would be done in the Panels.

10. Other scientific topics for information and/or discussion

The Scientific Committee was presented with the Open Science@EFSA project. The objective is to increase trust in EFSA's outputs by continuing to ensure independence, and enhancing transparency and openness. Thirtyfive measures have been identified and organised into different implementation times according to their readiness for deployment and potential impact on EFSA's organisational set-up.

11. Questions from and answers to Observers (in application of the Guidelines for Observers)

Please refer to Annex II.

12. Any other business

Due to the number of issues to be discussed at the next Plenary meeting, the Scientific Committee agreed to extend the meeting by half a day. The next Plenary meeting will therefore take place in Parma from 16 February (starting at lunch time to 18 February (lunch time) 2016.

The Chair closed the meeting by thanking the participants and the observers for their contributions.

ANNEX I

List of observers

Lastname	First name	Title	Company	Country Iso
Armasu	Andrada	Ms	Association of the European Self-Medication Industry (AESGP)	BEL
Arnaud	Ludovic	Dr	Fefana	BEL
Coppens	Patrick	Mr	Food Supplements Europe	BEL
Duncan	Jennifer	Miss	Exponent International Ltd.	GBR
Fernandez Canton	Rocio	Dr	Monsanto Europe S.A.	BEL
Garcia	Serna	Mrs	Laboratorios Ordesa	ESP
Georgieva	Violeta	Ms	EuropaBio	BEL
Hartwig	Markus	Mr	Red Bull GmbH	AUT
Iagallo	Sandra	Ms	Mead Johnson Nutrition	NLD
Odenwald	Hannah	Ms	Nestle' Health Science	CH
O'Sullivan	Aaron	Mr	Specialised Nutrition Europe	BEL
Prater	Donald	Dr	U.S. Food and Drug Administration (FDA)	BEL
Tweedale	Anthony C.	Mr	R.I.S.K. Consultancy	BEL

ANNEX II

Answers to questions from Observers

A dedicated session was organised in order to provide observers with answers to the questions submitted prior to the Plenary meeting, or that had arisen during the course of the Plenary discussion.

In preparation of the question/answer session with the Observers, the Head of the SCER Unit gave an overview of the on-going work of working groups and networks of the Scientific Committee. The Scientific Coordinators were invited to describe the mandate / Terms of Reference, current status of the projects and timeline with regard to public consultations and finalisation.

Pre-submitted Questions:

Ms. Andrada Armasu (AESGP) had asked about the timeline for the release of the new version of the Compendium of Botanicals: this question was answered as part of the report back on the Compendium activities – see section 9.1 of these minutes. She also asked about the contents and timeline for the guidance on risk assessment for infants and young children: this question was also answered as part of the report back on the Compendium activities – see section 9.1 of these minutes.

Ms. Violeta Georgieva (Europabio) asked for the views of the Scientific Committee regarding the recent inconclusive opinions published by the GMO Panel; the Scientific Committee was more specifically asked whether alternative approaches should be considered in case a piece of information is missing to avoid inconclusive opinions. The Vice-Chair of the GMO Panel clarified that the Panel is always using a weight of evidence approach for considering the evidence available for a given assessment. He also reminded the participants that the legislation sets a list of minimal data requirements that an applicant should provide to the Panel for assessing a GMO. If some of these data are missing, the Panel goes back to the applicant asking for the missing data. If the applicant refuses or is not in the position to provide the missing information, the Panel has no other choice than declaring the assessment inconclusive due to the lack of minimal data required for the assessment. It was made very clear that the weight of evidence approach is not a tool to compensate for insufficient data in this particular case.

Dr. Rocio Fernandez Canton (Monsanto) argued then that, in some cases, following the request for additional data sent by EFSA, the applicant explained why it considered that the requested additional data was not needed for EFSA's assessment but when reading the inconclusive opinion, this explanation was not reported. The Vice-Chair of the GMO Panel repeated that the minimal amount of data to be provided for the assessment is set by the legislation and underlined that it is not up to the applicant, but to EFSA to decide what data is relevant or not for the assessment of a GMO.

The Scientific Committee finally underlined the fact that inconclusive opinions are not specific to the GMO Panel. They have also been issued in other EFSA areas, such as the re-evaluation of food additives, or in the CONTAM area (evaluation of mycotoxins). In terms of follow up on an inconclusive opinion from a risk management point of view, the Representative of the European Commission explained that it all depends on the nature of the inconclusiveness. If qualitative risks have been identified but could not be quantified, a precautionary approach will be taken. If there is really no information due to lack of data, then a case-by-case approach will be taken.

Questions raised during the Plenary meeting:

Dr. Ludovic Arnaud (FEFANA) asked about the reason for delaying the publication of the FEEDAP opinion on the safety and efficacy of ethoxyquin. As explained in section 9.2, the reason was to ensure that the above mentioned-opinion and related web story were not overshadowed by the publication of the opinion on glyphosate, initially planned to be published the same day.

Mr. Aaron O'Sullivan (Specialised Nutrition Europe) asked about possible opportunities given to the industry to provide data and comments for the guidance on the risk assessment for infants and young children. Juliane Kleiner explained that, in addition to the public consultation that is systematically done for guidance documents prior to their finalisation, EFSA has several additional tools available for collecting data, such as launching an early call for data, or inviting a hearing expert to present a specific point during a working group meeting.

Ms. Sandra Lagallo (Mead Johnson Nutrition) asked for further information on the process for deciding on the priorities for the Scientific Committee 2015-2018 work programme. The Chair of the Scientific Committee summarised the brainstorming workshop held on 16 September 2015.

Ms. Violeta Georgieva (Europabio) asked for further details on EFSA's objective to put online all the data used for its assessments. It was clarified that EFSA aims at making "as far as possible" the data used for its assessments available online. The confidentiality issue for some of the data need indeed to be taken into account. EFSA is currently looking at the experience of its sister agencies such as ECHA, EMA or ECDC.

Dr. Rocio Fernandez Canton (Monsanto) asked about EFSA's view regarding electronic submission of applications. EFSA confirmed that its preference definitely goes to electronic format. Whether it is actually possible needs to be checked.

The representative of the European Commission reported the positive feedback from his colleagues from DG SANTE regarding EFSA's open Plenary meetings, explaining that these opportunities for increasing the dialogues with interested parties are much appreciated.