



## SCIENTIFIC COMMITTEE/AMU

### MINUTES OF THE 6<sup>th</sup> MEETING OF THE SC WORKING GROUP ON PROTOCOL DEVELOPMENT

**Held on 14th November, Teleconference**

**(Agreed on 26/11/2019)<sup>1</sup>**

#### Participants

■ Working Group Members:

External experts: Thorhallur Ingi Halldorsson (Chair) and Hanspeter Naegeli

EFSA staff (some attending only part of the meeting): Laura Martino, Elisa Aiassa, Francesca Baldinelli, Federica Lodi, Caroline Merten, Winy Messens, Valentina Rizzi, Jose Tarazona, Ariane Titz.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. Konstantinos Panagiotis Koutsoumanis and EFSA staff members Katleen Baert, Davide Arcella, Alfonso Lostia, Paola Manini, Claudia Paoletti, Sybren Vos could not participate.

#### 2. Adoption of agenda

The agenda was adopted without changes

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

<sup>1</sup> Minutes should be published within 15 working days of the final day of the relevant meeting.

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf)

<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **4. Revision of the technical report on a 'draft framework for protocol development for EFSA's non-application scientific assessments' before submission to the SC Panel for possible endorsement**

#### **5. Revision of the technical report on a 'draft framework for protocol development for EFSA's non-application scientific assessments' before submission to the SC Panel for possible endorsement (continue)**

AMU presented a summary of the structure of the revised document. The main revisions done to the document were highlighted

- Document shortened and clarity improved using a less technical language;
- Concept of 'extent of planning' replaced that of 'extent of comprehensiveness'. Clarification about difference between extent of planning and complexity of the methods;
- Table 1: as agreed in the previous meeting the extent of planning was reduced to two levels, one representing the "high extent of planning" and the other setting the minimum requirements for the content of a protocol (low extent). In between there is a huge range of possibilities that is not worth nor possible to detail in the recommendations. A revision of the Table was done in light of the concept of extent of planning (previously it was a mix between extent of planning and complexity/comprehensiveness of the methods). It is clarified that table1 covers steps from problem formulation to evidence synthesis for each individual sub-question. The step of evidence synthesis has been better detailed and options provided for the 'low' and 'high' extent of planning.
- Annexes were not revised.

During the meeting the WG further revised the document and discussed some key aspects:  
Table1: rationale of keeping recommendations for 'low' extent of planning and standard text for them (different levels of planning are acceptable depending on the characteristics of the mandate); revision of the recommendations provided for the 'high extent of planning'.

Pending issues to be addressed by AMU and shared with the WG members by 20<sup>th</sup> November evening:

- Definition of the types of assessment to which the recommendations are expected to be applied (currently defined as 'non applications' assessments);
- recommendations for evidence synthesis within sub-questions: re-shuffling the section that currently covers both synthesis within sub-questions and integration across sub-questions.
- add table to cover 'evidence integration across sub-questions' in a format similar to the one used for Table1 including options for 'low' and 'high' extent of planning.
- Annex revision

## **6. AOB - Next steps**

AMU will further revise the document based on the line taken during the meeting and circulate a new version by 20<sup>th</sup> November. The document will be submitted to Scientific Committee (SC) secretariat 21<sup>st</sup> November. It will be discussed at the SC Panel meeting at 4<sup>th</sup> December.

Depending on the types of comments received it might be decided to organise another short teleconference before the final publication. If only editorial and minor comments will be received, a new version of the draft framework, revised in light of the comments received by the SC, will be



circulated by AMU and published in the EFSA website and knowledge Junction after receiving approval of the WG members.

#### Document history

Document reference	Version 2.0
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Prepared by: Laura Martino	
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Reviewed by the WG members	
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Last date modified 26/11/2019	
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## SCIENTIFIC COMMITTEE/AMU

### MINUTES OF THE 5<sup>th</sup> MEETING OF THE SC WORKING GROUP ON PROTOCOL DEVELOPMENT

**Held on 15 October, Teleconference**

**(Agreed on 21/10/2019)<sup>1</sup>**

#### Participants

■ Working Group Members:

External experts: Thorhallur Ingi Halldorsson (Chair), Konstantinos Panagiotis Koutsoumanis, Hanspeter Naegeli

EFSA staff (some attending only part of the meeting): Laura Martino, Elisa Aiassa, Francesca Baldinelli, Federica Lodi, Caroline Merten, Paola Manini, Winy Messens, Valentina Rizzi, Jose Tarazona, Ariane Titz.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. EFSA staff members Katleen Baert, Davide Arcella, Alfonso Lostia, Claudia Paoletti, Sybren Vos sent apologies for absence.

#### 2. Adoption of agenda

The agenda was adopted without changes

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### 4. Feedback from the SC Panel on the opinion on protocol development

AMU presented a summary of the comments received from the SC Panel and the EC at the meeting held on the 12<sup>th</sup> of September:

- Table 1 on the types of EFSA mandates and questions was discussed but mainly focusing on the terminology. It was felt that is very difficult to reconcile the heterogeneity that we currently have in the terminology not only in EFSA but also in the scientific community;
- As for Table 2 on the steps and recommendations for planning the methods for answering individual sub-questions, it was commented that it should indicate when the use of each of the three levels of comprehensiveness would be more appropriate;
- EC asked about the type of output we are planning to have and it was decided to further discuss the issue internally. EC expressed interest in having the opportunity to look at the document and comment

AMU also informed that an internal meeting took place after the SC plenary to decide on the way forward.

As far as the document revision is concerned it was proposed:

- To take out the chapter on terminology that raised a lot of discussion and will be probably addressed in a separated project. Try to use a more „user friendly language“ in the main body of the text and illustrate difficult terms with examples;
- To move Table 1 and related text (section 3.2) to an Annex to focus the core text on Table 2 and the following section on evidence synthesis and integration that includes recommendations on how to set the protocol depending on the selected approach.
- To finetune Table 2 in order to better reflect also levels of comprehensiveness that are not the highest

Approach with SC

- a Technical report is submitted for endorsement (not adoption) to the SC as a draft document and published on EFSA website and Knowledge Junction;
- a 1 year pilot phase is performed on mandates identified in the RASA Units;
- after the pilot phase a final document is delivered possibly embedding the part related to problem formulation (TBD).

Approach with the EC

- ask feedback on the document to the EC for comments

The WG members agreed on the strategy.

#### 5. Revision of the SC opinion on protocol development after submission to the SC Panel



The deletion of the glossary and the move of Table 1 in an annex were agreed by the WG. Other minor revisions in the main text were discussed and agreed.

Most of the discussion focused on the revision of Table 2. It was reminded that this table covers a plan for sub-questions while section 4.2.2 addresses the plan for evidence synthesis and integration within and across sub-questions.

It was clarified that recommendations should not focus on the actual methodologies and their complexity and extensiveness but rather on the extent or detail of planning upfront. It was felt reasonable reducing the degree of planning to two levels, one representing the “golden standard” and the other setting the minimum requirements. In between there is a huge range of possibilities that is not worth nor possible to detail. A revision of Table 2 was done in light of this principle.

It was agreed that a step covering formulation of the sub-question will be put in a separated row for the literature review and added also to the other approaches.

## 6. AOB - Next steps

AMU will further revise the document based on the line taken during the meeting and circulate a new version by 31<sup>st</sup> October.

Next and last meeting is currently planned for 14th November by web conference (9:00-13:00). It was agreed to organise an additional teleconference towards the end of October to discuss revisions before the final meeting in November. AMU will launch a doodle to check the availability of experts and staff.

### Document history

Document reference	Version 1.0
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Prepared by: Laura Martino
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Reviewed by the WG members
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Last date modified 21/10/2019
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## SCIENTIFIC COMMITTEE/AMU

### MINUTES OF THE 4<sup>th</sup> MEETING OF THE SC WORKING GROUP ON PROTOCOL DEVELOPMENT

**Held on 2 September, Teleconference**

**(Agreed on 09/09/2019)<sup>1</sup>**

#### Participants

■ Working Group Members:

External experts: Thorhallur Ingi Halldorsson (Chair), Konstantinos Panagiotis Koutsoumanis, Hanspeter Naegeli

EFSA staff (some attending only part of the meeting): Elisa Aiassa, Katleen Baert, Yann Devos, Federica Lodi, Caroline Merten, Jose Tarazona, Ariane Titz.

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. EFSA staff members Laura Martino, Davide Arcella, Francesca Baldinelli, Alfonso Lostia, Paola Manini, Winy Messens, Claudia Paoletti, Valentina Rizzi, Sybren Vos sent apologies for absence.

#### 2. Adoption of agenda

The agenda was adopted without changes

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## 4. Discussion on the draft framework for protocol development

The WG discussed the main concepts presented in the document and revised the text of the draft output, where needed. It was agreed to substantially simplify and reduce the text to make it as concise as possible. The discussion focussed on the following sections:

- Objectives – It was clarified that the focus is EFSA’s non-application assessments;
- Terminology – This section was entirely revised. The concept of ‘formality’ for methods was replaced by the one of ‘comprehensiveness’;
- Scientific assessment process in EFSA and the importance of the planning phase – It was agreed to remove all repetitions compared to the Terminology section and revise the process for answering sub-questions (reduced to four options);
- Feedback and input were provided on part 2 of the recommendations for protocol development – It was agreed that the recommendations on ‘how to plan evidence synthesis and integration, including uncertainty analysis, would be revised by the chair and AMU staff after the meeting.

## 5. AOB - Next steps

The revised draft will be discussed by EFSA’s Scientific Committee (SC) at their plenary meeting on 12 September 2019.

AMU staff will inform the WG on the feedback of the SC and based on that the document will be revised and recirculated in due time before the next meeting on 15 October by web conference (13.30-17:30). Further teleconferences may be organised in between, if needed.

### Document history

Document reference	Version 1.0
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Prepared by: Elisa Aiassa
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Reviewed by the WG members
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Last date modified 09/09/2019
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## SCIENTIFIC COMMITTEE/AMU

### MINUTES OF THE 3<sup>rd</sup> MEETING OF THE SC WORKING GROUP ON PROTOCOL DEVELOPMENT

**Held on 1<sup>st</sup>-2<sup>nd</sup> July, Parma**

**(Agreed on 12/7/2019)<sup>1</sup>**

#### Participants

■ Working Group Members:

External experts: Thorhallur Ingi Halldorsson (Chair), Konstantinos Panagiotis Koutsoumanis, Hanspeter Naegeli

EFSA staff (some attending only part of the meeting): Francesca Baldinelli, Federica Lodi, Alfonso Lostia, Paola Manini, Caroline Merten, Valentina Rizzi, Elisa Aiassa, Laura Martino

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. EFSA staff members Davide Arcella, Katleen Baert, Winy Messens, Claudia Paoletti, Ariane Titz, Sybren Vos sent apologies for absence.

#### 2. Adoption of agenda

The agenda was adopted without changes

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### **4. ,6., 8., 9., 10., 11. Collegial discussion on the draft framework for protocol development**

The WG agreed to discuss main concepts in the document and revise the text where needed without going to the opinion line by line. Editorials and minor comments will be sent by the members of the WG to AMU.

Revision of the document focussed on:

- Table1 – list of EFSA question types: following bilateral meetings with representatives from the various units, questions on environmental risk assessment and monitoring were better described, the question on antimicrobial resistance was merged with the one of risk assessment on humans and animals. Any pending issues were discussed by the WG members and revisions made where needed. It is still pending whether surveillance should be merged with the efficacy question or the question on the assessment of methods (to be discussed with Francesca). The difference between scenario and non-scenario based questions was considered not appropriate by the WG. It was agreed to apply the terminology used in the EFSA GD on uncertainty.
- the flow diagram on environmental risk assessment was briefly described and discussed. It was agreed to simplify the three flow diagrams and use them to better illustrate the scientific assessment process in broad classes of questions;
- it was agreed to have a glossary of the terms used in the opinion that are key to understand what described in document. The glossary will be at the beginning of the document. A provisional list of terms requiring definition was also agreed.
- the figure showing the link between problem formulation and the choice to be made in the protocol was revised by the WG. The figure also served as a basis to describe the main elements to address when developing a protocol (part 2 of the document). The WG also suggested to add an outline of the protocol at the beginning of section 2.
- A discussion took place on whether part 2 of the document should focus on possible options for the headings of the protocol (content) or options for methodological choices to be done and reflected in the protocol (process). It was pointed out that the document can not become a guidance for methods that have not yet been developed/defined at EFSA. As a general principle, when identifying methodological options, it was agreed to refer as much as possible to existing guidance (EFSA and non EFSA) such as EFSA's GD on systematic review, EKE and uncertainty. In case referent documents/methods do not exist (as for the use of existing data from databases), it was agreed to state this in the opinion and take it to the attention of the SC to find an agreement. When describing the content/process, it was agreed to rename 'mandatory' with 'recommended' and to eliminate the 'desirable' option being improbable that it is implemented. It was suggested to find a different terminology for 'tiers of formality' being this unclear and easy to be confused with the tiered approach also described in the document. For the time being, the terminology 'degrees of formality (informal, semi-formal, formal)' was agreed (until better terminology is identified).

#### **12. AOB - Next steps**

WG members discussed the opportunity to plan additional meetings (TC) in order to address further revisions of the document before submitting it to the SC Panel in September and after receiving comments in preparation of final version for adoption.



The following dates were provisionally agreed: 2 september (13.30-17:30); 15 october (13.30-17:30); 26 november (13.30-17:30).

The chair offered to revise table1 to reduce the text and make the content for the various questions more harmonised. AMU will send to him a revised version by 5 July evening.

AMU will circulate a revised version of the whole document by 12<sup>th</sup> July. WG members will revise it by 27<sup>th</sup> July using dms to avoid parallel versions.

A further version will be made available by AMU before the meeting in September.

### Document history

Document reference	Version 1.0
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Prepared by: Laura Martino and Elisa Aiassa
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Reviewed by the WG members
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Last date modified	12 <sup>th</sup> July 2019
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## SCIENTIFIC COMMITTEE/AMU

### MINUTES OF THE 2<sup>nd</sup> MEETING OF THE SC WORKING GROUP ON PROTOCOL DEVELOPMENT

**Held on 7<sup>th</sup> June, Teleconference**

**(Agreed on 19<sup>th</sup> June 2019)<sup>1</sup>**

#### Participants

■ Working Group Members:

External experts: Thorhallur Ingi Halldorsson (Chair), Konstantinos Panagiotis Koutsoumanis (physically present), Hanspeter Naegeli

EFSA staff: Katleen Baert, Francesca Baldinelli, Federica Lodi, Alfonso Lostia, Winy Messens, Ariane Titz, Elisa Aiassa, Laura Martino

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. EFSA staff members Davide Arcella, Yann Devos, Paola Manini, Caroline Merten, Claudia Paoletti, Valentina Rizzi, Sybren Vos sent apologies for absence.

#### 2. Adoption of agenda

The agenda was adopted without changes

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## 4. Collegial discussion on the revised list of EFSA questions and on the revised document on protocol development

A brief presentation was given to explain:

### 1. Revision done on the list of EFSA's questions

- Following bilateral meetings with representatives from the various units, some questions were merged, new ones were put on the list. All of them were revised to better reflect the mandates most frequently received by the various Panels/Units/teams.
- two flow diagrams were set to describe two questions: 1. risk assessment in humans and animals of chemicals, novel food, feed additives, GMO and active substances different from chemical; 2. Scenario-based assessments. The purpose of the diagrams was to illustrate how the main questions can be split in hierarchical sub-questions each of which, at the finest level, requires the choice of a specific method to be addressed in the protocol and the identification of evidence needs.

### 2. the link between problem formulation and the choice to be made in the protocol.

- ### 3. the 'catalogue' of possible approaches to address sub-questions in the protocol (and subsequently in the assessment) and the related tiers that reflect different level of formality for each approach.

All the items presented were discussed in detail and led to revision of the content of the table of questions, the flow diagrams and the link between problem formulation and protocol.

It was agreed to complete revision of the table of question notably for what pertains the question on environmental risk assessment and the monitoring/surveillance. Bilateral meetings will be organised with the concerned colleagues. The two questions will be also displayed in a flow diagram. It was also agreed to complete the draft of the catalogue of approaches and the related tiers. Some explanatory text will be introduced to clarify the approach taken, the terminology used and the applicability of the protocol in EFSA context.

## 5. Any Other Business

It was decided to provide a short presentation on the progresses made by the Working Group at the next SC Panel Meeting (25-26<sup>th</sup> June). Laura and Elisa will prepare a draft of few slides to be revised and presented by the chair.

The group was informed about delay in the start of the activities related to Problem formulation.

## 6. Next meeting

The next meeting (physical) will take place 1<sup>st</sup> July (13:30-17:30) and 2<sup>nd</sup> July (9:00-17:30).

### Document history

Document reference	Version 1.0
Prepared by: Laura Martino	
Reviewed by the WG members	
Last date modified	19 <sup>th</sup> June 2019



## SCIENTIFIC COMMITTEE/AMU

### MINUTES OF THE 1<sup>st</sup> MEETING OF THE SC WORKING GROUP ON PROTOCOL DEVELOPMENT

Held on **7<sup>th</sup>-8<sup>th</sup> May, Parma**

**(Agreed on 17<sup>th</sup> May 2019)<sup>1</sup>**

#### Participants

■ Working Group Members:

External experts: Thorhallur Ingi Halldorsson (Chair), Konstantinos Panagiotis Koutsoumanis, Hanspeter Naegeli

EFSA staff (some attending only part of the meeting): Davide Arcella, Katleen Baert, Federica Lodi, Paola Manini, Caroline Merten, Ariane Titz, Sybren Vos, Elisa Aiassa, Laura Martino

■ Hearing staff: Maria Chiara Magri

#### 1. Welcome and apologies for absence

The Chair welcomed the participants. EFSA staff members Francesca Baldinelli, Alfonso Lostia, Winy Messens, Claudia Paoletti, Valentina Rizzi sent apologies for absence.

#### 2. Adoption of agenda

The agenda was adopted without changes

#### 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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<sup>3</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



#### 4. Tour de table

Participants introduced themselves.

#### 5. Presentation of the scope of the WG and working plan followed by discussion

A presentation was given to explain motivation of the project, objectives, timelines and link with other EFSA's initiatives. Presentation was followed by Q&A.

#### 6. Presentation of the introductory concepts and draft for a framework on protocol development

A presentation was given to explain introductory concepts related to the EFSA's scientific assessment process, the problem formulation and protocol development definition and the need to modulate their level of formality and complexity in light of the type of mandate.

It was clarified that identification of the mandate types and the associated quality and scientific value concept are beyond the scope of this WG.

#### 7. Collegial discussion on the draft for a framework on protocol development

The draft document on protocol development template was presented and discussed. The main focus was:

Discussion of Table1 describing classification of types of question that EFSA receives. It was agreed to have an agnostic approach and look at the commonalities among Panels/domains in order to favour harmonisation and adoption of a common approach among different panels when similar questions are addressed. A revised table was drafted linking sub-questions to broad questions and showing the commonalities across different EFSA domains. It was agreed to have it discussed and refined before next meeting. Representative staff from each Unit will have the role of discussing the draft table in their unit and make proposals for revision in light of the comments received.

Discussion of the draft template for Protocol tailored to the various mandate types (table 2 and 3). It was agreed to take out part related to the process for PF and PD. It was agreed to introduce steps of the scientific assessment process (data collection, data validation/appraisal, data synthesis/integration). AMU staff will work and revise the template for the next meeting.

#### 8. Any Other Business

It was decided to move the date of the third meeting from to the 2<sup>nd</sup> (whole day) and 3<sup>rd</sup> (half-day) July to 1<sup>st</sup> (13.30 to 17.30) and 2<sup>nd</sup> (9-17.30) July to better fit calendars of the members from SC Panel. Placeholder invitation already modified.



## 9. Next meeting

The next meeting will take place on 7th June 2019 via teleconference.

### Document history

Document reference	Version 1.0
Prepared by: Laura Martino	
Reviewed by the WG members	
Last date modified	17 <sup>th</sup> May 2019