

## SCIENTIFIC COMMITTEE

# 14<sup>th</sup> Working Group meeting on Guidance (GD) on protocol development for EFSA generic scientific assessments

26-27 June, 5 July 2023

14:00-18:00

MINUTES - Agreed on 17 July 2023



**Location:** Webconference

### Attendees:

○ Working Group Members:

Thorhallur Ingi Halldorsson (chair)

Konstantinos Panagiotis Koutsoumanis

Hanspeter Naegeli (05/07/2023)

Andrew Kraft (05/07/2023)

Katya Tsaïoun

Susanne Hougaard Bennekou

○ Hearing Experts<sup>1</sup>:

Greg Paoli (26-27/06/2023)

○ EFSA:

MESE unit: Davide Arcella (26-27/06/2023), Elisa Aiassa, Fulvio Barizzone (26/06/2023 and 05/07/2023), Laura Martino, Špela Supej

FEEDCO unit: Luisa Ramos Bordajandi (26/06/2023)

NIF unit: Ariane Titz (26-27/06/2023), Paolo Lenzi (05/07/2023)

FIP unit: Federica Lodi

BIOHAW unit: Valentina Rizzi, Winy Messens (26-27/06/2023), Andrea Gervelmeyer (26/06/2023 and 05/07/2023)

PREV unit: Anna Lanzoni (26/06/2023 and 05/07/2023)

PLANTS unit: Giuseppe Stancanelli (05/07/2023)

## I. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Andrea Gervelmeyer (27/06/2023, EFSA, BIOHAW unit), Andrew Kraft (26-27/06/2023, WG member), Anna Lanzoni (27/06/2023, EFSA, PREV unit), Ariane Titz (05/07/2023, EFSA, NIF unit), Davide Arcella (05/07/2023, EFSA, MESE unit), Fulvio Barizzone (27/06/2023, EFSA, MESE unit), Giuseppe Stancanelli (26-27/06/2023, EFSA, PLANTS unit), Greg Paoli (05/07/2023, hearing expert), Hanspeter Naegeli (26-27/06/2023, WG member), Luisa Ramos Bordajandi (27/06/2023 and 05/07/2023, EFSA, FEEDCO unit), Maeve Cushen (EFSA, TS unit), Paolo Lenzi (26-27/06/2023, EFSA, NIF unit), and Winy Messens (05/07/2023, EFSA, BIOHAW unit).

## II. Adoption of agenda

The agenda was adopted without changes.

## III. Declarations of Interest of Working Groups members

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<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>



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.

#### **IV. Agreement of the minutes of the 13<sup>th</sup> Working Group meeting held on 17-19 January 2023, via web-conference**

The [minutes of the 13<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 25 January 2023.

#### **V. Scientific topic(s) for discussion**

##### **a. Project update**

EFSA MESE staff gave an update of the project as follows:

1. 30 January 2023: EFSA received feedback on the draft Guidance (GD) from SANTE. This triggered some revisions which were agreed in writing by the WG.
2. 5 February 2023: The GD was reviewed by two Scientific Committee (SC) members, namely the chairs of GMO and CONTAM panels.
3. 15 February 2023: The GD was endorsed for public consultation (PC) by the SC.
4. 13 March – 15 May 2023: Public consultation
  - a. Objective: to gather feedback and input from interested parties to further improve the guidance document before its adoption by the EFSA's Scientific Committee, scheduled for September 2023.
  - b. The template for developing EFSA's protocols (Annex A) was shared with the public for information only.
  - c. The total number of electronic submissions of comments on the GD was 21 (13 from two separate private citizens and 8 from German Federal Institute for Risk Assessment).
  - d. The comments received through the PC were collected and addressed in the new Annex B to the Guidance.
  - e. Additional comments were received outside the PC (via the referent WG member) from some scientific Panels, working groups and staff members. These comments were addressed directly in the guidance document.
5. 28 March 2023: EFSA held an open Info session on the draft Guidance on protocol development ([link](#)).

##### **b. Revision of the draft GD**

The focus of this WG meeting was to address the comments received within and outside the PC and agree on the necessary revisions to the draft GD. The following sections of the GD were discussed and agreed on during the WG meeting:

- Abstract:

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<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)



- Explanation added that APRIO is not mandatory (although recommended) and that its advantages are foreseen.
- A short outline of the 5 approaches for answering individual (sub-)questions added.
- Summary:
  - Summary revised to include the agreed-upon changes from all other sections.
- Section 'Scope, degree of obligation and applicability of this guidance':
  - A paragraph on 'how to perform the assessment when domain-specific guidance exists' added.
- Section 'Steps in protocol development':
  - A paragraph on 'protocols developed in phases' added to address the exceptional situations when a highly detailed protocol is needed but it is not possible to plan everything upfront.
- Section 'Translation of the mandate term(s) of reference into assessment question(s) and sub-questions':
  - The concept of 'lower/higher tier' questions and sub-questions was discussed. It was agreed to keep the concept 'tier' and refer to it with numbers only and not terms like 'lower/higher'.
  - A paragraph on 'when to stop breaking down a sub-question' was amended and clarified.
  - An arrow addressing more/less granular questions and sub-questions added to some figures.
- Section 'Using mathematical/statistical models':
  - Text in the GD was edited and clarified.
  - It was highlighted that the steps on how to answer a (sub-)question using a mathematical/statistical model can be implemented in a slightly different order depending on the situation. Two of the steps (Identification and description of the model) were merged.
- Section 'Synthesising and integrating evidence within- and across sub-questions':
  - Definitions of 'evidence synthesis' and 'evidence integration' discussed and revised.
  - Other minor editorial changes made.
- Section 'Conclusions and recommendations':
  - Section edited to address the foreseen advantages of APRIO, highlight that the use of APRIO, although not mandatory, is recommended, and explain the situations when domain-specific guidance exists.
- Section 'Recommendations for future research, 'Interactive repository of EFSA protocols':
  - The text in this section as clarified and reduced.

EFSA MESE staff informed the WG on the start of a new project to develop an interactive repository of protocols. This project will also include the consolidation of the harmonised classification of EFSA questions and sub-questions' that had been initiated in the draft framework for protocol development (2020) and that it was decided not to cover in this guidance.

### **c. Template for protocols (Annex A)**

The Template for protocols was revised by EFSA staff considering all comments received from the WG members and re-checking its consistency with the GD document. EFSA's EKE experts and information specialist were consulted for the relevant parts of the Template. Some aspects from PRISMA-P statement (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) were also integrated in the Template.

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During the meeting the WG went through the document and agreed on some minor revisions. It was emphasised that the structure of the protocol should be flexible, acknowledging the need for customising the Template on a case by case. The intention behind the Template is to encompass a wide range of scenarios, considering both high and low extents of planning. However, the users will have to tailor and selectively modify the parts of the Template depending on the situation.

#### **d. Public consultation report (Annex B)**

The WG assessed the comments on the GD received during the PC and discussed the appropriate replies to include in an additional Annex (Annex B). The template for protocols (Annex A) was shared with the public during the PC for information only. The WG still received a few comments on it. It was collectively decided that those comments would not be addressed, as they fell outside the scope of the public consultation.

#### **e. Final agreement**

The guidance and its accompanying documents (Template for protocols - Annex A, and Public consultation report - Annex B) were approved by the WG, who agreed to submit them to the Scientific Committee for possible adoption provided the necessary editorial changes.

## **VI. Other business**

The WG members acknowledged the hearing expert Greg Paoli for his invaluable contribution to the discussions.

## **VII. Next steps**

- The WG was informed that there would not be further Rapporteur activity on the guidance.
  - The guidance and the Template for protocols will be shared with SANTE for keeping them up to date.
  - On 20 and 21 September 2023 the GD will be presented at the SC plenary for possible adoption.
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## SCIENTIFIC COMMITTEE PANEL

# 13<sup>th</sup> Working Group meeting on Guidance (GD) on protocol development for EFSA generic scientific assessments



17 - 19 January 2023

14:00-18:00 / 14:00-18:00 / 14:00-18:00

MINUTES - Agreed on 25 January 2023

**Location:** VIDEO/WEB/TELE-conference

### Attendees:

○ Working Group Members:

Thorhallur Ingi Halldorsson (chair)

Konstantinos Panagiotis Koutsoumanis

Hanspeter Naegeli (19/01/2023)

Andrew Kraft

Susanne Hougaard Bennekou

○ Hearing Experts<sup>1</sup>:

Greg Paoli

○ EFSA:

MESE unit: Davide Arcella, Elisa Aiassa, Fulvio Barizzzone (18-19/01/2023), Laura Martino, Špela Supej

FEEDCO unit: Luisa Ramos Bordajandi (18-19/01/2023), Chantra Eskes (18/01/2023)

NIF unit: Ariane Titz (17-18/01/2023), Paolo Lenzi

FIP unit: Federica Lodi

BIOHAW unit: Valentina Rizzi, Winy Messens, Andrea Gervelmeyer (18-19/01/2023)

TS unit: Maeve Cushen

PREV unit: Anna Lanzoni (18-19/01/2023)

PLANTS unit: Alba Brancato (18-19/01/2023), Giuseppe Stancanelli (17-18/01/2023)

## I. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Alba Brancato (17/01/2023, EFSA, PLANTS unit), Andrea Gervelmeyer (17/01/2023, EFSA, BIOHAW unit), Anna Lanzoni (17/01/2023, EFSA, PREV unit), Ariane Titz (19/01/2023, EFSA, NIF unit), Fulvio Barizzzone (17/01/2023, EFSA, MESE unit), Giuseppe Stancanelli (19/01/2023, EFSA, PLANTS unit), Hanspeter Naegeli (17-18/01/2023, WG member), Katya Tsaion (WG member), Luisa Ramos Bordajandi (17/01/2023, EFSA, FEEDCO unit).

## II. Adoption of agenda

The agenda was adopted without changes.

## III. 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

<sup>1</sup> As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: <http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf>

<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)



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.

#### **IV. Agreement of the minutes of the 12<sup>th</sup> Working Group meeting held on 25<sup>th</sup>, 26<sup>th</sup>, and 27<sup>th</sup> October 2022, via web-conference**

The [minutes of the 12<sup>th</sup> Working Group meeting](#) were agreed by written procedure on 8<sup>th</sup> November 2022.

#### **V. Scientific topic(s) for discussion**

##### **i. Project update**

EFSA MESE staff gave an update of the project as follows:

1. On November 16<sup>th</sup>, 2022 the draft Guidance (GD) was presented for the second reading at the Scientific Committee (SC) plenary, which was very supportive and gave positive feedback on the overall project, acknowledging the progress made. The discussion at the SC focused on problem formulation and the APRIO examples. The definitions of the A-P-R-I-O elements were clarified and agreed on. The major issue identified was the across-domain 'semantic barrier', which the SC proposed to solve by attaching to each A-P-R-I-O definition further examples from each EFSA field. The SC acknowledged and emphasised the advantages of APRIO. At the SC plenary, the draft Template (Annex A to the draft GD) was outlined and its scope explained. The SC suggested to give it a more user-friendly format, and this was implemented by EFSA MESE staff.
2. Harmonised classification of EFSA assessment questions and sub-questions. The working group was informed about the decision to take out of the project the development of this classification, as it would require resources which were not originally planned.
3. Change to WG composition: Jason Montez had to withdraw from the working group as of 1<sup>st</sup> January 2023.

##### **ii. Revision of the draft GD**

Following the proposal from the SC, EFSA MESE staff prepared a new table on APRIO elements which contained examples for the different EFSA domains, next to each definition. The content of the table was discussed by the domain experts and revisions were agreed. New examples for 'Intervention' were also included, and for the cases when it was not possible to identify an example (e.g. for panels FAF and GMO) it was added 'Generally not applicable'.

Three major recommendations at the end of the GD were outlined to the WG members. It was agreed that the recommendations are ready to be shared with the SC. The WG members also agreed that a short general conclusion is needed at the end of the GD.

##### **iii. APRIO examples**

The focus of this WG meeting was the discussion on the various APRIO examples. The following examples were presented by the various WG members: Aspergillus/Aflatoxin B1, High Pressure Processing technique, Formaldehyde (hazard assessment), and Phthalates (exposure assessment).

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- For the Aspergillus/Aflatoxin B1 example a new figure depicting the conceptual model and the connections between different assessment questions in different EFSA fields was presented and discussed. The figure will be in the main text of the GD in section 5.4. The WG agreed to make slight revisions to the figure (e.g. try to add all A-P-R-I-O elements at high level and add risk assessment for livestock). MESE WG members will work on it, in view of next SC plenary. Overall the WG gave positive feedback on the figure. The APRIO table on Aspergillus/Aflatoxin B1 example in the Appendix was also re-discussed and agreed on after some slight revisions (Mode of Action SQs to be merged).
- It was agreed that the line 'Not relevant' in all the examples in the Appendix would be replaced with 'Not applicable'.
- During the discussion on the High Pressure Processing technique example the concepts of Intervention vs Efficacy in the context of APRIO were extensively re-discussed as it was realised that the difference between the two was still not fully clear. It was agreed to add a clarification of the differences between Intervention and Efficacy to the main text. Definitions of the terms were discussed in-depth and the main concepts were agreed on. EFSA MESE staff will work on revising the definitions.
- APRIO example on Formaldehyde was presented to the WG for the first time and agreed on. It was emphasised that this example shows how APRIO can work in a hazard assessment framework that is (slightly) different from EFSA's. The way some of the APRIO elements are defined is slightly different from other examples, as well as the degree of granularity of the sub-questions, showing how these can change (and still be valid) depending on the view of those formulating the problem.
- Example on Phthalates was presented and agreed on by the WG members without any additional comments.

#### **iv. Open Info session on 28 March 2023**

An open info session on the GD will be held on 28<sup>th</sup> of March 2023 (2:30-5:30 pm CET). It will be entirely web-based and hosted on the platform Microsoft Teams live events. The pre-announcement about the event was already published on the EFSA website ([link](#)). The WG members were kindly asked to advertise the event and spread the message to their contacts.

The scope of the Open Info session is to provide a clear overview of the draft guidance to those interested to provide comments via the public consultation and to address questions to enhance the understanding of the draft guidance document.

Draft agenda for the open info session was discussed. Some WG members were asked to present the APRIO examples from their field. EFSA MESE staff will follow up on the next steps to define the agenda and prepare the info session.

## **VI. Next steps and meetings**

Next steps:

- On 15<sup>th</sup> February 2023 the GD will be presented at the SC plenary for endorsement before Public Consultation. GMO and CONTAM Panels' chairs will review the draft guidance before the submission to the SC, hearing expert Greg Paoli will attend the plenary.
  - Abstract and summary are currently under development and will be shared with the WG chair before the SC plenary.
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## MEETING MINUTES - 17 - 19 January 2023

### 13<sup>th</sup> Working Group meeting on Guidance (GD) on protocol development for EFSA generic scientific assessments



- From 13<sup>th</sup> March until 15<sup>th</sup> May 2023 there will be a 9-week Public Consultation on the draft GD (the Template will be available for information only). Staff/Panel experts can use this time for providing further feedback (one individual feedback per unit/team and/or panel, collected by the referent staff in the WG).
- Open info session on the draft GD will be held on 28<sup>th</sup> March 2023, 2:30-5:30 pm CET.
- Next WG meeting will be at the end of June/beginning of July 2023. EFSA MESE staff to confirm the dates as soon as possible.
- The GD is planned to be published on by the end of 2023.

Next WG meetings (all web-based, 2-6 pm CET):

Year	Month	Date	n. of half days	Mtg n.
2023	June/July	26-27 June (2 half days) 3-6 July (4 half days) (exact dates tbc)	6	14



## SCIENTIFIC COMMITTEE

### MINUTES OF THE 12<sup>TH</sup> MEETING OF THE WORKING GROUP ON Guidance (GD) on protocol development for EFSA generic scientific assessments

**VIDEO/WEB/TELE-conference, 25<sup>th</sup>, 26<sup>th</sup>, and 27<sup>th</sup> October 2022**

**(Agreed on 8<sup>th</sup> November 2022)**

#### Participants

■ Working Group Members:

Thorhallur Ingi Halldorsson (chair)

Konstantinos Panagiotis Koutsoumanis (25/10/2022 and 27/10/2022)

Hanspeter Naegeli

Greg Paoli (hearing expert)

Katya Tsaïoun (25-26/10/2022)

Andrew Kraft

Susanne Hougaard Bennekou (25/10/2022 and 27/10/2022)

Jason Montez (25-26/10/2022)

■ EFSA:

MESE unit: Davide Arcella, Elisa Aiassa, Fulvio Barizzone (25-26/10/2022), Laura Martino, Olaf Mosbach-Schulz (27/10/2022), Eugen Christoph (27/10/2022), Špela Supej

FEEDCO unit: Luisa Ramos Bordajandi (25/10/2022)

NIF unit: Ariane Titz (25/10/2022), Paolo Lenzi (27/10/2022)

FIP unit: Federica Lodi

BIOHAW unit: Valentina Rizzi (25-26/10/2022), Winy Messens (25/10/2022 and 27/10/2022), Andrea Gervelmeyer (27/10/2022)

TS unit: Maeve Cushen (26-27/10/2022)

PREV unit: Anna Lanzoni (26/10/2022)

PLANTS unit: Giuseppe Stancanelli (27/10/2022)

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alba Brancato (EFSA, PLANTS unit), Konstantinos Panagiotis Koutsoumanis (26/10/2022, WG member), Katya Tsaion (27/10/2022, WG member), Susanne Hougaard Bennekou (26/10/2022, WG member) and Jason Montez (27/10/2022, WG member).

## 2. Adoption of agenda

The agenda was adopted after agreeing to add to item 5 (meeting day 1) a discussion on the definition of 'Intervention' and on the concepts of 'Efficacy' vs 'Intervention'.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</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.

## 4. Topics for discussion

### 4.1. Project update

EFSA MESE staff gave an update of the project as follows:

1. On September 21<sup>st</sup>, 2022 the draft Guidance (GD) was presented for first reading at the Scientific Committee (SC) plenary, which gave positive feedback on the overall project and acknowledged the progress made. At that meeting, Greg Paoli (hearing expert) presented Risk Sciences International's (RSI) report 'Problem Formulation for EFSA Scientific Assessments' and the APRIO paradigm ([link](#)). The SC acknowledged the value of this new paradigm, substantiated by the huge analysis done by RSI. The need for multiple examples from the various EFSA fields was emphasised and it was agreed to present some at the next SC plenary.
2. Status of project deliverables:
  - Guidance, Template for protocols (Annex A to GD) and six APRIO examples (Aflatoxin B1, Phthalates, GMO example, Avian Influenza, Diagnostic test for Brucellosis and High Pressure Processing Technique): advanced (pending some working group (WG) discussion). Two additional APRIO examples (Formaldehyde and Sweeteners) require some further (minor) work and are not tabled for discussion at this WG meeting.
  - Harmonised classification of EFSA assessment questions and sub-questions: further substantial work and collegial discussion within EFSA and at WG level is needed (not tabled for discussion at this WG meeting).
3. Overall project status. Overall, the project is advanced. However, the WG was informed that the planning for 2023 is being revised to include a consultation/approval process (to be defined) within EFSA scientific staff, in addition to the one at Scientific Committee level. This is to ensure the guidance be tailored to the various EFSA domains, practical and easy to implement. Therefore, the deadline for finalising the project will likely be postponed as

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<sup>1</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>2</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)

well as the public consultation and the workshop. This will also allow for further work on the harmonised classification of EFSA assessment questions and sub-questions.

#### **4.2. APRIO definitions and examples**

The definition of each A-P-R-I-O element in the draft guidance was re-discussed and amended. To increase clarity, it was agreed to add a short list of examples from the various EFSA domains, next to each definition.

As for the examples of APRIO-formulated assessment questions and sub-questions, the importance of outlining that they are hypothetical and not exhaustive was emphasised. The following examples were presented by the various WG members, slightly revised, and selected for being presented at the SC plenary (pending some further minor revisions by the relevant WG members and, for Aflatoxin B1 and GMO, consultation with panel vice-chairs and/or chair): Aflatoxin B1 (effect and exposure assessment – relevant to multiple EFSA domains), GMO example, Avian Influenza, and diagnostic test accuracy for Brucellosis. The Phthalates example (exposure assessment) was not discussed, but it was agreed that it is ready for being shared with the SC (if needed).

The concepts of Intervention vs Efficacy in the context of APRIO were extensively discussed as it was realised that the difference between the two was not fully clear. It was agreed to develop an example for microbiological hazards, to include in the GD. MESE and BIOHAZ WG members will work on it, in view of next WG mtg.

It was also clarified that the APRIO elements can be characterised differently depending on the view of those formulating the problem at hand, and this is acceptable if it does not affect the clarity of the question/sub-question and the identification of the evidence needs. However, if the APRIO elements are not consistently interpreted *across the various EFSA assessments*, in the long term this will have an impact on the comparability across EFSA mandates (assessments). Therefore, a consistent application of APRIO elements is recommended.

#### **4.3. Revision of the draft GD**

The points in the draft GD that were new/revised (mainly based on the agreements from the previous WG meeting) were taken to the attention to the WG and, where needed, re-discussed.

Overall, the WG did not identify anything controversial aspects in the draft GD.

The section on the use of expert judgement was rediscussed. The definition of the types of question that can be answered using this approach was revised. The WG agreed to clarify at the beginning of the 'approaches section' that common and best practice in all approaches (and not only when using expert judgement) implies i) a clear definition of the assessment (sub-)question, ii) the use of the appropriate expertise and iii) the documentation of the approach applied. The definition of evidence from scientific literature and study reports was revised and agreed.

#### **4.4. Revision of draft 'Template for Protocols' (Annex A)**

The structure and major revisions since the last WG mtg were outlined. Major points raised:

- 'Planning uncertainty analysis'. It was agreed to add a disclaimer to emphasise that in each step of each approach it is recommended to try and plan as much as possible the methods to address uncertainty. Ideally, specific examples would help. However, it was acknowledged that they are not easy to develop as planning uncertainty analysis as well as implementing it is uncharted. In the long term, a solution could be to create a living repository of good examples of 'how to plan uncertainty analysis', to complement the guidance and the template. This repository would be progressively and continuously populated as the number of examples grows. This idea is being discussed within EFSA.

- 'Planning the methods for integrating evidence across sub-questions'. Same as for planning uncertainty analysis, a living repository of examples would help.
- 'Planning ad hoc calls for data'. This part was clarified, and suggestions added to the Template. It was clarified that the protocol can cover only ad hoc call for data and would not work for those calls for data that are continuous or required by the legislation.

Even if the template was not discussed in detail, it was agreed that it is worth sharing it with the SC as it complements the GD and helps explain its scope and structure (see below).

## 5. Agreement on documents to submit to EFSA Scientific Committee

It was agreed to present the following documents at the next SC plenary in November (16<sup>th</sup> of November 2022):

1. Draft Guidance (outline of the changes since the last submission to the SC).
2. Draft Template (with a disclaimer outlining that the Template is draft, highlighting the parts that require further WG discussion and clarifying the purpose of this document).
3. APRIO examples (see above):
  - a. Aflatoxin B1 (or Phthalates)
  - b. GMO example
  - c. Avian Influenza and Diagnostic test for Brucellosis.

## 6. Next steps and meetings

Next steps in view of next WG mtg:

- Work on the Harmonised classification of EFSA assessment questions and sub-questions.
- Concept of Intervention vs Efficacy: development of a BIOHAZ example.
- APRIO examples: if possible, High Pressure Processing Technique, Sweeteners and Formaldehyde

The planning for 2023 is being revised and will be discussed with the WG chair. In this context, the WG meeting originally scheduled on the 22<sup>nd</sup> and 23<sup>rd</sup> of November 2022 was cancelled. The new plan will be shared with the WG as soon as possible.

Next WG meetings (all web-based, 2-6 pm CET):

Year	Month	Date	n. of half days	Mtg n.
2023	January	17, 18, 19	3	13



## SCIENTIFIC COMMITTEE

### MINUTES OF THE 11<sup>TH</sup> MEETING OF THE WORKING GROUP ON Guidance (GD) on protocol development for EFSA generic scientific assessments

**VIDEO/WEB/TELE-conference, 12<sup>th</sup>, 13<sup>th</sup>, and 14<sup>th</sup> September 2022**

**(Agreed on 20<sup>th</sup> September 2022)**

#### Participants

■ Working Group Members:

Thorhallur Ingi Halldorsson (chair)  
Konstantinos Panagiotis Koutsoumanis  
Hanspeter Naegeli (14/09/2022)  
Greg Paoli (hearing expert) (13-14/09/2022)  
Katya Tsaïoun  
Andrew Kraft  
Susanne Hougaard Bennekou (13-14/09/2022)

■ EFSA:

MESE unit: Davide Arcella (13-14/09/2022), Elisa Aiassa, Fulvio Barizzzone, Laura Martino, Olaf Mosbach-Schulz (13/09/2022), Eugen Christoph (13/09/2022)  
FEEDCO unit: Luisa Ramos Bordajandi  
NIF unit: Ariane Titz, Paolo Lenzi  
FIP unit: Federica Lodi  
BIOHAW unit: Valentina Rizzi, Winy Messens  
TS unit:  
PREV unit: Anna Lanzoni (13-14/09/2022)  
PLANTS unit: Giuseppe Stancanelli (13/09/2022)

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Hermine Reich (EFSA, PLANTS unit), José Vicente Tarazona and Marios Georgiadis (EFSA, MESE unit), Andrea Gervelmeyer (EFSA, BIOHAW unit), Maeve Cushen (EFSA, TS unit) and Jason Montez (WG member).

## 2. Adoption of agenda

The agenda was adopted after agreeing to move agenda item 6 (i.e. draft guidance, section 4 - Harmonised classification of EFSA assessment questions and sub-questions [...]) to the last day of the meeting, to allow the participation of Greg Paoli as hearing expert.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</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.

## 4. Topics for discussion

### 4.1. Project update

The EFSA MESE staff gave an update of the project as follows:

1. Project on track according to plan agreed at previous WG meetings.
2. Documents under development (follow up):
  - a. Draft guidance: revised by the Rapporteur and sent to EFSA Scientific Committee (SC) for first reading at their plenary on 21 September 2022. Pending points requiring further WG discussion flagged to SC and tabled for discussion at current WG meeting (see next section in the minutes).
    - Harmonised classification of EFSA assessment questions and sub-questions (section 4 and Appendix of GD). Tabled for being introduced and discussed for first time at current WG meeting.
  - b. 'Template for protocols' (Annex A to GD): tabled for discussion at current WG meeting. This document aims at guiding the users step by step through the process of planning an EFSA scientific assessment by providing suggestions, examples, and links to relevant documents.
  - c. Additional examples of EFSA questions and sub-questions formulated using the new APRIO paradigm (Annex B to GD) to be revised and agreed by next WG meeting.
3. Risk Sciences International report 'Problem Formulation for EFSA Scientific Assessments' published ([link](#))
4. EFSA Standard Operating Procedure SOP-007 on generic mandates updated and published on EFSA repository. All protocol-related parts aligned with current status of guidance (e.g. high/low extent of planning, when to publish a protocol, etc.)

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<sup>1</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>2</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)

## 4.2. Revision of the draft GD

The points in the draft GD that required further WG discussion and agreement were addressed as follows (summary of major agreements):

1. Section 6.4 ('Decision to scope out assessment sub-question(s)'): it was decided to remove this section and explain that *during* the definition of the sub-questions (SQs) and the conceptual model there can be SQs that are already known to be of limited relevance and thus not included in the conceptual model. It was also agreed to explain that scoping out SQs may then happen *after* problem formulation, during the assessment process, when the evidence becomes clearer.
2. Section 6.5 ('Definition of the relative priority of the assessment question(s) and sub-questions'). It was decided to keep this section including the mention of the use of sensitivity analysis for assessing the possible impact of SQs. It was decided to reference a real-case EFSA example, if published.
3. Some terminology was re-discussed and agreed (e.g. 'evidence from published and unpublished scientific literature', 'mathematical/statistical model') as well as one example of conceptual model (figure 6).
4. It was emphasised that uncertainty analysis is inherent in the scientific assessment process and not an additional step at the end.
5. It was agreed to explain that evidence integration can take place also across AQs, depending on how the mandate and the terms of reference are written by the mandate requestor.
6. Section 4 ('Harmonised classification of EFSA assessment questions and sub-questions [...]'): scope and text clarified. This classification, originally developed in EFSA 2020 draft framework for protocol development ([link](#)) and subsequently revised by EFSA's contractor Risk Sciences International ([link](#)) offers a tool for reading across EFSA domains. It was emphasised that this supports a common, across-domain approach to developing protocols within EFSA. The classification is being revised by EFSA MESE staff and will be shared with the WG by the next mtg.
7. Section 6.3, definition of 'Intervention' (APRIO elements) re-discussed. WG members invited to check the examples of A-P-R-I-O elements added to Appendix B.
8. Section 12.1, concept/term 'deviation from protocol' re-discussed and replaced by 'amendment to protocol'.

## 4.3. Introduction and revision of 'Template for Protocols'

Major points discussed and agreed are summarised as follows:

1. To clarify the scope and emphasise flexibility of the template by adding a disclaimer at the beginning.
2. It was agreed to add an optional section 'Interpretation of terms of reference' to cover the fact that the interaction with the mandate requestor often takes place also before starting problem formulation
3. Section on problem formulation: agreed to add additional example templates for conceptual models showing a pathway to arm and an interaction between assessment *questions*.
4. It was agreed to reduce the number of examples to keep the document as lean as possible.
5. Section on Expert knowledge elicitation (EKE):
  - All aspects related to *planning* an EKE will be covered in this template.

- To this end, EFSA EKE experts started to draft this section (and will remain the responsible for its continuous update).
- WG members (especially the ones with experience in EKE) to check it and ensure alignment/clarity.
- The case when 'expert judgement is collected via collegial discussion in the WG' will also be covered in the Template.

## 5. Any Other Business

It was outlined that the draft GD and all related documents shall be shared with the panels only after the endorsement by the SC and possibly before or, if not possible, during, the public consultation (see next section). However, it was agreed that it would be useful to inform the panels and units/teams about the project and its progress. To facilitate this, a standard ppt will be prepared by MESE staff for being adapted as needed and used by the WG members at their panel and unit/team meetings.

Standing point: EFSA staff to try and identify new mandates where APRIO could be tested, if possible, before the publication of the GD.

## 6. Next steps and meetings

Next steps:

- Sep 21<sup>th</sup>, 2022: first reading of draft GD by EFSA SC. The WG will be informed about the outcomes of the discussion.
- Nov 2022: first reading of 'Template for protocols', 'Harmonised classification of EFSA assessment questions and sub-questions' and 'additional APRIO examples' by EFSA SC.
- Feb 2023: possible endorsement by SC for public consultation.
- 13 March - 1 May 2023: public consultation.
- 28-29 March 2023 (place tbc): in-person workshop on the draft GD shared for public consultation.
- June 2023: possible adoption by SC.
- July 2023: publication of guidance.

Next WG meetings (all web-based, 2-6 pm CET):

Year	Month	Date	n. of half days	Mtg n.
2022	October	25, 26, 27	3	12
	November	22, 23	2	13
2023	January	17, 18, 19	3	14
	February/March	28, 1, 2	3	15
	April	4	1	16
	May	23, 24, 25	3	17



## SCIENTIFIC COMMITTEE

### MINUTES OF THE 10<sup>TH</sup> MEETING OF THE WORKING GROUP ON Guidance (GD) on protocol development for EFSA generic scientific assessments

**VIDEO/WEB/TELE-conference, 13<sup>th</sup> and 15<sup>th</sup> June 2022**

**(Agreed on 30<sup>th</sup> June 2022)**

#### Participants

■ Working Group Members:

Thorhallur Ingi Halldorsson (chair)  
Konstantinos Panagiotis Koutsoumanis (13/06/2022)  
Hanspeter Naegeli (15/06/2022)  
Greg Paoli (hearing expert)  
Katya Tsaïoun  
Andrew Kraft  
Jason Montez  
Susanne Hougaard Bennekou (13/06/2022)

■ EFSA:

MESE Unit: Davide Arcella (15/06/2022), Elisa Aiassa, Fulvio Barizzone (13/06/2022), Laura Martino, Marios Georgiadis (13/06/2022), Raquel Costa  
FEEDCO Unit: Luisa Ramos Bordajandi  
NIF Unit: Ariane Titz, Paolo Lenzi  
FIP Unit: Federica Lodi  
BIOHAW Unit: Andrea Gervelmeyer, Valentina Rizzi, Winy Messens  
TS Unit: Maeve Cushen  
PREV: Anna Lanzoni  
PLANTS: Giuseppe Stancanelli (13/06/2022)

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Hermine Reich and José Vicente Tarazona.

## 2. Adoption of agenda

The agenda was adopted without any changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</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.

## 4. Scientific topics for discussion

### 4.1. Project update

The Methodology and Scientific Support (MESE) unit gave an update of the project, which covered what happened since the last WG meeting and the revised interim milestones, previously agreed with the WG chair.

As for the first aspect, the WG was informed about the follow up given at the plenary of EFSA Scientific Committee (SC) on 27 April 2022 (where the SC supported the advance of the project) and the presentation at the EFSA cross cutting WG on Uncertainty on 10 May 2022. At this latter event, the Uncertainty WG suggested to consider, for developing the 'Template for protocols' (Annex to the GD on protocol development) the 'uncertainty analysis checklists' informally defined by the contractor providing training to different panels considering the EFSA GD on Uncertainty (which should anyhow remain the reference document). At this meeting, it was also agreed that the EFSA Uncertainty WG would be regularly updated to ensure alignment between the two GD.

As for the revised interim milestones, the main goal of the WG meeting was outlined: i.e. to try and anticipate the submission of the draft GD for first reading and discussion by EFSA SC already at their plenary in September 2022. The deadline for submitting for first reading the 'Template for protocols' (November 2022), for the public consultation on the draft GD (March - April 2023), as well as for publishing the final GD (July 2023) would not change, pending the interim endorsements and adoption by the SC. The exact date of the one-day workshop on the draft guidance (placeholder: 28 - 30 March 2023) will be confirmed after the WG meeting.

### 4.2. Revision of the draft GD

The major changes to the draft guidance (based on the WG agreements) done by MESE since the last meeting were presented.

Then, for each section of the GD, the topics that required more discussion, identified by MESE by scanning all comments provided by the WG members before the meeting, were outlined. It was

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<sup>1</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>2</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)

clarified that all comments/suggestions would then be considered and addressed in the draft GD that will be prepared and shared after the meeting.

Higher priority aspects and related agreements are summarised as follows:

- In the section 'Interpretation of the terms of reference', the 'degree of prescriptiveness' of the guidance was clarified and the text amended accordingly and agreed.
- In the section 'Methods for developing this guidance', it was decided to add some further details on the results of the pilot phase of EFSA (2020) draft framework for protocol development and not publish the related internal report as supplementary information to the final GD
- In the section 'Outline of the steps for developing protocols at EFSA', it was agreed to have a figure outlining the whole process instead of a text Box.
- In the section 'Problem formulation', subsection 'Identification of assessment questions...', the fact that in EFSA mandates the differentiation into assessment questions and sub-questions is not black or white was emphasised. A figure will be added to show the case when a term of reference (ToR) of a mandate leads to multiple assessment questions (using a BIOHAZ example), as opposite to the one when one ToR corresponds to one assessment question only. It will also be clarified that assessment questions can be interdependent or not. The definition of 'conceptual model' was revised and agreed. In addition, 'when to stop breaking down an assessment question into sub-questions' was extensively discussed and the explanation agreed and added. It was decided to include an example to help clarify this aspect.
- In the section 'Problem formulation', subsection 'Harmonised approach based on the APRIO paradigm', the WG agreed on the aspects of problem formulation (and, overall, protocol development) where APRIO helps and the ones where APRIO is less useful. It was agreed that APRIO is not necessary for formulating 'descriptive sub-questions'. To address the comments made by some WG members on the meaning of the elements of the A-P-R-I-O paradigm (in particular, the P and the R), Greg Paoli (one of the developers of the APRIO concept) presented and clarified the definitions developed in the project on problem formulation outsourced by EFSA and awarded to Risk Sciences International. The WG agreed on the explanations and decided to add some context before the APRIO definitions, to help clarify them and the fact that these terms can have different meanings, depending on the field. However, it was also outlined that some 'agility' is needed in the interpretation, trying to think across domains and not only within individual domains.
- In the section 'Problem formulation', it was agreed to merge the subsections 'Less relevant sub-questions' and 'Higher priority questions and sub-questions' naming it 'Sub-questions of different priority' (or alike).
- The scope of the subsection 'Harmonised classification of EFSA questions and sub-questions...' was clarified, i.e. to explain the across-domain similarities of EFSA questions and sub-questions and how this can help harmonise and standardise the entire process for protocol development (not only problem formulation). It was agreed to give more emphasis to this part by moving it above in the draft GD as a separate section (and not as part of problem formulation).
- In the section 'Approaches to answering sub-questions', merging the approach 'using literature' and the approach 'using data from databases other than literature' will be reconsidered. The term 'formal model' will be clarified.
- In the section 'When to consider the protocol final?', adding the case when a protocol is developed in phases (e.g., AOP development) will be considered.
- It was agreed to have a disclaimer in the beginning of the guidance saying that the guidance will be complemented by the annex.

### 4.3. APRIO examples

The WG members that developed the APRIO examples shared their experience. Some examples are in the core text of the GD, while others were drafted in standalone documents which the WG agreed to try and share (when finalised) with the SC and possibly publish as supplementary information to the final GD.

Based on the experience in the examples, it was agreed to:

- underline that the examples of APRIO-formulated questions and sub-questions are not exhaustive for the mandates used, and alternatives are possible.
- try and better explain each APRIO element in the examples, at least as far as the Output (O) is concerned. This would allow the detection of nuances and important differences between sub-questions.
- explain that APRIO is applicable regardless of the approach that will be applied for answering the sub-questions, i.e. not only for the cases when e.g. systematic review is used.

In addition, it was noted that for some mandates the application of APRIO was more straightforward than for others.

It was also outlined that testing APRIO 'retrospectively' (i.e. on already existing mandates where question and sub-question formulation had already been done) was a bit 'artefact' and it was agreed that an exhaustive example developed using a new mandate would be very beneficial. EFSA staff were invited to try and identify new mandates where APRIO could be tested exhaustively, if possible, before the publication of the GD.

## Any Other Business

### 4.4. Next steps

The WG agreed to submit the draft guidance (except the classification of EFSA questions and sub-questions, which will be included later in the process) to the Scientific Committee for first reading and discussion at their plenary on 21 – 22 September 2022. To this end, there will be one additional written exchange on a revised version of the GD (possibly finished by mid-July). The GD will not be re-discussed at the WG mtg in September, which will mostly be dedicated to the 'Template for EFSA protocols'.

### 4.5. Next meetings

The next WG meetings are reported in the table below.

Month	Mtg n.	Timing	n. half days	Agreed dates
Sept	11	14:00-18:00	3	12, 13, 14 September
October	12	14:00-18:00	2	25, 27 October
Nov/Dec	13	14:00-18:00	2	30 November 2 December



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 9<sup>TH</sup> MEETING OF THE WORKING GROUP ON GUIDANCE ON PROTOCOL DEVELOPMENT

**VIDEO/WEB/TELE-conference, 5<sup>th</sup>, 6<sup>th</sup> and 8<sup>th</sup> April 2022**

**(Agreed on 22<sup>nd</sup> April 2022)**

#### Participants

■ Working Group Members:

Thorhallur Ingi Halldorsson (chair)  
Konstantinos Panagiotis Koutsoumanis  
Hanspeter Naegeli  
Greg Paoli (hearing expert)  
Katya Tsaioun  
Andrew Kraft (5/04/2022 and 6/04/2022)  
Jason Montez (8/04/2022)

■ EFSA:

MESE Unit: Davide Arcella, Elisa Aiassa, Fulvio Barizzone (5/04/2022 and 8/04/2022), José Tarazona (5/04/2022 and 8/04/2022), Laura Martino, Marios Georgiadis, Raquel Costa  
FEEDCO Unit: Luisa Ramos Bordajandi (5/04/2022 and 8/04/2022)  
NIF Unit: Ariane Titz (5/04/2022 and 6/04/2022), Paolo Lenzi  
FIP Unit: Federica Lodi  
BIOHAW Unit: Andrea Gervelmeyer (5/04/2022 and 6/04/2022), Valentina Rizzi (5/04/2022 and 8/04/2022), Winy Messens  
TS Unit: Maeve Cushen  
PREV Unit: Anna Lanzoni

## 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Susanne Hougaard Bennekou, Hermine Reich and Giuseppe Stancanelli.

## 2. Adoption of agenda

The agenda was adopted without any changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</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.

## 4. Scientific topic(s) for discussion

### 4.1. Project update

Some experts were new to the WG. It was clarified that Greg Paoli participates to this working group as hearing expert only. Each member briefly introduced him/herself.

MESE presented an overview of the Protocol Development project from 2019 to 2021 directed at the new WG members, and the new chapter and timelines for 2021-2023. It was explained that, after endorsement by the Scientific Committee, the draft guidance will be shared for public consultation (possibly in March-April 2023) and a workshop will be held during the consultation (possibly around the end of March 2023).

### 4.2. Framework for Problem formulation

Greg Paoli presented the background and outcomes of a project on problem formulation developed by Risk Science International as EFSA contractor. This included a new paradigm for formulating questions and sub-questions (the 'APRIO' concept) and examples of questions and sub-questions expressed using it.

MESE gave further clarifications on the Problem Formulation project and informed the working group that the related final report will soon be published.

### 4.3. Revision of the draft GD

The major changes to the draft guidance based on previous agreements were presented. The draft guidance was discussed, and the necessary changes agreed.

In the section 'Introduction', the sub-section 'Background and terms of reference as provided by the requestor' was presented and the sub-sections 'Interpretation of the terms of reference' and 'Cases where new protocols are not necessary' were discussed and agreed. The working group agreed that the guidance is for EFSA generic mandates (i.e., non-application assessments) and therefore decided to use examples, especially for the figures, from this type of assessments. However, it was also decided to clarify upfront that the guidance can also be

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<sup>1</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>2</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)

useful for those application assessments for which the regulatory framework is 'less detailed' (i.e., the relevant legislation and complementary guidance do not fully detail the data requirements and the methods for data collection, validation/appraisal, analysis/synthesis).

The section 'Problem formulation' (newly added) was extensively discussed, together with specific examples. It was agreed to clarify how the new framework for problem formulation was developed.

In the section 'Approaches to answering sub-questions', the sub-section on 'Using mathematical models' (newly added) was discussed as well as the expert judgement approach mentioned in this section.

The section 'Protocols as tools to meet the requestor's needs' was briefly discussed.

Attention of the WG was brought to the 'Reporting protocols' section.

MESE shared and presented two published EFSA protocols, focusing on the problem formulation part and on the method applied for selecting which of the sub-questions would be addressed using a more rigorous approach such as e.g., formal expert knowledge elicitation, or systematic review, and which would be answered using simpler/less formal/more narrative approaches.

## 5. Any Other Business

### 5.1. Next steps

The new organization of Teams was presented and WG members were asked to fill an excel file with the title and link of protocols developed by EFSA.

WG members were also asked to test the new paradigm for questions and sub-questions' formulation ('APRIO') on an example from their domain and to share with the WG their examples, along with any related issues/benefits, by the 6/05/2022, so that the 'APRIO' framework can be finetuned, if needed. The examples of APRIO-formulated questions can also be from application assessments with a 'less detailed' regulatory framework.

A doodle will be sent to the WG members to define the dates for the workshop in March 2023.

### 5.2. Next meetings

The next meeting will be on the 13<sup>th</sup> and 15<sup>th</sup> of June 2022.

Month	Mtg n.	Timing	n. half days	Agreed dates
June	10	14:00-18:00	2	13, 15 June
Sept	11	14:00-18:00	3	12, 13, 14 September
October	12	14:00-18:00	2	25, 27 October
Nov/Dec	13	14:00-18:00	2	30 November 2 December



METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 8<sup>TH</sup> MEETING OF THE WORKING GROUP ON GUIDANCE ON PROTOCOL DEVELOPMENT

**VIDEO/WEB/TELE-conference, 31<sup>st</sup> January -2<sup>nd</sup> February 2022**

**(Agreed on 10<sup>th</sup> February 2022)**

#### Participants

■ Working Group Members:

Thorhallur Ingi Halldorsson (chair) (TH)

Konstantinos Panagiotis Koutsoumanis (KPK)

Hanspeter Naegeli (HN) (31/01/2022 and 01/02/2022)

■ EFSA:

MESE Unit: Davide Arcella (DA), Elisa Aiassa (EA), Fulvio Barizzzone (FB), José Tarazona (JT) (02/02/2022), Laura Martino (LM) (01/02/22 and 02/02/22), Raquel Costa (RC)

FEEDCO Unit: Luisa Ramos Bordajandi (LRB) (02/02/2022), Paola Manini (PM) (31/01/2022 and 02/02/2022)

NIF Unit: Ariane Titz (AT) (01/02/22 and 02/02/22), Paolo Lenzi (PL)

FIP Unit: Federica Lodi (FL) (31/01/2022 and 02/02/2022)

BIOHAW Unit: Andrea Gervelmeyer (AG), Valentina Rizzi (VR), Winy Messens (WM)

ED Office: Yann Devos (YD) (31/01/2022)

TS Unit: Maeve Cushen (MC)

GPS Unit: Ilias Papatryfon (IP) (31/01/2022), Gelda Finning (GF) (31/01/2022)

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Hermine Reich, Sybren Vos, Marios Georgiadis and O'Dea Eileen.

## 2. Adoption of agenda

The agenda was adopted without any changes.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</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.

## 4. Scientific topic(s) for discussion

### 4.1. Project update

Some members were new in the WG. Each of the members briefly introduced him/herself.

The need for additional expertise in the WG was identified for evidence-based methods applied in fields relevant for EFSA, methods for protocol development including problem formulation particularly for broad assessments and expertise from international organisations responsible for scientific assessments in fields relevant to EFSA to enhance harmonisation and identify possible synergies. Four external experts for the fields in need were identified and contacted. The DOI assessment process is ongoing, and it is foreseen that they attend the next WG meeting in March.

Timelines were presented denoting that the framework for problem formulation should be available in the end of February/beginning of March. Therefore, in the March or April meetings, it might be possible to start discussing about its incorporation in the draft guidance.

MESE informed that the charter is being revised to cover new tasks and deliverables. The next meeting dates were presented, and invitations have already been sent to the WG members.

MESE highlighted that the final output will consist of 2 documents: the guidance on protocol development describing the background and theory, and the template or table of contents for protocols representing a practical tool to help develop protocols published as an annex to the guidance.

### 4.2. Publication of Quality Policy and impact on protocol

GPS presented an overview of the Quality Policy, a document with the bases and principles about what EFSA aims to achieve with regard to quality in risk assessment and communication, where quality means meeting requestors' expectations (e.g., European Commission, MS). In Scientific advice, EFSA needs to consider four interdependent elements: fitness for purpose, timeliness, clarity/coherence/consistency, and scientific value (the latter comprises impartiality, methodological rigour, transparency, and engagement).

MESE presented a proposal of how the approach for protocol development and dissemination can help the implementation of the Quality Policy in Scientific advice. Protocol development can influence the 'scientific value' element, using already existing and allowed options for impartiality, transparency and engagement, illustrated in EFSA's Standard Operating Procedure for generic mandates (SOP\_007 - revised version is not publicly available yet and the old version can be found at this [link](#)).

### 4.3. Revision of the draft GD

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<sup>1</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>2</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)

The outline of the draft guidance was reviewed.

The draft guidance was presented and discussed, and the necessary changes agreed. Not all sections were revised as some sections were not consolidated yet. In the section 'Introduction', most sub-sections were briefly discussed. Main focus was given in revising the section 'Protocol development: the planning phase of EFSA's scientific assessments' except the 'Problem formulation' sub-section and the section 'Protocols in practice' (covering practical aspects related to protocol implementation and dissemination at EFSA).

AHAW and BIOHAZ team representatives presented examples where mathematical models were used in scientific assessments, also to reply to specific sub-questions.

The WG briefly went through the annex (protocol template). It was asked to the WG members to go through the protocol template, make comments and add examples by the 21<sup>st</sup> of February.

## 5. Any Other Business

### 5.1. Next meetings

The next meeting will be in one month, on the 3<sup>rd</sup> of March 2022.

Month	Mtg n.	Timing	n. half days	Agreed dates
Mar	9	14:00-18:00	3	3, 7, 8 March
April	10	14:00-18:00	2	5, 6 April
May	11	14:00-18:00	2	16, 17 May
June	12	14:00-18:00	2	13, 15 June
Sept	13	14:00-18:00	2	12, 13 September
October	14	14:00-18:00	2	25, 27 October
Nov/Dec	15	14:00-18:00	2	30 November 2 December



ASSESSMENT AND METHODOLOGICAL SUPPORT UNIT

## SCIENTIFIC COMMITTEE

### MINUTES OF THE 7<sup>TH</sup> MEETING OF THE WORKING GROUP ON GUIDANCE ON PROTOCOL DEVELOPMENT

**VIDEO/WEB/TELE-conference, 14-16 December 2021**

**(Agreed on 21 December 2021)**

#### Participants

■ Working Group Members:

Thorhallur Ingi Halldorsson (chair) (TH)  
Konstantinos Panagiotis Koutsoumanis (KPK)  
Hanspeter Naegeli (HN)

■ EFSA:

AMU Unit: Elisa Aiassa (EA), Fulvio Barizzzone (FB), Laura Martino (LM)  
FEED Unit: Paola Manini (PM)  
PRES Unit: Hermine Reich (HR)  
NUTRI Unit: Ariane Titz (AT)  
FIP Unit: Federica Lodi (FL)  
BIOCONTAM Unit: Marco Binaglia (MB), Valentina Rizzi (VR), Winy Messens (WM)  
ALPHA Unit: Sybren Vos (SV)  
DATA Unit: Davide Arcella (DA), José Gomez Ruiz (JR)  
SCER Unit: José Tarazona (JT), Yann Devos (YD)  
TS Unit: Eileen O’Dea (EO)  
GMO Unit: Paolo Lenzi (PL)

#### 1. Welcome and apologies for absence

The Chair welcomed the participants.

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Apologies were received from Francesca Baldinelli, Caroline Merten, Agnès De-Sesmaisons-Lecarre (first and second day), Valentina Rizzi (second day)

## 2. Adoption of agenda

The agenda item 'AOB – enlargement of the WG' was anticipated to the beginning of the second day.

## 3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</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.

## 4. Tour de table

The WG reconvened after more than 1 years. Some members were new in the WG. Each of the members briefly introduced him/herself.

## 5. Scientific topic(s) for discussion

### 5.1. Update on the project

AMU provided an update on the status of the project. After the publication of the draft framework for protocol development and the conclusion of the pilot phase, feedback was collected from the project managers testing the recommendations and summarised in a report. The summary of the feedback and the proposal for a way forward were presented to the Joint Science Meeting members, the RAMPro and the Scientific Committee. The latter agreed to reconvene the WG to transforming the document in a cross-cutting guidance and integrating the framework for problem formulation in it.

Updates were provided also on the ongoing of the contract dealing with problem formulation. Revision of the questions classification has been completed. The final report is expected by February 2022.

Tentative timelines of the WG activities were presented. It is envisaged to submit a draft GD for possible endorsement at the November 2022 SC Meeting and publish the final version of the GD by May 2023 after the launch of the public consultation in December 2022.

### 5.2. SOP\_007 and protocol

AMU presented the content of the SOP\_007 with a focus on the parts that provide instructions on decisions related to the extent of planning, publication of the protocol (before or together with the output of the assessment), responsibility for drafting the protocol, procedures to check completeness and clarity (tollgate#1), approval of the protocol.

It was emphasised that the protocol cannot be a living document and it needs to be finalised before starting the assessment. The challenges in drafting some parts of the protocol (e.g. evidence synthesis and integration including uncertainty analysis) were acknowledged and it was highlighted the need for flexibility in the extent of planning (low versus high).

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<sup>1</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>2</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)

### **5.3. 'Draft framework for protocol development': outcomes of the pilot phase**

AMU presented a summary of the feedback received after the pilot phase and a proposal for main revisions to be introduced in the document. Feedback was collected via EU survey and via spontaneous comments submitted by some colleagues and units. The weakest points were represented by lack of case examples, user-friendliness and fit-for-purpose. Clarity was considered sufficient, whereas structure, specificity and length scored above sufficiency. To address deficiencies in the document it was proposed to move the recommendations currently in tables 1-5 into a template including suggestions for the content of each section in the protocol and examples of low and high extent of planning. A list in excel was created including the link to the existing protocols. In the future when the RRR! Project will be completed, this should be replaced by a repository linking protocols with other elements of the same mandates (e.g. search string, code, data model). A series of revisions will be applied to the core text of the document to improve clarity, user-friendliness and fit-for-purpose.

### **5.4. 'RRR!: Retrievable, Reproducible, Reusable knowledge for scientific assessments'**

AMU presented the plan for the RRR! Project. The latter is aimed at making the elements of an assessment easily retrievable, reproduceable and reusable. This should represent a long-term solution to the repository of the protocols.

### **5.5. Discussion on agenda items 7 and 8**

It was emphasised the need to keep the document simple and short as much as possible. It was suggested to use text from real protocols to provide examples of the content of the protocol. It was highlighted the need to provide better recommendations on the criteria for deciding whether to adopt a low or high extent of planning. It was emphasised the need to provide instructions for the reporting of the deviations to the protocol and the overall methodology (currently spread among protocol, deviation, material and methods) to achieve clarity and transparency at the same time. AMU to make a proposal to be discussed at the next WG meeting.

### **5.6. Revision of Annex A 'PD template'**

AMU suggested to start the revision of the document from the new template that should become an annex to the guidance. Some items to be revised in the core text should become clearer doing this exercise. The WG went through the proposed revised text and amended it further. The section on problem formulation was kept aside waiting for the report from the contractor. The recommendations related to the methods for 'using the evidence from scientific literature and/or directly submitted to EFSA were discussed and revised.

The case of the call for data was extensively discussed since it represents a source of evidence that could fall under different approaches (i.e. survey with questionnaire; structured data collection; collection of papers). Each member of the WG to check if prototypical call for data in their unit/panel is properly covered.

It is suggested to evaluate whether 'methods for triangulation' could be integrated in the section on the appraisal of the internal validity of the individual studies. TH to provide reference to AMU. AMU to assess their relevance.

It is suggested that AMU checks the feasibility of collapsing sections 3.1.3.1 and 3.1.3.2

It is agreed to add in the core text of the document: 1. Clarification that protocol should include, when relevant, methods to be used to deal with new evidence made available after data collection is closed; 2. Clarification of the concept of nested protocols; 3. Definition of the data model (in the glossary)

## 6. Any Other Business

### 6.1. Enlargement of the WG

It was agreed to extend the working group by adding additional expertise in evidence-based methods applied to risk assessments across the breadth of EFSA's domain: evidence-based toxicology, protocol development for chemical risk assessment, nutrition and problem formulation. It is suggested that expertise should be sought as much as possible in international organisations with remit similar to EFSA's. This would allow enhancing harmonisation and finding synergies.

### 6.2. Next meetings

A doodle will be launched soon to identify dates for the upcoming meetings. Tentative dates are listed in the table below. It is requested to the WG members to block their calendars with placeholders.

Month	Mtg n.	Timing	Half days	Possible dates
Jan/Feb	8	14:00-18:00	3	24, 25, 27, 31 January 1, 2, 3 February
Feb/Mar	9	14:00-18:00	3	28 February 1, 2, 3, 7, 8, 10 March
April	10	14:00-18:00	2	4, 5, 6, 7, 26, 27, 28, 29
May	11	14:00-18:00	2	16, 17, 18, 19, 20
June	12	14:00-18:00	2	13, 15, 16, 17
Sept	13	14:00-18:00	2	12, 13, 14, 15
October	14	14:00-18:00	2	14, 25, 26, 27
Nov/Dec	15	14:00-18:00	2	28, 29, 30 Nov 1, 2 Dec



## 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'.

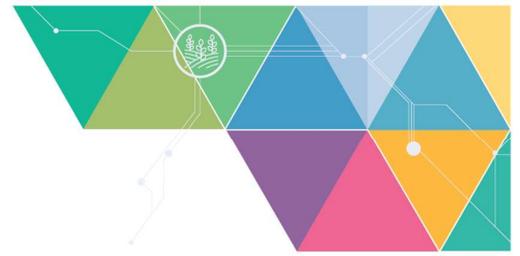
Pending issues to be addressed by AMU and shared with the WG members by 20<sup>th</sup> November evening:

- 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
Prepared by: Laura Martino	
Reviewed by the WG members	
Last date modified 26/11/2019	



## 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.

<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. 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
Prepared by:	Laura Martino
Reviewed by the WG members	
Last date modified	21/10/2019



## 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.

<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. 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
Prepared by: Elisa Aiassa	
Reviewed by the WG members	
Last date modified 09/09/2019	



## 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>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. ,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
Prepared by: Laura Martino and Elisa Aiassa	
Reviewed by the WG members	
Last date modified	12 <sup>th</sup> July 2019

## 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.

<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. 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

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