



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 9TH MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 10 June 2020, web meeting

(Agreed on 12 June 2020)

Participants

- Working Group Members:
Susanne Bennekou Hougaard, Tony Fletcher, Matthias Greiner, Thor Halldorsson, Evangelia Ntzani, Neil Pearce, Marco Vinceti
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
AMU Unit: Laura Ciccolallo, Marios Georgiadis
SCER Unit: Andrea Gervelmeyer
- Others:
Not Applicable

1. Welcome and apologies for absence

The participants were welcomed. Apologies were received from Stephen Parnell.

¹ 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>.

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, 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. Agreement of the minutes of the 8th Working Group meeting held on 03 June 2020

The minutes of the 8th Working Group meeting held on 03 June 2020 were agreed by written procedure on 05 June 2020.

5. Hearing Expert (s)

Not applicable

6. Scientific topic(s) for discussion

6.1. Revision of section 4.3

The Working Group members discussed the updated draft section on appraisal and integration of epidemiological evidence in EFSA scientific assessments. Tasks for finalizing the text were agreed.

6.2. Revision of case studies of study appraisal using a Risk of Bias tool

The Working Group members discussed the example appraisals of randomised controlled trial studies and observational studies that illustrate how to appraise individual studies using a Risk of Bias tool. Needs for further refinement of the text were agreed, and drafting tasks for the remaining case studies were distributed.

7. Any Other Business

Not Applicable

8. Next meeting(s)

No further meeting is scheduled.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 8TH MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 03 June 2020, web meeting

(Agreed on 05 June 2020)

Participants

- Working Group Members:
Tony Fletcher, Thor Halldorsson, Neil Pearce, Marco Vinceti
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
AMU Unit: Laura Ciccolallo
SCER Unit: Andrea Gervelmeyer
- Others:
Not Applicable

1. Welcome and apologies for absence

¹ 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>.

The participants were welcomed. Apologies were received from Stephen Parnell, Susanne Bennekou Hougaard and Matthias Greiner. Evangelia Ntzani and Neil Pearce joined the meeting for agenda point 6.2.

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, 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. Agreement of the minutes of the 7th Working Group meeting held on 12-14 May 2020

The minutes of the 7th Working Group meeting held on 12-14 May 2020 were agreed by written procedure on 20 May 2020.

5. Hearing Expert (s)

Not applicable

6. Scientific topic(s) for discussion

6.1. Revision of section 4.3

The Working Group members discussed the current draft of the section on appraisal and integration of epidemiological evidence in EFSA scientific assessments. Needs for further subsections and paragraphs were identified and drafting tasks were assigned and agreed.

6.2. Revision of case studies of study appraisal using a Risk of Bias tool

The Working Group members discussed the draft appraisal of a randomised controlled trial study that is the first of three case studies of the guidance document that illustrate how to appraise individual studies using a Risk of Bias tool. Needs for further refinement of the text were agreed, and drafting tasks for the remaining case studies were assigned and agreed.

7. Any Other Business

Not Applicable

8. Next meeting(s)

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The next meeting is scheduled for 10 June 2020 (web meeting).



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 7TH MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 12-14 May 2020, web meeting

(Agreed on 20 May 2020)

This meeting, originally scheduled as a physical meeting, was converted into a teleconference to avoid traveling to EFSA in line with the measures established to reduce the risk of coronavirus infection.

Participants

■ Working Group Members:

Susanne Bennekou Hougaard, Tony Fletcher, Matthias Greiner, Thor Halldorsson, Evangelia Ntzani, Neil Pearce, Marco Vinceti

■ Hearing Experts¹:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

AMU Unit: Laura Ciccolallo, Marios Georgiadis

SCER Unit: Andrea Gervelmeyer

■ Others:

Not Applicable

¹ 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>.

1. Welcome and apologies for absence

The participants were welcomed. Apologies were received from Stephen Parnell. Matthias Greiner was not able to attend the meeting on 12/05, Susanne Bennekou Hougaard was unable to attend the meeting on 14/05, Evangelia Ntzani was unable to attend the meeting in the afternoon of 14/05.

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, 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. Agreement of the minutes of the 6th Working Group meeting held on 19 March 2020

The minutes of the 6th Working Group meeting held on 19 March 2020 were agreed by written procedure on 30 March 2020.

5. Hearing Expert (s)

Not applicable

6. Scientific topic(s) for discussion

6.1. Revision of section 4.3

The Working Group members discussed the current draft of the section on appraisal and integration of epidemiological evidence in EFSA scientific assessments. Needs for further text were agreed and drafting tasks were assigned.

6.2. Revision of sections 4.1 and 4.2

The Working Group members discussed the remaining comments in sections 4.1 and 4.2 and provided suggestions for alternative or additional text and examples. A table providing an overview of the different epidemiological study designs was drafted. Needs for further refinement of the text were agreed, and drafting tasks were assigned.

7. Any Other Business

Not Applicable

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

8. Next meeting(s)

The next meeting is scheduled for 03 June 2020 (web meeting).



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 6TH MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 19 March 2020, web meeting

(Agreed on 30 March 2020)

Participants

■ Working Group Members:

Susanne Bennekou Hougaard, Tony Fletcher, Matthias Greiner, Thor Halldorsson, Evangelia Ntzani, Neil Pearce,
Marco Vinceti

■ Hearing Experts¹:

Not Applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

AMU Unit: Laura Ciccolallo, Marios Georgiadis
SCER Unit: Andrea Gervelmeyer

■ Others:

Not Applicable

¹ 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>.

1. Welcome and apologies for absence

The participants were welcomed. Apologies were received from Stephen Parnell.

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, 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. Agreement of the minutes of the 5th Working Group meeting held on 28 January 2020

The minutes of the 5th Working Group meeting held on 28 January 2020 were agreed by written procedure on 05 February 2020.

5. Hearing Expert (s)

Not applicable

6. Scientific topic(s) for discussion

6.1. Revision of section 4.3

The Working Group members discussed the current draft of the section on appraisal and integration of epidemiological evidence in EFSA scientific assessments. Further subsections were agreed, and drafting tasks were assigned. The deadline for completing the drafting tasks is 03 April 2020.

6.2. Revision of sections 4.1 and 4.2

The Working Group members agreed to address the remaining comments in sections 4.1 and 4.2 by providing suggestions for alternative or additional text and examples. The deadline for these tasks is 03 April 2020.

6.3. Revision of workplan

As of July 2020, all SCER resources scheduled for supporting the Working Group on appraisal and integration of evidence from epidemiological studies will be re-assigned to supporting other urgent tasks of EFSA. Consequently, the work on the guidance needs to be paused; a re-start date cannot be determined at this stage. To use the achievements made so far, it has been proposed to publish the document with the first three sections (4.1, 4.2, 4.3) as an intermediate output in June 2020. This would enable EFSA Panels to start applying the general concepts explained in these three chapters and gain further experience with appraising epidemiological evidence for their scientific assessments. When restarting the work on the guidance at a later stage, these experiences could inform the drafting

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

of the last section (4.4) on the use of epidemiological evidence for specific scientific assessment questions, that will address the specific issue raised by the different panels.

7. Any Other Business

Not Applicable

8. Next meeting(s)

The next meeting is scheduled for 12-14 May 2020 (web meeting).



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 5TH MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 28 January 2020, web meeting

(Agreed on 05 February 2020)

Participants

- Working Group Members:
Tony Fletcher, Matthias Greiner, Thor Halldorsson, Evangelia Ntzani, Neil Pearce,
Marco Vinceti
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
AMU Unit: Laura Ciccolallo, Marios Georgiadis
SCER Unit: Andrea Gervelmeyer
- Others:
Not Applicable

1. Welcome and apologies for absence

¹ 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>.

The participants were welcomed. Apologies were received from Susanne Bennekou Hougaard and Stephen Parnell.

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, 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. Agreement of the minutes of the 4th Working Group meeting held on 21-22 November 2019

The minutes of the 4th Working Group meeting held on 21-22 November 2019 were agreed by written procedure on 29 November 2019.

5. Hearing Expert (s)

Not applicable

6. Scientific topic(s) for discussion

6.1. New rules for expert compensation scheme

EFSA's new rules for expert compensation have been presented. The compensation has been increased and extended to cover also one day of preparatory work for each meeting day, to better reflect the time experts spend on drafting documents and preparing before the Working Group and Panel meetings.

6.2. Revision of workplan

The SCER Unit had to re-assign resources scheduled for supporting the Working Group on appraisal and integration of evidence from epidemiological studies in 2020 to other urgent tasks of EFSA. As a consequence, the deadline for the guidance has been postponed for 9 months, to September 2021. The new workplan for 2020 was presented to the WG members.

6.3. Revision of section 4.2

The Working Group members reviewed the draft section presenting key epidemiological concepts relevant for evidence appraisal and discussed how the remaining issues highlighted by the Scientific Committee at its plenary meeting on 4-5 December 2019 could be addressed. Drafting tasks were assigned.

6.4. Revision of section 4.3

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The Working Group members discussed the current draft of the section on appraisal and integration of epidemiological evidence in EFSA scientific assessments. Subsections were agreed and drafting tasks were assigned.

7. Any Other Business

Not Applicable

8. Next meeting(s)

The next meeting is scheduled for 19 March 2020 (web meeting).



SCIENTIFIC COMMITTEE AND EMERGING RISKS UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 4TH MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 21-22 November 2019, Parma

(Agreed on 29 November 2019)

Participants

- Working Group Members:
Tony Fletcher, Matthias Greiner, Thor Halldorsson (chair), Susanne Bennekou Hougaard, Stephen Parnell, Marco Vinceti
Neil Pearce has participated via teleconference
- Hearing Experts¹:
Marco Zeilmaker and Henning Thole (for item 6.3)
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
AMU Unit: Laura Ciccolallo, Marios Georgiadis
SCER Unit: Andrea Gervelmeyer
- Others:
Not Applicable

¹ 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>.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Evangelia Ntzani.

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 Independence² and the Decision of the Executive Director on Competing Interest Management³, 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. Agreement of the minutes of the 3rd Working Group meeting held on 27 September 2019, teleconference

The minutes of the 3rd Working Group meeting held on 27 September 2019 by teleconference were agreed by written procedure on 07 October 2019.

5. Hearing Expert (s)

Dr Marco Zeilmaker and Dr Henning Thole were invited to present their views for item 6.3 of the present meeting.

6. Scientific topic(s) for discussion

6.1. Finalisation of section 4.2

The Working Group members discussed the draft section presenting key epidemiological concepts relevant for evidence appraisal and agreed changes. The new version will be tabled at the Scientific Committee plenary meeting on 4-5 December for discussion.

6.2. Revision of section 4.3

The Working Group members revised the current draft of the section on appraisal and integration of epidemiological evidence in EFSA scientific assessments. Subsections were agreed and drafting tasks were assigned.

6.3. Feedback from RIVM and BfR activities on epidemiological studies in risk assessment

The RIVM project aims at a better integration of epidemiological studies in toxicological risk assessment and explores possibilities to adapt existing methodologies, both for toxicological risk assessment and the design of future epidemiological studies. A core group involving experts in risk assessment, toxicology, epidemiology, statistics and modelling is discussing potential quality criteria for existing epidemiological and toxicological studies, as well as suitability criteria for existing epidemiological and toxicological studies for derivation of health-based guidance values (HBGV). The

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

group shall also set up criteria for future epidemiological and toxicological studies (both quality and suitability) and possibilities to adapt current risk assessment methodology. The project has been extended to 2020.

The BfR project intends to develop a toolbox for the evaluation of individual observational studies, based on existing guidelines and tools, from which domains and criteria to assess the quality will be extracted and compiled. The new tool will be tested and discussed with users before publication of the tool in English. Currently, the domains, items and application areas are being extracted from the more than 140 tools identified through a literature review.

7. Any Other Business

Not Applicable

8. Next meeting(s)

The next meeting is scheduled for 28 January 2020 (web meeting).

SCIENTIFIC COMMITTEE

MINUTES OF THE 3rd MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 27 September 2019, web meeting

(Agreed on 07 October 2019)

Participants

■ Working Group Members:

Tony Fletcher, Thor Halldorsson (chair), Susanne Bennekou Hougaard, Evangelia Ntzani, Neil Pearce, Marco Vinceti

Apologies: Matthias Greiner

■ Hearing Experts:

Not applicable

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

AMU Unit: Laura Ciccolallo, Marios Georgiadis

SCER Unit: Andrea Gervelmeyer

■ Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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. Agreement of the minutes of the 2nd Working Group meeting held on 27-28 June 2019, Parma

The minutes of the 2nd Working Group meeting held on 27-28 June 2019 were agreed by written procedure on 10 July 2019.³

5. Hearing Expert

Not applicable

6. Scientific topics for discussion

6.1. Presentation of feedback from Scientific Committee on the current draft guidance

The Working Group was informed about the feedback received from the Scientific Committee on the draft text of sections 4.1 and 4.2. The Committee expressed its satisfaction with section 4.1 and indicated several points that should be further developed in section 4.2.

6.2. Discussion and revision of the current draft guidance

The WG experts discussed the current draft in the light of the suggestions received from the Scientific Committee. Drafting tasks and timelines were agreed for further developing sections 4.2 and 4.3.

7. Any Other Business

Not applicable

8. Next meeting

The next meeting of the Working Group will be held on 21-22 November 2019 in Parma.

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

³ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-epidemiological-studies.pdf>

SCIENTIFIC COMMITTEE

MINUTES OF THE 2nd MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 27-28 June 2019, Parma

(Agreed on 10 July 2019)

Participants

■ Working Group Members:

Tony Fletcher, Matthias Greiner (participated via teleconference), Thor Halldorsson (chair), Susanne Bennekou Hougaard, Evangelia Ntzani (participated via teleconference), Neil Pearce, Marco Vinceti

■ Hearing Experts:

Marco Zeilmaker

■ European Commission and/or Member States representatives:

Not Applicable

■ EFSA:

AMU Unit: Laura Ciccolallo, Marios Georgiadis, Fulvio Barizzzone

SCER Unit: Andrea Gervelmeyer

■ Others:

Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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. Agreement of the minutes of the 1st Working Group meeting held on 20-21 March 2019, Parma

The minutes of the 1st Working Group meeting held on 20-21 March 2019 were agreed by written procedure on 28 March 2019.³

5. Hearing Expert

Dr Marco Zeilmaker was invited to present his view for item 6.1 of the present meeting.

In accordance with EFSA's Policy on Independence⁴ and the Decision of the Executive Director on Competing Interest Management⁵, EFSA invited Dr Zeilmaker to submit an Annual Declaration of Interest. His participation in the present meeting was limited to providing testimony, without the possibility to take on any role undertaken by members of the Working Group (i.e. not possible to draft or be involved in the discussion or the adoption of a scientific output), in accordance with the applicable legal framework⁶.

6. Scientific topics for discussion

6.1. Presentation of projects on the use of epidemiological studies in risk assessment at RIVM and BfR

The Working Group was informed about two projects of Member States' sister agencies, RIVM and BfR, that are partly covering the topic of the SC guidance. RIVM It was decided that hearing experts from both institutions will inform the SC WG, to achieve potential synergies and avoid overlaps between the activities.

6.2. Presentation of EFSA experience with using epidemiological studies in its risk assessments

The WG has requested EFSA's Knowledge and Innovation Community on Epidemiology to carry out a survey to capture the experience of the different EFSA Panels with using epidemiological studies in their scientific assessments, as well as their specific needs for guidance. The results of the survey

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

³ <http://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-epidemiological-studies.pdf>

⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

⁵ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

⁶ Decision of the Executive Director on Competing Interest Management, Article 9:
http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



were presented. The needs expressed by the different Panels will be addressed in the guidance document.

6.3. Discussion and revision of the current draft guidance

The first two sections of the document, in which an introduction on epidemiological studies and the key concepts of evidence appraisal are explained, were discussed and revised by the WG experts. It is planned that these sections be submitted to the SC for review at its September plenary meeting.

6.4. Presentation of EFSA experience with Critical Appraisal Tools (CATs)

The WG was informed about the current experience of the different EFSA Panels with using critical appraisal tools. An overview of the different tools that have been used for appraising evidence for a wide range of scientific assessment questions was provided, as well as the feedback from EFSA staff and experts from their application.

6.5. Discuss how to address different critical appraisal tools in the guidance

The WG discussed how critical appraisal tools should be addressed in the guidance document. The section will be further discussed and drafted after the summer.

7. Any Other Business

7.1. Using Teams and Microsoft Office 365 – tips and support

WG experts were directed to a help and support page where the necessary information for communicating on Teams and co-editing documents online are explained.

8. Next meeting

The next meeting of the Working Group is scheduled for 27 September 2019 as a web meeting.

SCIENTIFIC COMMITTEE

MINUTES OF THE 1ST MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 20-21 March 2019, Parma

(Agreed on 28 March 2019)

Participants

- Working Group Members:
Tony Fletcher, Matthias Greiner, Thor Halldursson (chair), Susanne Bennekou Hougaard, Evangelia Ntzani (participated via teleconference), Marco Vinceti
- Hearing Experts¹:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
AMU Unit: Laura Ciccolallo, Marios Georgiadis
SCER Unit: Andrea Gervelmeyer
- Others:
Not Applicable

1. Welcome and apologies for absence

The Chair welcomed the participants.

¹ 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>.



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 Independence² and the Decision of the Executive Director on Competing Interest Management³, 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. Presentation of the mandate

EFSA's current experience with appraisal of evidence was presented and an overview of the different critical appraisal tools that have been used in EFSA's assessments so far was provided. The background of the mandate and its terms of reference were presented.

4.2. Discussion of the structure of the document and definition of the approach for drafting the sections: evidence to be used, methods of summarising evidence

The document structure was discussed, and its main sections and subsections were agreed. The first 2 sections of the document will set the basis for giving guidance on how to appraise and interpret findings from different types of epidemiological evidence and its application in EFSA scientific assessments, by providing relevant definitions of epidemiological studies and the key concepts in appraisal of evidence. The third section will explain how to appraise and integrate evidence from epidemiological studies, while the last section of the guidance will address the use of epidemiological studies for the specific risk assessment questions of the different EFSA panels.

4.3. Actions and timelines

Actions and timelines were agreed. It is foreseen to present the draft of the first two sections of the guidance document to the Scientific Committee at its plenary meeting in June 2019.

5. Any Other Business

5.1. Present collaboration platform and way of drafting

The WG team and its various channels on Microsoft Teams were presented. Experts were advised on how to access it and how to collaborate in drafting the scientific output online.

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

³ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



6. Next meeting(s)

The next meeting is scheduled for 27-28 June 2019.

SCIENTIFIC COMMITTEE

MINUTES OF THE KICK-OFF MEETING OF THE WORKING GROUP ON APPRAISAL AND INTEGRATION OF EVIDENCE FROM EPIDEMIOLOGICAL STUDIES

Held on 12-13 December 2018, Parma (Italy)

(Agreed on 11 January 2019)

Participants

- Working Group Members:
Thor Halldorsson (Chair)
Marco Vinceti
Tony Fletcher has participated via teleconference, in agenda point 5
- Hearing Experts:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
AMU Unit: Laura Ciccolalla, Marios Georgiadis
SCER Unit: Andrea Gervelmeyer
- Others:
Simon More (Chair of the Scientific Committee) has participated in agenda point 4.

1. Welcome and apologies for absence

The Chair welcomed the participants. Tony Fletcher did not participate in agenda points 1-5.



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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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. Briefing WG on mandate background

The working group members were informed about the needs regarding the use and appraisal of epidemiologic evidence of the different EFSA Panels.

4.2. Drafting Terms of Reference

Discussions were held on the scope of the guidance document. The working group felt that the emphasis of the guidance document should be on the use and appraisal of evidence from human observational studies in EFSA assessments, while also covering the use and appraisal of other epidemiologic studies, as well as other target populations (e.g. plants, animals).

4.3. Drafting outline of guidance document structure

It was discussed that the guidance would need a short introduction that creates a common understanding of epidemiologic studies.

This should be followed by an explanation of the key concepts of evidence appraisal with relevant definitions, of, e.g., internal and external validity, causation vs. association, and effect measure modification.

The third section of the guidance document should outline the factors to consider when appraising epidemiological evidence. In that section, issues such as validity vs. quality of studies, sources and direction of bias, ways to identify specific types of bias in specific study designs should be covered. This section should further explain the appraisal of study validity, e.g. assessing prevention and control of confounding, randomization, blinding, matching, etc. It should also address the correct use of Critical Appraisal Tools (CATs) for appraising individual studies, e.g. outline necessary considerations when setting inclusion criteria and highlight the consequences of choices made when using CATs. Finally, guidance should be provided on how to summarize that output within a given evidence stream.

In the fourth section, considerations of appraisal of epidemiologic evidence for specific scientific assessment questions such as efficacy assessments, hazard identification, hazard characterization, and exposure assessments would be made, highlighting how the output from the appraisal work

¹ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

² http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf



described in the previous sections can be applied in the assessments of EFSA's panels. This section will also contain direction on specific practical issues, where guidance is currently needed, such as how evidence from human observational studies can be used for dose–response assessments using benchmark dose (BMD) modelling.

4.4. Draft of workplan, tasks, milestones and timeline

The first three sections of the guidance document should be developed by a core of methodology experts until mid-2019. The working group considered a consultation of the first 3 sections of the guidance document targeted at evidence appraisal experts and epidemiologists in the third quarter of 2019. Panel-specific issues that need to be addressed in the fourth section of the document should be gathered while developing sections 1-3. The fourth section of the document should be developed involving toxicology experts, closely collaborating with panel members, by the third quarter of 2020. A workshop/symposium at an international conference, e.g. on toxicology, in early 2020 could be organised to receive additional input for this section. The guidance should be adopted and published by the end of 2020.

The meetings of the working group will be planned early 2019.

5. Any Other Business

Not Applicable

6. Next meeting(s)

The next working group meeting will be convened in March 2019.