SCIENTIFIC COMMITTEE

26th Working Group meeting on Read Across

23 May 2025
09:30-17:00
MINUTES - Agreed on 12 June 2025

Location: Web conference

Attendees:

- Working Group Members:
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad (Qasim) Chaudhry, Tamara Coja

- Hearing Experts[1]:
  Mark Cronin[2]

- Observers:
  N/A

- EFSA:
  MESE: Lucian Farcal, Ana Diges
  PLANTS: Rositsa Serafimova

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from George Cartlidge and Andrew Worth.

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[3] and the Decision of the Executive Director on Competing Interest Management[4], 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 25th Working Group meeting held on 8 May 2025, via web-conference

The minutes of the 25th Working Group meeting were agreed by written procedure on 12 May 2025.

V. Scientific and Technical Topics

[1] As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[2] Participated to the Agenda items 1-7 (specifically on the discussion related the revision of the read-across guidance (Item 5.1)
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

5.1 Draft Guidance

The WG discussed and integrated the remaining portion of the feedback received during the public consultation after a second screening carried out by the WG and EFSA staff. Comments were jointly reviewed following the order of the document, placing special focus on those related to uncertainty assessment and communication.

VI. Any Other Business

6.1 Next Steps and Tasks

A list of actions to finalise the guidance was compiled to be implemented by mid-June. The WG will integrate the remaining edits and suggestions received during the public consultation in the draft document to allow for a final editorial review of the document before it is presented to the Scientific Committee at the plenary meeting 2-3 Jul 2025.

Additionally, the responses to the comments will be published in a separate technical report regarding the public consultation outcome.

VII. Next Meetings

Currently, there are no additional meetings scheduled.

SCIENTIFIC COMMITTEE

25th Working Group meeting on Read Across

8 May 2025
09:30-17:00
MINUTES - Agreed on 12 May 2025

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- Working Group Members:
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad (Qasim) Chaudhry

- Hearing Experts[1]:
  Mark Cronin[2]

- Observers:
  ECHA: George Cartlidge

- EFSA:
  MESE: Lucian Farcal, Ana Diges, Alicia Paini
  FIP[3]: Yi Liu, Ana Criado, Natalia Kovalkovicova, Cristina Fernandez-Fraguas

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tamara Coja (WG member). George Cartlidge attended only until lunch break.

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[4] and the Decision of the Executive Director on Competing Interest Management[5,] 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 24th Working Group meeting held on 25 February 2025, via web-conference

The minutes of the 24th Working Group meeting were agreed by written procedure on 7 March 2025.

[1] As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups": https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[2] Participated to the Agenda items 1-7 (specifically on the discussion related the revision of the read-across guidance (Item 5.2)
[3] Participated to the Agenda Item 5.3
[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

V. Scientific and Technical Topics

5.1 Workshop Follow-Up

The WG was informed on the status of the workshop report and follow-up actions. The preparation of the final version of the report and necessary internal approvals will be carried out once minor editorial revisions are completed. The report is set to be made available to the Scientific Committee plenary meeting in July 2025, as additional information to the draft guidance. Participants feedback has been generally helpful and the content well-received, aiding in refining the report and EFSA event organisation.

5.2 Draft Guidance

The WG discussed and integrated a portion of the feedback received during the public consultation after an initial screening carried out by EFSA staff. Comments were jointly reviewed following the order of the document, until Section 4. Notable scientific and technical topics stemming from the comments included the alignment with other read-across frameworks and purposes, the guidance on the uncertainty assessment and the integration of the approach within the weight of evidence (WoE). Remaining comments are to be addressed leading up to and during the next meeting.

5.3 Brainstorming on possible application of the guidance to different contexts of use

EFSA staff from the FIP Unit described the context and sought advice on whether and how the read-across guidance can be applied to complex mixtures, specifically, food enzymes. WG experts shared views on the commonalities among the safety assessments while highlighting the unique challenges arising from not-well defined complex mixtures and biological preparations. The experts proposed language edits within the draft guidance to clarify the current applicability domain.

VI. Any Other Business

6.1 Next Steps and Tasks

A list of actions was compiled to be implemented and discussed in the next WG meeting. The WG will mainly continue to integrate the suggestions received during the public consultation and refine the draft guidance. The updated version will be finalised with the WG at the next meeting prior to presenting the document to the Scientific Committee for discussion and possible adoption.

VII. Next Meetings

The next meeting of the WG will be held on 23 May 2025 via web conference.

SCIENTIFIC COMMITEE

24th Working Group meeting on Read across

25 February 2025 (9.30-17.00)

MINUTES - Agreed on 7 March 2025

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad (Qasim) Chaudhry
- ***Hearing experts[1]:***
  Mark Cronin[2]
- ***Observers***:
  ECHA: George Cartlidge
- ***EFSA:***
  MESE: Lucian FARCAL, Ana DIGES, Alicia PAINI

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tamara Coja (WG member) and Andrew Worth (observer). George Cartlidge attended after the lunch break.

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[3] and the Decision of the Executive Director on Competing Interest Management[4], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings 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 23rd Working Group meeting held on 14th Jan 2025 via web-conference

The minutes of the 23rd Working Group meeting were agreed by written procedure on 22nd Jan 2025.

V. Scientific and technical topics

5.1 Feedback from the SC on the draft guidance

[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] Participated in the Agenda items 1-7 (specifically on the discussion related the revision of the read-across guidance (item 5.1) and preparation of the workshop (item 5.2)
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The Scientific Committee's comments from the last plenary meeting (February 19th-20th 2025) were compiled into a document and systematically addressed by the Working Group members during the meeting. The comments addressed several issues, e.g. the title of the guidance, the uncertainty assessment approach, conclusions and few other technical aspects that needed to be clarified. Outstanding tasks or those requiring further consideration were allocated to Working Group members for completion by 3rd March, with the aim of finalising the revised document for public consultation.

5.2 Workshop preparation

Preparation of the upcoming workshop took place, including clarifications on logistics and the program, and finalisation the workshop outline. Several read-across case studies that will be presented at the workshop were reviewed. The Chairs and moderators will review the workshop structure and questions to be addressed and refine as needed.

VI. Any Other Business

6.1 Next steps and tasks

Next steps include finalising the document version for public consultation and reviewing workshop materials to ensure consistency and logical content, setting the stage for a productive discussion.

VII. Next meeting

The next meeting of the WG will be held in May 2025 via web conference, specific date to be defined.

SCIENTIFIC COMMITEE

23rd Working Group meeting on Read across

14 January 2025 (9.30-17.00)

MINUTES - Agreed on 22 Jan 2025

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad (Qasim) Chaudhry
- ***Hearing experts[1]:***
  Mark Cronin[2]
- ***Observers***:
  ECHA: George Cartlidge
- ***EFSA:***
  MESE: Lucian FARCAL, Ana DIGES, Alicia PAINI

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Tamara Coja (WG member) and Andrew Worth (observer).

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[3] and the Decision of the Executive Director on Competing Interest Management[4], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings 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 22nd Working Group meeting held on 8th Nov 2024 via web-conference

The minutes of the 22nd Working Group meeting were agreed by written procedure on 22nd Nov 2024.

V. Scientific and technical topics

5.1 Revision of the draft guidance

[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] P Participated in the Agenda items 1-7 (specifically on the discussion related the revision of the read-across guidance (item 5.1) and preparation of the workshop (item 5.2)
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The WG addressed outstanding comments from the previous consultation, refined language technicalities and aligned content with other documents on read-across available (e.g. at ECHA and OECD). Special attention was dedicated to Section 5, related to the second objective of the mandate ToR on the applicability domain of the read-across. The new version of the draft guidance will be prepared for the next SC plenary (scheduled on 19-20 Feb 2025), seeking for the endorsement from the SC before the document will be opened for public consultation.

5.2 Preparation of read-across workshop

The group reviewed the outline of the read-across workshop (27-28 March 2025), including the agenda and activity descriptions, to ensure a cohesive and impactful event. The presentations and planned activities were discussed. The structure and content of the workshop were refined to foster meaningful discussions on implementing read-across in regulatory risk assessment, aligning with the expectations of attendees. Additionally, the group developed initial questions for the panel discussion and the case studies for breakout sessions to enhance engagement and promote practical learning. Finalisation of the discussion questions and case studies will be completed during the next WG meeting, while event logistics and organisation will be resolved internally and in coordination with the relevant EFSA services.

VI. Any Other Business

6.1 Next steps and tasks

Major next actions include preparation of the draft guidance for submission to the Scientific Committee plenary in February by addressing a shortlist of remaining tasks identified during the meeting. Parallelly, the WG and EFSA staff will finalise upcoming workshop details and planning to open event registrations at the end of January.

VII. Next meeting

The next meeting of the WG will be held on 25 February 2025 via web conference.

SCIENTIFIC COMMITEE

22nd Working Group meeting on Read across

8 Nov 2024 (9.00-16.30)

MINUTES - Agreed on 22 Nov 2024

EUROPEAN FOOD SAFETY AUTHORITY

Location: Webconference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad (Qasim) Chaudhry, Tamara Coja

- ***Hearing experts[1]:***
  Mark Cronin[2]

- ***Observers***:
  ECHA: George Cartlidge

- ***EFSA:***
  MESE: Lucian FARCAL, Ana DIGES, Alicia PAINI,
  PLANTS: Rositsa SERAFIMOVA

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received from Andrew Worth (Observer, EC JRC).

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[3] and the Decision of the Executive Director on Competing Interest Management[4], 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 21st Working Group meeting held on 10th Oct 2024 via web-conference

[1] As defined in Article 34 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] Participated in the Agenda items 1-7 (specifically on the discussion related the read-across steps in Item 5.1)

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The minutes of the 21st Working Group meeting were agreed by written procedure on 24th Oct 2024.

V. Scientific and technical topics

5.1 Revision of the draft guidance

The WG continued to discuss and update the draft guidance based on the comments received within the targeted consultation. The focus of the discussion was on Section 4 of the guidance that described the steps of the read-across approach. This section has been re-organised and the text was refined to make the steps clearer and easier to be followed by the users. Some of text has been moved to the Annexes where some detailed explanations are included.
The workflow diagram has been also updated to reflect the changes in the text and to make cleared its iterative approach.
Overall, the WG worked on aligning the different sections of the guidance that describes the read-across steps (e.g. the diagram and new table in Section 4, description of the steps in Sections 4.1 to 4.6 and Annex 1, ensuring their consistency).
The list of terminologies and definitions has been also updated, that is aligned with the other documents on read-across available at ECHA and OECD. Moreover, overall harmonisation of the text in relation the use of some terms has been checked and will include few more iterations before the finalisation of the document.
As a next step, the WG will look closer at the general comments received during the targeted consultation and address them before the next SC plenary meeting to be held in Feb 2025. At that meeting, the draft document should be ready for discussion and proposed for endorsement for public consultation.

VI. Any Other Business

6.1 Dissemination and collaborations activities

The WG members were consulted regarding the planned workshop (estimated to be organised in Q1/Q2 2025). Ideas regarding the format as well as the content of the sessions were discussed. The workshop will be addressed to risks assessors as well as applicants that might apply read-across in their work, looking at different guidance documents in this area but also clarifying some technical and scientific aspects related to the application of read-across in risk assessment.

6.2 Next steps and tasks

A list of actions was compiled to be implemented and discussed in the next WG meeting.

The WG will continue to integrate the suggestions received during the targeted consultation and refine the draft guidance. The updated version will be further presented and discussed with the Scientific Committee of EFSA (Feb 2025).

VII. Next meeting

The next meeting of the WG will be held on 14 January 2025 via web conference.

SCIENTIFIC COMMITEE

21st Working Group meeting on Read across

10 October 2024 (9.30-17.00)

MINUTES - Agreed on 24 Oct 2024

Location: Webconference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad Chaudhry, Tamara Coja

- ***Hearing experts[1]:***
  Mark Cronin[2]

- ***Observers***:
  ECHA: George Cartlidge

- ***EFSA:***
  MESE: Lucian FARCAL, Ana DIGES, Alicia PAINI
  PLANTS: Rositsa SERAFIMOVA

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received from Andrew Worth (Observer, EC JRC).

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[3] and the Decision of the Executive Director on Competing Interest Management[4,] 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 20th Working Group meeting held on 2nd May 2024 via web-conference

[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] Participated in the Agenda items 1-7 (specifically on the discussion related the read-across steps in Item 5.2)

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The minutes of the 20th Working Group meeting were agreed by written procedure on 15th May 2024.

V. Scientific and technical topics

5.1 Overview of the targeted consultation

The WG was informed on the status of the targeted consultation on the draft guidance, that included EFSA's Units and Panels, but also other organisations (e.g. EU Agencies, EC JRC, OECD). This was finalised on 30 Sep 2024 with more than 600 comments received, including scientific & technical clarifications, editorial changes and some general comments or suggestions. The WG will consider the comments to update the draft guidance to be further discussed with the Scientific Committee of EFSA.

The WG discussed also regarding the organisation of a workshop (e.g. Q1 2025) to cover some of the questions addressed during the targeted consultation and other aspects related to the application of read-across in the risk assessment of chemicals. In the next period the WG will be consulted on a draft proposal of the workshop and its design.

5.2 Refinement of the guidance

The WG discussed the comments received within the targeted consultation, focusing first on the scientific & technical issues. These covered a wide range of aspects, e.g. harmonisation and definition of some technical terms used in the guidance, examples of uses within regulatory frameworks, refinement of the read-across workflow and its steps. For the latter, the WG members discussed different options for making the guidance easier to be followed by the potential users (e.g. clear definition of the steps, aspects related to data-gaps in each step and mentioning of their iterative profile, conclusion and documentation of the read-across assessment).
The WG looked also into reducing some redundancies of the text and increase the readability of the document. For the next period, the effort should be put in solving most of the technical questions, solving all editorial issues and further harmonisation / alignment of different sections of the guidance and its annexes.

VI. Any Other Business

6.1 Next steps and tasks

A list of actions was compiled to be implemented and discussed in the next WG meeting.

The WG will continue to integrate the suggestions received during the targeted consultation and refine the draft guidance. The updated version will be further presented and discussed with the Scientific Committee of EFSA (expected Feb 2025).

VII. Next meeting

The next meeting of the WG will be held on **8 November 2024** via web conference.

SCIENTIFIC COMMITEE

20th Working Group meeting on Read across

02 May 2024 (9.30-17.00)

MINUTES - Agreed on 14 May 2024

Location: Webconference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad Chaudhry

- ***Hearing experts***[1]:
  Mark Cronin[2]

- ***Observers***:
  ECHA: George Cartlidge
  EC-JRC: Andrew Worth

- ***EFSA:***
  Lucian Farcal, Georgia Bompola (MESE Unit)

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Tamara Coja.

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[3] and the Decision of the Executive Director on Competing Interest Management[4], 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 19th Working Group meeting held on 21st March 2024 via web-conference

[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] Participated in the Agenda items 1-7 (specifically on the refinement of the guidance discussed under Item 5.2)

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The minutes of the 18th Working Group meeting were agreed by written procedure on 8th April 2024.

V. Scientific and technical topics

5.1. Feedback from the Scientific Committee

The WG was informed on the feedback received during the 118th plenary meeting of the Scientific Committee (SC) (10-11 Apr 2024), when the Guidance was made available to the SC, for discussion. Some general and also specific comments were received, that were considered by the WG members in order to improve the structure and the readability, but also clarified on terminologies, and different technical and scientific aspects. These were discussed under Item 5.2. An updated version of the Guidance will be shared with the SC for the next plenary meeting on 29-30 May 2024.

5.2. Refinement of the guidance

The WG discussed and agreed on re-organising the sections of the Guidance, in order to put more emphasis on the actual practical guidance, while more background information for each step will be part of the Annexes. Several terms used in the Guidance (e.g. related to the mechanisms, toxicokinetics, toxicodynamics, abbreviations) were checked and was agreed to further harmonise them along the document.

Further, the WG members discussed all pending comments and issues in the Guidance and clarified on specific technical and scientific issues.

VI. Any Other Business

6.1. Preparation of targeted consultation

The WG was informed on the next steps, including a targeted consultation on the draft version of the Guidance. The consultation will be addressed to the scientific Units and Panels at EFSA, as well as other EU Agencies. The exact plan for this consultation will be shared with the WG after the next SC plenary meeting.

6.2. Next steps and tasks

The WG was also informed on the status of the procurement OC/EFSA/SCER/2021/04 deliverables and plans for the publication of its Final Report.

A list of actions was compiled to be implemented and discussed in the next WG meeting.

VII. Next meeting

The next meeting of the WG will be held in **Q3/Q4 2024** via web conference. The exact date will be decided later.

SCIENTIFIC COMMITEE

19th Working Group meeting on Read across

21 March 2024 (9.00-13.00)

MINUTES - Agreed on 8 April 2024

Location: Webconference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad Chaudhry, Tamara Coja

- ***Observers***:
  ECHA: George Cartlidge

- ***EFSA:***
  Lucian Farcal, Georgia Bompola (MESE Unit), Georges Kass (NIF Unit), Rositsa Serafimova (PLANTS Unit), Paola MANINI (FEEDCO Unit, for Agenda item 5.2)

I. Welcome and apologies for absence

The Chair welcomed the participants.

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[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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.

Agreement of the minutes of the 18th Working Group meeting held on 1st March 2024 via web-conference

The minutes of the 18th Working Group meeting were agreed by written procedure on 15th March 2024.

[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

IV. Scientific and technical topics

5.1 Refinement of different sections of the guidance

The WG discussed and completed some of the sections of the guidance referring to the existing framework and guidance on read-across (section 2), in silico tools and their use in different steps of the read-across workflow (Section 3.6.1), the utility of read-across in risk assessments and finally on the applicability domains for the read across (Section 5). For the latter, the conclusions from two procurement projects will be integrated.
The version of the guidance resulted after this meeting will be presented and discussed at the next plenary meeting of the Scientific Committee (10-11 April 2024).

5.2 Information on ongoing assessment cases at EFSA

In this session, a case study involving read-across performed by the WG Feed Flavourings of FEEDAP Panel[3] was presented to the WG. The members of WG read-across were informed on the ongoing assessments performed and discussed on the approach taken in the case related to botanical preparations. In addition, this exercise aimed also to ensure alignment with the ongoing guidance development and that the WG is informed on real-cases in which read-across might be applied.

V. Any Other Business

6.1 Next steps and tasks

A list of actions was compiled to be implemented and discussed in the next WG meeting.

VI. Next meeting

The next meeting of the WG will be held on **2nd May 2024** via web conference.

[3] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/feedap

SCIENTIFIC COMMITEE

18th Working Group meeting on Read across

1 March 2024 (9.30-17.00)

MINUTES - Agreed on 15 March 2024

Location: Webconference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad Chaudhry, Tamara Coja
- ***Hearing Experts[1]:***
  Mark Cronin[2]
- ***Observers***:
  ECHA: George Cartlidge
- ***Contractors:***
  Sylvia Escher[3] and Jenny Irwan[3]
- ***EFSA:***
  Lucian Farcal, Georgia Bompola (MESE Unit), Georges Kass (NIF Unit), Rositsa Serafimova (PLANTS Unit).

I. Welcome and apologies for absence

The Chair welcomed the participants.

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[4] and the Decision of the Executive Director on Competing Interest Management[5,] 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.

[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] Participated in the Agenda items 1-7 (specifically on issues related to Section 3 and 4 of the guidance)
[3] Participated in the Agenda items 5.2 (progress report on procurement OC/EFSA/SCER/2021/04)
[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

IV. Agreement of the minutes of the 17th Working Group meeting held on 13-14th February 2024 via web-conference

The minutes of the 17th Working Group meeting were agreed by written procedure on 26th February 2024.

V. Scientific and technical topics

5.1 Annex 4. Terminologies

The WG discussed briefly on the utility of the terminology section, concluding that it should be kept and to include the definition of most relevant terms used in the guidance, aligning in this way with the other frameworks. The section, will be further updated with additional terms, as needed.

5.2 Progress report on the procurement project (OC/EFSA/SCER/2021/04)

In this session, the contractor presented the final report of the project "Identification of the applicability domain (in terms of toxicological endpoints and chemical space) for the use of Read-Across in food safety". The main achievements, reflected in the final report, were presented and included details regarding the methodology applied (e.g. different similarity approaches, integration of chemical, toxicological and metabolic information, NAMs), workflows proposed, databases and chemicals analysed. The WG appreciated the achievements and engaged in detailed discussion on the approach. In addition, the WG provided detailed feedback and suggestions, to be provided in writing to the contractor and that will support the finalisation of the report and preparation for publication.

5.3 Section 5. Applicability domain

The WG discussed the options for inclusion in the Guidance the knowledge generated in the above-mentioned procurement project. Thus, the learning and recommendations from this project, as well from other contracts should be reflected in this section, currently under development by the WG. The WG discussed also on a set of principles and elements that can be included, generally applicable to different domains, while the specific details can be available from the procurement report.

5.4 Section 2. Existing frameworks and guidance

The WG revised the text related to the exiting frameworks and used generally as reference for the application of read across in other areas. References to other EFSA or ECHA guidance documents that apply read-across approach will be also included and reflected in the updated version of the guidance.

5.5 Section 3.6.1 Tools for read-across

This section was reorganised and discussed by the WG members. The current structure and content included referenced to different tools, their brief description as well as their possible usability in the steps of the read-across guidance. The latest refinement facilitated the readability and usability of this section. The tools also now summarised in a Table.

5.6 Utility of read across in regulatory risk assessments

This section is still under development and refinement by the WG and will be included as a last part of the actual guidance (within Section 4).

In addition, some additions and reorganisation in Sections 3 were also discussed and to be further checked by the WG members.

VI. Any Other Business

6.1 Next steps and tasks

A list of actions was compiled to be implemented and discussed in the next WG meeting.

VII. Next meeting

The next meeting will be held on **21st March 2024** via web conference.

SCIENTIFIC COMMITEE

17th Working Group meeting on Read across

13 February 2024 (14:00-17.00) &
14 February (9:30-12:30) 2024

MINUTES - Agreed on 26 Feb 2024

Location: Webconference

Attendees:

- ***Working Group Members:***
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad Chaudhry, Tamara Coja
- ***Hearing Experts[1]:***
  Mark Cronin
- ***EFSA:***
  Lucian Farcal, Georgia Bompola (MESE Unit), Georges Kass (NIF Unit), Rositsa Serafimova (PLANTS Unit), Juan Manuel Parra Morte (PREV Unit)
- ***Observers***:
  ECHA: George Cartlidge

  EC-JRC: Andrew Worth

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Andrew Worth for 13th February and Tamara Coja for 14th February 2024.

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[2] and the Decision of the Executive Director on Competing Interest Management,[3] 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.

Certain interests were declared orally by the members before the beginning of the meeting. For further details on the outcome of the screening of the Oral Declaration of Interest made at the beginning of the meeting, please refer to the Annex.

[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] 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

IV. Agreement of the minutes of the 16th Working Group meeting held on 16th November 2023 via web-conference

The minutes of the 16th Working Group meeting were agreed by written procedure on 5th December 2023.

V. Status of the mandate and timelines

Within this agenda item the Working Group was informed about the updated timelines of the mandate and expected finalisation of the guidance (EFSA-Q-2020-00413). Hence, the project planning with adjusted dates for the final results expected from the procurement project OC/EFSA/SCER/2021/04, deliverables, internal and external consultations and engagement activities to be considered was presented to the WG.

VI. Knowledge transfer from the procurement project

The working group was informed that the Final Report deriving from the procurement project OC/EFSA/SCER/2021/04 will be available after 15th Feb 2024, followed by an evaluation of the WG on the integration of the results into the guidance. The results will be presented by the contractor during the next WG meeting.

VII. Scientific topics for discussion

7.1 General status of the guidance

In this session each Section of the working draft of the Guidance was briefly examined to review the updates that were included by the WG members since the last meeting. Comments and the new text provided were briefly discussed and the text was refined.

7.2 Section 1. Introduction

The new text in relation to the Section 3.1 1 Targeted audience, use and degree of obligation was thorougly discussed by the WG and the text was updated accordingly.

Section 2. Existing frameworks and guidance

A comparative table of existing Frameworks and Guidance on Read Across was assessed, in relation also to the OECD Guidance on Grouping of Chemicals and ECHA RAAF that constitutes the bases for the other documents. It was proposed that the table is expanded with more examples of EFSA guidance documents, in which read across is introduced. As a next step, a summary table will be included in the Guidance, as well a statement regarding the similarities or differences with the existing documents.

7.3 Section 3. Framework for the EFSA read-across guidance

In this session, the discussions were focused on the sub-section "Tools for read-across" that should be re-arranged (e.g. merge of some paragraphs and headings) to avoid duplications

and redundancy of the text. To render the information more reader-friendly, presentation of the content in a tabular format was suggested.

Section 4. Guidance

Within this section, the WG members discussed on a new text referring to the "utility of RAx in regulatory risk assessments". Several aspects were discussed, including the contexts of use and adequacy of predictions depending on the purpose of use, the relation to the validated or non-standard methods and input data, etc. These will be reflected in a new sub-section at the end of Section 4 (or Section 1) of the guidance, depends on its final version.

7.4 Section 5. Applicability domain of the Guidance

In this Section, knowledge from the procurement project OC/EFSA/SCER/2021/04 will be incorporated as an example of applicability of the Guidance for some of the toxicological endpoints. The WG will discuss and decide other aspects that need to be elaborated to fulfil the second Terms of reference, i.e. to identify the applicability domain (in terms of toxicological endpoints and chemical space) for the use of RAx in food safety.

7.5 Annexes

The WG members discussed on the content of Annex 3 (on examples of case studies) and Annex 4 (terminologies and definitions relevant to read across). For Annex 4, the text has been evaluated and minor changes will be further implemented, including the update of its heading. For Annex 4, the WG will work on further refinements and alignment with other frameworks.

VIII. Any Other Business

8.1 Next steps and tasks

A list of actions was compiled and discussed within the WG, to be achieved before the discussion of the document at the SC plenary meeting in 10-11 April 2024.

IX. Next meeting

The next meeting will be held on **1st March 2024** via web conference.

Annex

Interests and actions resulting from the Oral Declaration of Interest done at the beginning of the meeting

NO CONFLICT: With regard to this meeting, Dr. Mark Cronin declared the following interests: a) member of a Working Group as part of the ECETOC HH Transformation Programme, b) funding from Concawe regarding grouping of petroleum constituents for persistence, bioaccumulation and toxicity and c) funding from the UKRI as part of the European Union Quantum-Tox EIC Pathfinder

project. Also, Dr. Emilio Benfenati declared the following interests: a) involvement in the Quantum-Tox EIC Pathfinder project.

In accordance with EFSA's Policy on Independence[4] and the Decision of the Executive Director on Competing Interest Management[5], and taking into account the specific matters discussed at the meeting in question, the interests above were not deemed to represent a Conflict of Interest for the experts concerned.

[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

SCIENTIFIC COMMITEE

16th Working Group meeting on Read across

16 November 2023
09:30 - 17:00
MINUTES - Agreed on 5 December 2023

Location: Webconference

Attendees:

- ***Working Group Members***:
  Susanne Hougaard Bennekou (Chair), Emilio Benfenati, Romualdo Benigni, Mohammad Chaudhry, Tamara Coja
- ***Hearing Experts***[1]:
  Mark Cronin[2]
- ***Contractors***:
  Sylvia Escher[3] and Jenny Irwan[3]
- ***Observers***:
  ECHA: George Cartlidge
- ***EFSA***:
  Lucian FARCAL, Alexis NATHANAIL, Georgia BOMPOLA

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Takashi Yamada (Hearing Expert) and Andrew Worth (Observer).

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[4] and the Decision of the Executive Director on Competing Interest Management[5], 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.

[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] Participated in Agenda items 1-9 (*read across tools and approaches, to be further reviewed by the WG*)
[3] Participated in Agenda item 7.1 (*reported on the procurement project progress: OC/EFSA/SCER/2021/04*)
[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

IV. Agreement of the minutes of the 15th Working Group meeting held on 1 September 2023, in via web-conference

The minutes of the 15th Working Group meeting were agreed by written procedure on 13 September 2023.

V. Feedback from the Scientific Commitee

The working group was informed on the feedback received following the preliminary reading guidance during the 115th plenary meeting of the Scientific Committee held on 20-21 Sep 2023 (*see the meeting minutes*[6]). Overall, the SC supported the work already made on the draft guidance and encouraged the continuation of the work according to the plan. Regarding some specific comments received, the WG discussed e.g. on the weight that needs to be placed on *in silico* data, QSAR models or other tools. These aspects will be further clarified in the guidance section on available in silico models/tools. Regarding the applicability of the guidance to mixtures, the WG recognised that this is a complex issue and needs further reflection. Although the mixtures were not included in the initial scope of the guidance and despite the complexity, some elements of the guidance may be used also for mixtures. Regarding the SC's advice for further interactions with other EU Agencies (e.g. ECHA, EMA) and Member States, the WG was informed and discussed the consultation plan to be implemented in 2024.

VI. Status of the mandate and planning

Within this Agenda item, the project planning and timelies for its milestones and deliverables was presented and discussed. The WG discussed on the timelines towards finalisation of the overall guidance, adjustments of the timelines in relation to the upcoming results from the procurement project OC/EFSA/SCER/2021/04 (*presented in the next Agenda item*), internal and external consulations and engagement activities required and additional scientific aspects to be considered in the guidance. Based on these discussions, an updated timetable will be made available to the WG.

VII. Scientific topics for discussion

7.1 Progress report on the procurement project (OC/EFSA/SCER/2021/04)

Sylvia Escher and Jenny Irwan (hearing experts in this meeting) presented an update on the procurement project "*Identification of the applicability domain (in terms of toxicological endpoints and chemical space) for the use of Read-Across in food safety*". Specifically, the presentation referred to the development of read-across assessment workflows (WF) integrating information on biological, metabolic and toxicological information. For this purpose, a large database of data-rich substances has been built, which comprises different toxicity studies with oral route of exposure, including subacute to chronic toxicity, developmental toxicity and ADME studies. Qualitative data on metabolic pathways were collected. Data have been collected from publicly available EFSA Draft/Renewal Assessment Reports (DAR/RAR). NAM (*in vitro*) data originated from Tox21/ToxCast1 projects are used for calculating biological similarity. The WFs are constructed using case studies on toxic compound (propiconazole) and less toxic compound (iodosulfuron-methyl sodium) to explore steps and various options of data combination. Two different pesticides were used as hypothetical target compounds to establish the following workflows:

[6] https://www.efsa.europa.eu/en/events/115th-plenary-meeting-scientific-committee

- WF 1: Murcko Scaffolds generation, followed by biological similarity and predicted biokinetics data.
- WF 2: Chemical similarity (MACCS, dice), followed by biological similarity and shared metabolites.
- WF3: Biological similarity, followed by chemical similarity and ADME properties (ongoing)

The WG discussed on the project outcomes and the use in the context of the guidance development (knowledge transfer) that will take place once the final report will be available.

7.2 Guidance Section 2. Existing Frameworks and Tools for Read-across

The WG discussed on the section of the guidance covering the existing frameworks and guidance (ECHA, OECD, etc.), in order to perform a comparison of selected guidance regarding their scope, context of use, applicability domain, targeted users and any other overlapping or different aspects that might be relevant for such a comparison. This exercise will also include a cross-check with read-across approaches already in use at EFSA (e.g. flavourings, pesticides). The section in the guidance will be refined in order to reflect these elements.

Additional aspects related to terminologies, statements on the use of the guidance, case studies, etc. will be further integrated in the working document.

VIII. Any Other Business

8.1 Next steps and tasks

A list of actions was compiled and discussed within the WG.

IX. Next meeting

The next meeting will be held on **13-14 February 2024**.

SCIENTIFIC COMMITTEE

15th Working Group meeting on RAx

1 September 2023
09:30-17:00
MINUTES - Agreed on 13 September 2023

Location: Web conference

Attendees:

- Working Group Members:
  Emilio Benfenati, Aldo Benigni, Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair)
- Hearing Experts:
  Mark Cronin
- Observers:
  George Cartlidge (ECHA)
- EFSA:
  Alexis Nathanail, Georges Kass, Rositsa Serafimova, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Takashi Yamada and Andrew Worth.

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[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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.

[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

IV. Agreement of the minutes of the 14th Working Group meeting held on 3 July 2023, via web-conference

The minutes of the 14th Working Group (WG) meeting were agreed by written procedure on 17 July 2023.

V. Scientific topics for discussion

a. Guidance revision - Chapters 1, 3, 4

Refinements and revisions were made to the latest draft version of the guidance during the meeting, focusing particularly on Chapter 1 (Introduction), Chapter 3 (Framework for the EFSA Read-across Guidance) and Chapter 4 (Stepwise Read-across Guidance). Each expert updated the WG on the revisions made to the different sections of the guidance. Written comments previously provided by WG members were examined and addressed.

b. Preparation of questions to the Scientific Committee

The WG discussed and prepared a few key questions for the Scientific Committee (SC) to ask for feedback, as a first draft of parts of the draft guidance will be presented at the 115th SC Plenary to be held on 20-21 September 2023.

VI. Any other business

The tasks for the next meeting were discussed and agreed upon.

VII. Next meeting

The dates for the next meetings will be available in the upcoming weeks.

SCIENTIFIC COMMITTEE

14th Working Group meeting on RAx

3 July 2023
09:30-12:30
MINUTES - Agreed on 17 July 2023

Location: Web conference

Attendees:

- Working Group Members:
  Emilio Benfenati, Aldo Benigni, Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair)

- Hearing Experts:
  Mark Cronin

- EFSA:
  Alexis Nathanail, Rositsa Serafimova, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from:
George Cartlidge, Andrew Worth, Takashi Yamada.

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[1] and the Decision of the Executive Director on Competing Interest Management[2,] 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 13th Working Group meeting held on 30 May 2023, via web-conference

The minutes of the 13th Working Group (WG) meeting were agreed by written procedure on 14 June 2023.

[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

V. Scientific topics for discussion

a. Guidance revision Chapters 3 & 4

Refinements and revisions were made to the latest draft version of the guidance during the meeting, focusing particularly on Chapter 3 (Considerations for the Development of the Guidance) and Chapter 4 (Read Across Guidance). Each expert updated the WG on the revisions made to the different sections of the guidance. Written comments previously provided by WG members, and suggestions on how to structure the main sections of the guidance, were examined and addressed.

VI. Any other business

The tasks for the next meeting were discussed and agreed upon.

VII. Next meeting

The 15th RAx WG meeting will be held via web conference on the 1st of September.

SCIENTIFIC COMMITTEE

13th Working Group meeting on RAx

30 May 2023
09:30-13:00 / 14:30-17:00
MINUTES - Agreed on 14 June 2023

Location: Web conference

Attendees:

- Working Group Members:
  Emilio Benfenati, Aldo Benigni, Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair)
- Hearing Experts:
  Mark Cronin, Takashi Yamada[1]
- Observers:
  George Cartlidge (ECHA)[2], Worth Andrew[3] (JRC-ISPRA)
- EFSA:
  Alexis Nathanail, Silvia Tangianu, Juan Manuel Parra Morte, Rositsa Serafimova[4]

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from:
Rositsa Serafimova for the first half of the meeting.

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[5] and the Decision of the Executive Director on Competing Interest Management[6,] 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.

[1] Participated in agenda items 1 to 6
[2] Participated in agenda items 5 to 8
[3] Participated in agenda items 1 to 5
[4] Participated in agenda items 7 to 8
[5] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[6] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Agreement of the minutes of the 12th Working Group meeting held on 24 & 26 April 2023, via web-conference

The minutes of the 12th Working Group meeting were agreed by written procedure on 11 May 2023.

V. Scientific topics for discussion

a. Tour de table – Introduction of new expert

A brief tour de table was conducted to introduce the new expert (Emilio Benfenati) as a full member of the Working Group (WG).

b. Uncertainty assessment finalisation

The experts updated the WG on the uncertainty assessment approach developed for the Read Across (RAx) guidance. The developed uncertainty assessment proposal was presented to EFSA's Uncertainty WG for feedback and suggestions. The WG reached a consensus on the presented approach with a few minor revisions and comments to be addressed.

c. NAMs text

The progress of the NAMs text in the guidance was presented to the WG. Written comments previously provided by WG members and suggestions on how to integrate this content with other sections of the guidance were examined and addressed.

d. Guidance revision

Refinements and revisions were made to the latest draft version of the guidance during the meeting. Additional comments on the guidance were provided by the WG members.

VI. Any other business

The tasks for the next meeting were discussed and agreed upon.

VII. Next meeting

The 14th RAx WG meeting will be held via web conference on the 3rd of July.

SCIENTIFIC COMMITTEE

12th Working Group meeting on RAx

24 & 26 April 2023
10:00-13:00 / 10:00-13:00
MINUTES - Agreed on 11 May 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web conference

Attendees:

- Working Group Members:
  Aldo Benigni, Qasim Chaudhry, Susanne Hougaard Bennekou (Chair)
- Hearing Experts:
  Mark Cronin, Takashi Yamada
- Observers:
  George Cartlidge (ECHA)[1], Worth Andrew[2] (JRC-ISPRA)
- Contractor (Fraunhofer):
  Sylvia Escher[3], Jenny Irwan[4]
- EFSA – MESE Unit:
  Alexis Nathanail, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from:
Andrew Worth for the first day of the meeting.
Tamara Coja for both days of the meeting.

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[5] and the Decision of the Executive Director on Competing Interest Management[6], 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.

[1] Participated in agenda items 1 to 7
[2] Participated in agenda items 7 to 9
[3] Participated in agenda item 8
[4] Participated in agenda item 8
[5] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[6] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Agreement of the minutes of the 11th Working Group meeting held on 20 & 21 February 2023, via web-conference

The minutes of the 11th Working Group meeting were agreed by written procedure on 7 March 2023.

V. Scientific topics for discussion

a. Updated framework figure

A revised proposal for the read across (RAx) framework was presented to the Working Group (WG). Suggestions were made and changes were implemented.

b. Data matrix guidance text

The progress of the data matrix text in the guidance was presented to the WG. Written comments previously provided by WG members were examined and addressed.

c. Uncertainty guidance text

The experts updated the WG on the uncertainty assessment in RAx, together with a proposal for an uncertainty template checklist to be included in the guidance. The developed uncertainty assessment proposal was presented to EFSA's Uncertainty WG for feedback and comments on the 2nd of May. Resulting revisions will be discussed in the next RAx WG meeting.

d. Guidance comments and revision

Refinements and revisions were made to the draft version of the guidance during the meeting. Additional comments on the guidance were provided by the WG members.

e. RAx procurement progress update

Sylvia Escher from the ITEM department of Fraunhofer, the contractor of EFSA's RAx project (OC/SCER/2021/04), updated the WG on the progress and results of their work concerning grouping and application of RAx. Case study proposals were discussed with the WG experts and feedback was taken on board.

VI. Any other business

The tasks for the next meeting were discussed and agreed upon.

The need for a new expert to support the RAx guidance development has been identified. The Chair of this WG has agreed to appoint Emilio Benfenati as a new member of the WG.

VII. Next meeting

The 13th RAx WG meeting will be held via web conference on the 30th of May.

SCIENTIFIC COMMITTEE

11th Working Group meeting on RAx

20 & 21 February 2023
10:00-13:00 / 10:00-13:00
MINUTES - Agreed on 7 March 2023

Location: Web conference

Attendees:

- Working Group Members:
  Aldo Benigni, Qasim Chaudhry[1], Tamara Coja, Susanne Hougaard Bennekou (Chair)
- Hearing Experts:
  Mark Cronin, Takashi Yamada
- Observers:
  George Cartlidge (ECHA), Worth Andrew (JRC-ISPRA)
- EFSA – MESE Unit:
  Alexis Nathanail, Silvia Tangianu

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Qasim Chaudhry for the second day of the meeting.

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[2] and the Decision of the Executive Director on Competing Interest Management[3], 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.

[1] Participated in items 1 to 6
[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

IV. Agreement of the minutes of the 10th Working Group meeting held on 5 & 6 December 2022, via web-conference

The minutes of the 10th Working Group meeting were agreed by written procedure on 21 December 2022.

V. Scientific topics for discussion

a. RAx WG workplan 2023 and resources

The timeframe of activities and resources of the Working Group (WG) on read-across (RAx) meetings were discussed.

b. Framework considerations - EU-ToxRisk

The WG was presented with the EU-ToxRisk RAx workflow, and a revised proposal for the RAx framework was discussed.

c. Uncertainty guidance text

The experts updated the WG on the uncertainty assessment in RAx, together with a comprehensive template to be included in the guidance. Written comments previously provided by WG members were examined and addressed.

d. Data matrix guidance text

The progress of the data matrix template and guidance text were presented to the WG. The role of New Approach Methodologies (NAM) data to further support analogue selection, identify common adverse outcome pathways (AOP) and the inclusion of examples of Integrated Approaches to Testing and Assessment (IATA) were discussed.

e. Addressing existing comments on the guidance

Refinements and revisions were made to the draft version of the guidance during the meeting. WG experts were invited to provide additional input in their respective areas of expertise. Written comments on the guidance provided by WG members were addressed and agreed during the meeting.

VI. Any other business

The tasks for the next meeting were distributed.

VII. Next meeting

The 12th RAx WG meeting will be held on 24 and 26 April 2023 as two half day meetings, via web conference.

The 13th RAx WG meeting was agreed to be held via web conference on the 30th of May as all-day meeting.

METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 10th MEETING OF THE WORKING GROUP ON RAx

Held on 5 & 6 December 2022 via Teleconference

(Agreed on 21 December 2022)

Participants

- Working Group Members:

  Aldo Benigni, Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair)

- Hearing Experts:

  Mark Cronin, Takashi Yamada

- Observers:

  George Cartlidge (ECHA)

- Contractor (Fraunhofer):

  Sylvia Escher[1]

- EFSA:

  Alexis Nathanail, Georges Kass[2], Juan Manuel Parra Morte[3], Silvia Tangianu

[1] Participated in item 7
[2] Participated in items 1 to 6
[3] Participated in items 5 to 9

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 Independence[4] and the Decision of the Executive Director on Competing Interest Management,[5] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Update from RAx presentation to the Scientific Committee

The Working Group (WG) was updated on the feedback received from the Scientific Committee (SC) regarding the development of the read-across (RAx) guidance, given at the 111th SC Plenary (17th of November 2022). In addition to feedback on the framework presented, the discussion also revolved around the impact of the new guidance to past applications of RAx in EFSA's Opinions and the incorporation of new approach methodologies (NAMs) into the guidance.

5. Data matrix template proposal

The progress on the data matrix template proposal was presented to the Working Group (WG). The current internationally developed templates by OECD, as well as the ECHA 2008 templates and their implementation into the OECD QSAR Toolbox were discussed, with proposals on the adoption of such templates and adaptations into EFSA's RAx guidance.

6. Genotoxicity RAx case study

The WG was updated on the application of RAx in predicting substances' genotoxicity profiles, considering different scenarios. In this project, results from different genotoxicity tests were compared to those obtained from the RAx approach. In certain scenarios there was agreement of outcomes, but deviations were observed in case of low quality of available data.

7. Update from the RAx procurement project

Sylvia Escher from the ITEM department of Fraunhofer, the contractor of EFSA's RAx project (OC/SCER/2021/04), updated the WG on the progress and results of their work concerning grouping and application of RAx. The on-going work concerned incorporation of kinetic

[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

parameter data and refinement of outputs using shared metabolites to better identify suitable source compounds. At a later stage, biological similarity will also be investigated within the context of RAx between target, source and metabolites of substances.

8. Uncertainty template proposal

The experts updated the WG on the uncertainty assessment in RAx and presented a preliminary template to be included in the guidance. A system to classify uncertainties as low, medium and high levels was also presented and discussed.

9. Next steps and distribution of tasks

The tasks for the next WG meeting were distributed and agreed upon. The dates for the next meetings will be available in the upcoming weeks.

METHODOLOGY AND SCIENTIFIC SUPPORT UNIT

SCIENTIFIC COMMITTEE

MINUTES OF THE 9th MEETING OF THE WORKING GROUP ON RAx

Held on 28 & 29 September 2022 via Teleconference

(Agreed on 21 November 2022)

Participants

- Working Group Members:

  Aldo Benigni, Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair)

- Hearing Experts:

  Mark Cronin, Takashi Yamada

- Observers:

  George Cartlidge (ECHA)

- Contractor (Fraunhofer):

  Sylvia Escher, Jenny Irwan

- EFSA:

  Georges Kass, Rositsa Serafimova, Alexis Nathanail

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. ECHA's reflections on read-across and OECD IATA case studies

In this agenda item reflections from the application of read-across (RAx) and grouping within ECHA's various regulatory processes were presented to the Working Group (WG). An overview of ECHA's Read-Across Assessment Framework (RAAF) was also provided to facilitate discussions on the compatibility and alignment of RAAF with EFSA's RAx guidance that is currently under development. In addition, recommendations on how to improve RAx and utilise state-of-the-art methodologies such as NAMs and the QSAR Toolbox in the context of RAx were discussed. During this session, experiences from OECD Integrated Approaches to Testing and Assessment (IATA) case studies were shared with the members of the WG on the use of RAx in repeated-dose toxicity assessment of chemicals. The presentation highlighted aspects for appropriate analogue selection and data gap filling, as well as comments received on uncertainties and how those were addressed.

5. Template proposals for data matrix and uncertainty analysis in read-across

The progress on data matrix and uncertainty assessment in RAx was presented by experts of the WG, along with concrete proposals for the relevant templates to be included in the Guidance document. For data matrix, the current internationally developed templates were shown, with proposals on the adoption of such templates and incorporation into EFSA's guidance. Key considerations for all steps of the RAx framework were identified and categorised into major and minor uncertainties. The main sources of uncertainty for a number of key considerations have been identified and a system to classify uncertainties as low, medium and high levels was proposed and discussed.

[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

6. Use of NAMs in regulatory risk assessment and read-across

A key element of EFSA's RAx Guidance development is utilisation of new approach methodologies (NAMs) data to support analogue justification and support data gap filling strategies. The experts shared information of the state-of-play as regards use of NAM approaches in regulatory risk assessment and RAx and their experiences from relevant case studies.

7. RAx contractor session: Identification of the applicability domain for the use of read-across in food safety

In this final session of the WG meeting, Sylvia Escher and Jenny Irwan from the ITEM department of Fraunhofer, which is the contractor for EFSA's RAx project (OC/SCER/2021/04) informed the WG on the progress and first results of their work concerning grouping and application of RAx. The project deals with the identification of the applicability domain (in terms of toxicological endpoints and chemical space) for the use of RAx in food safety. More specifically, the project aims to gather and assess an extensive dataset of repeated dose and toxicokinetics studies from pesticide active substances and metabolites to assist the development of the RAx guidance for analogue identification, integration of metabolites in RAx workflows, utilisation of NAM data and optimisation and refinement of parameters for successful implementation of RAx approaches.

8. Next steps and distribution of tasks

The tasks for the next meeting were distributed and agreed upon. The next RAx WG meeting will be held on the 5th and 6th of December as teleconference.

SCIENTIFIC COMMITTEE

MINUTES OF THE 7th MEETING OF THE WORKING GROUP ON RAx

Held on 20 & 25 April 2022 via Teleconference

(Agreed on 05 May 2022)

Participants

- Working Group Members:

  Aldo Benigni, Qasim Chaudhry (Day 2), Tamara Coja, Susanne Hougaard Bennekou (Chair), Grace Patlewicz

- Hearing Experts:

  Mark Cronin, Takashi Yamada

- Observers:

  Kim Petersen (WHO) (Day 2), Andrew Worth (JRC) (Day 2)

- EFSA:

  Georges Kass (Day 1), Rositsa Serafimova, Alexis Nathanail

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Development of a stepwise approach for the draft guidance

During the 7th Read Across meeting the Working Group continued drafting the Guidance on the Use of the Read Across Approach in Food Safety Assessment. The experts provided the remaining text parts to complete a first complete draft of the read across workflow section. More specifically, new text was generated for the following steps: Building of data matrix and data gap filling strategy, Uncertainty assessment and Reduction of uncertainties. The hearing experts Mark Cronin and Takashi Yamada were invited to present to the WG their knowledge and experience on these topics.

5. Next steps and distribution of tasks

The tasks for the next meeting were discussed and agreed upon.

[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

SCIENTIFIC COMMITTEE

MINUTES OF THE 6th MEETING OF THE WORKING GROUP ON RAx

Held on 12-13 January 2022 via Teleconference,

(Agreed on 25 January 2022)

Participants

- Working Group Members:

  Aldo Benigni (Day 2), Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair), Grace Patlewicz

- Hearing Experts:

  Mark Cronin, Takashi Yamada (Item 4)

- Observers:

  George Cartlidge (ECHA), Kim Petersen (WHO) (Day 2), Andrew Worth (JRC)

- EFSA:

  Georges Kass, Rositsa Serafimova, Alexis Nathanail

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Development of a stepwise approach for the draft guidance

The WG presented and discussed the progress made on the text of the draft guidance concerning the use of read across approach in food safety. More specifically, progress was made on the following steps of the draft document: problem formulation, data gap analysis, analogue identification and analogue evaluation. During the second day, the WG formulated the remaining steps comprising the read across workflow and discussed in more detail the key considerations necessary to perform a read across assessment. The hearing experts Mark Cronin and Takashi Yamada were invited to present to the WG their knowledge and experience on these topics.

5. Next steps and distribution of tasks

The tasks for the next meeting were discussed and agreed upon.

[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

SCIENTIFIC COMMITTEE

MINUTES OF THE 5th MEETING OF THE WORKING GROUP ON RAx

Held on 13-14 September 2021 via Teleconference,

(Agreed on 04 October 2021)

Participants

- Working Group Members:

  Aldo Benigni, Qasim Chaudhry, Tamara Coja (day 2), Susanne Hougaard Bennekou (Chair), Grace Patlewicz

- Hearing Experts:

  Mark Cronin (Items 4 and 5), Sylvia Escher (Item 4), Takashi Yamada (Items 4 and 5)

- Observers:

  George Cartlidge (ECHA), Kim Petersen (WHO) (day 1), Magda Sachana (OECD)

- EFSA:

  Georges Kass, Rositsa Serafimova

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Discussion of the Horizon 2020 EU-ToxRisk Project NAM-based RAx draft Paper

A draft paper developed under the Horizon 2020-funded project EU-ToxRisk and which analyses the potential contribution of NAM approaches (in silico and in vitro) to support Rax was presented to the WG by the hearing expert Sylvia Escher. The WG discussed the draft paper and provided their comments and recommendation. The hearing experts Mark Cronin and Takashi Yamada were invited to comment as well based on their knowledge and experience on the use of NAM approaches in RAx.

5. Development of a stepwise approach for the draft guidance

The WG analysed the individual steps for a RAx workflow and discussed the key steps to identify the key considerations necessary to perform a RAx. The hearing experts Mark Cronin and Takashi Yamada were invited to present to the WG their knowledge and experience on these steps.

6. Next steps and distribution of tasks

The tasks for the next meeting were discussed and agreed upon.

[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

SCIENTIFIC COMMITTEE

MINUTES OF THE 4th MEETING OF THE WORKING GROUP ON RAx

Held on 9 July 2021 via Teleconference,

(Agreed on 3 August 2021)

Participants

- Working Group Members:

  Aldo Benigni, Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair), Grace Patlewicz

- Hearing Experts:

  Mark Cronin (Item 4), Takashi Yamada (Item 4)

- Observers:

  George Cartlidge (ECHA), Kim Petersen (WHO), Magda Sachana (OECD)

- EFSA:

  Georges Kass, Rositsa Serafimova

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Discussion of draft guidance and approach proposed

The WG discussed the draft prepared. Specifically, the drafted contributions on problem formulation in RAx, analogue identification & evaluation and grouping of chemicals were discussed. The hearing experts Mark Cronin and Takashi Yamada were invited to present to the WG their knowledge and experience on these topics.

5. Next steps and distribution of tasks

The tasks for the next meeting were discussed and agreed upon.

[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

SCIENTIFIC COMMITTEE

MINUTES OF THE 3rd MEETING OF THE WORKING GROUP ON RAx

Held on 30 April 2021 via Teleconference

(Agreed on 26 May 2021)

Participants

- **Working Group Members:**

  Aldo Benigni, Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair), Grace Patlewicz

- **Hearing Experts:**

  Marc Cronin (Item 4), Takashi Yamada (Item 4)

- **Observers:**

  George Cartlidge (ECHA), Kim Petersen (WHO), Magda Sachana (OECD)

- **EFSA:**

  Paolo Colombo, Georges Kass, Fabiola Pizzo, Rositsa Serafimova

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Discussion of draft guidance and approach proposed

The WG discussed the draft prepared. Specifically, the draft framework was presented and discussed in the context of EFSA guidance documents that should be linked to the RAx guidance. The hearing experts Marc Cronin and Takashi Yamada were invited to present to the WG their knowledge and experience on RAx frameworks and uncertainty assessment.

5. Next steps and distribution of tasks

The tasks for the next meeting were discussed and agreed upon.

[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

SCIENTIFIC COMMITTEE

MINUTES OF THE 2nd MEETING OF THE WORKING GROUP ON RAx

Held on 4 December 2020 via Teleconference

(Agreed on 23 December 2020)

Participants

- **Working Group Members:**

  Qasim Chaudhry, Tamara Coja, Susanne Hougaard Bennekou (Chair), Grace Patlewicz

- **EFSA:**

  Anna Lanzoni, Georges Kass, Fabiola Pizzo, Rositsa Serafimova

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled

[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

out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Planning of the technical content of the RAx project to be outsourced

The WG discussed and agreed on the technical content of the project to identify the applicability domain (in terms of toxicological endpoints and chemical space) for the use of RAx in food safety.

5. Next steps and distribution of tasks

The tasks for the next meeting were discussed and agreed upon.

SCIENTIFIC COMMITTEE

MINUTES OF THE 1st MEETING OF THE WORKING GROUP ON RAx

Held on 22 & 25 September 2020 via Teleconference,

(Agreed on 13 October 2020)

Participants

- **Working Group Members:**

  Aldo Benigni, Tamara Coja, Susanne Hougaard Bennekou (Chair), Grace Patlewicz

- **Hearing Experts**:

  Mark Cronin, Takashi Yamada (for sections 4-5)

- **Observers**:

  George Cartlidge (ECHA), Qasim Chaudhry (SCCS), Kim Petersen (WHO), Magdalini Sachana (OECD)

- **EFSA:**

  Paolo Colombo, Anna Lanzoni, Georges Kass, Fabiola Pizzo, Rositsa Serafimova

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 Independence[1] and the Decision of the Executive Director on Competing Interest Management,[2] EFSA screened the Annual Declaration of Interest filled out by the working group members invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting were identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

4. Presentation of the Mandate

The mandate and Terms of Reference were presented. The main objective of this mandate is to develop a framework and guidance on the use of Read Across (RAx) in risk assessment, and to identify the applicability domain (in terms of toxicological endpoints and chemical space) for the use of RAx in food safety.

5. Interpretation of the Terms of Reference and development of the Scientific Opinion

A discussion on the interpretation of the Terms of Reference took place and considered existing RAx frameworks, including ECHA's RAAF, and the need to provide specific guidance for EFSA's needs. The key elements to be considered for the identification of the applicability domain (in terms of toxicological endpoints and chemical space) for the use of RAx in food safety, including the types of chemicals and databases were discussed.

6. Next steps and distribution of tasks

The tasks for the next meeting were discussed and agreed upon.

[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