SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

22nd Working Group meeting on Historical Control Data

21 (9:00-18:00) – 22 (9:00-13:00) May 2025

MINUTES – Agreed on 2 Jun 2025

EUROPEAN FOOD SAFETY AUTHORITY

Location: EFSA and web-conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Experts[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Tommaso Giorgi, Anna Lanzoni

Methodology and Scientific Support (MESE) Unit: Laura Martino

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 21st Working Group meeting held on 10-11 Apr 2025, via web-conference

The minutes of the 21st Working Group meeting were agreed by written procedure on 29 Apr 2025.

4. 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.

5. Scientific topics for discussion

The Working Group discussed the feedback received from the PPR Panel reviewers. Comments to the draft Opinion and Annexes were addressed as considered appropriate.

[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

Planning for next steps was also discussed and agreed. The draft Opinion with Annexes will be presented to the PPR Panel for possible adoption during the plenary in Jun.

6. Any Other Business

None.

7. Next meeting

Not applicable.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

21st Working Group meeting on Historical Control Data

10 (9:00-18:00) – 11 (9:00-13:00) Apr 2025

MINUTES – Agreed on 29 Apr 2025

Location: Web-conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Experts[1]:
  BfR: Carsten Kneuer, Susanne Rudzok, Gyamfi Akyianu, Veronika Staedele
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo

  Methodology and Scientific Support (MESE) Unit: Laura Martino

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 20th Working Group meeting held on 12 Mar 2025, via web-conference

The minutes of the 20th Working Group meeting were agreed by written procedure on 21 Mar 2025.

4. 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.

5. Hearing Experts

A technical hearing was organised with the contractor (BfR) of the outsourcing project PO/EFSA/PREV/2024/05 – 'Testing approach for the use and reporting of Historical Control

[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

Data (HCD) in regulatory studies'. The contractor was invited to present results for the 2 tested case studies and answering questions as needed by the Working Group.

6. Scientific topics for discussion

The Working Group discussed on the pending replies to Public Consultation comments and related amendments in the Opinion/Annexes.

The Contractor for PO/EFSA/PREV/2024/05 presented for Working Group discussion the results for the 2 tested case studies (count and continuous data) as captured in the draft Final Report.

Planning for next steps was also discussed and agreed. The draft Opinion with Annexes will be reviewed by the PPR Panel (28 Apr-9 May) before its finalisation for possible adoption in Jun.

7. Any Other Business

None.

8. Next meeting

The next meeting will be held on 21 (9:00-18:00) and 22 (9:00-13:00) May 2025 as physical meeting in Parma.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

20th Working Group meeting on Historical Control Data

12 Mar 2025 (9:00-18:00)

MINUTES – Agreed on 21 Mar 2025

Location: Web-conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Experts[1]:
  BfR: Carsten Kneuer, Susanne Rudzok, Gyamfi Akyianu, Veronika Staedele
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo

  Methodology and Scientific Support (MESE) Unit: Laura Martino

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 19th Working Group meeting held on 3 Mar 2025, via web-conference

The minutes of the 19th Working Group meeting were agreed by written procedure on 7 Mar 2025.

4. 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.

5. Hearing Experts

A technical hearing was organised with the contractor (BfR) of the outsourcing project PO/EFSA/PREV/2024/05 – 'Testing approach for the use and reporting of Historical Control

[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

Data (HCD) in regulatory studies'. The contractor was invited to present preliminary results for case study 2 and answering questions as needed by the Working Group.

6. Scientific topics for discussion

The Working Group discussed on the pending replies to Public Consultation comments and related amendments in the Opinion/Annexes. Also, structure of the Opinion/Annexes was revised and agreed.

The Contractor for PO/EFSA/PREV/2024/05 presented for Working Group discussion preliminary results for case study 2 (continuous data). Based on Working Group feedback colelcted to the Interim Report 1, some revisions for case study 1 (count data) were also presented.

Planning for next steps was also discussed and agreed.

7. Any Other Business

None.

8. Next meeting

The next meeting will be held on 10 (9:00-18:00) and 11 (9:00-13:00) Mar 2025 as teleconference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

19th Working Group meeting on Historical Control Data

3 Mar 2025 (14:00-16:00)

MINUTES – Agreed on 7 Mar 2025

EUROPEAN FOOD SAFETY AUTHORITY

Location: Web-conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Ian Dewhurst, Bertrand Desprez, Emily Mcvey, Martin Wilks (Chair)
- Hearing Experts[1]:
  BfR: Carsten Kneuer, Susanne Rudzok, Veronika Staedele
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni, Tommaso Giorgi

  Methodology and Scientific Support (MESE) Unit: Laura Martino

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 18th Working Group meeting held on 30 Jan 2025, via web-conference

The minutes of the 18th Working Group meeting were agreed by written procedure on 12 Feb 2025.

4. 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.

5. Hearing Experts

A technical hearing was organised with the contractor (BfR) of the outsourcing project PO/EFSA/PREV/2024/05 – 'Testing approach for the use and reporting of Historical Control

[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

Data (HCD) in regulatory studies'. The contractor was invited to present deliverable 2 (Interim Report 1) and answering questions as needed by the Working Group.

6. Scientific topics for discussion

The contractor for PO/EFSA/PREV/2024/05 presented results from testing the proposed approach to case study 1 (count data) as captured in the Interim Report 1 (deliverable 2). Preliminary feedback was provided by the Working Group.

Planning next steps was also discussed and agreed.

7. Any Other Business

None.

8. Next meeting

The next meeting will be held on 12 Mar (9:00-18:00) as teleconference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

18th Working Group meeting on Historical Control Data

31 Jan 2025 (9:00-18:00)

MINUTES – Agreed on 12 Feb 2025

Location: Parma and web-conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Bertrand Desprez, Emily Mcvey, Martin Wilks (Chair)
- Hearing Experts[1]:
  BfR: Carsten Kneuer, Susanne Rudzok, Gyamfi Akyianu, Veronika Staedele

  Hasselt University: Stijn Jaspers
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino

1. Welcome and apologies

The Chair welcomed the participants. Apologises were received by Ian Dewhurst.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 17th Working Group meeting held on 13-14 Nov 2024, via web-conference

The minutes of the 17th Working Group meeting were agreed by written procedure on 27 Nov 2024.

4. 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.

5. Hearing Experts

A technical hearing was organised with the contractor (BfR) of the outsourcing project PO/EFSA/PREV/2024/05 – 'Testing approach for the use and reporting of Historical Control

[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

Data (HCD) in regulatory studies'. The contractor was invited to present deliverable 1 and answering questions as needed by the Working Group. Furthermore, a technical hearing was organised with the contractor (Hasselt University) of the outsourced project specific contract n.3 implementing Framework contract No OC/EFSA/AMU/2020/02 - 'Reliability of percentile estimators'. The contractor was invited to present preliminary outcomes from the investigation on the minimum number of studies and sample size for HCD and answering questions as needed by the Working Group.

6. Scientific topics for discussion

The Working group discussed on the status of the replies to Public Consultation comments and related amendments in the Opinion/Annexes. The need and feasibility to address an additional case study with an ecotoxicity endpoint was also discussed.

The contractor for 'Testing approach for the use and reporting of Historical Control Data (HCD) in regulatory studies' presented for Working Group discussion draft protocols (deliverable 1) for the two case studies to be tested (count and continuous data on mammalian toxicity endpoints).

The contractor for 'Reliability of percentile estimators' presented for Working Group discussion preliminary results on the minimum number of historical control studies to achieve a sufficient coverage of the prediction interval for the concurrent control.

Planning for addressing comments from the Public Consultation and amendments to the Opinion/Annexes was agreed and tasks allocated. An additional ad hoc WG meeting was agreed on 3 Mar to discuss deliverable 2 of the ongoing PO/EFSA/PREV/2024/05 (technical hearing with BfR).

7. Any Other Business

None.

8. Next meeting

The next meeting will be held on 3 Mar (14:00-16:00) as teleconference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

17th Working Group meeting on Historical Control Data

13th (14:00-18:00) 14th (9:00-18:00) Nov 2024

MINUTES – Agreed on 27 Nov 2024

Location: Parma and web-conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
  Carsten Kneuer, Susanne Rudzok, Gyamfi Akyianu
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 16th Working Group meeting held 17-18 Sep Jun, via web-conference

The minutes of the 16th Working Group meeting were agreed by written procedure on 30 Sep 2024.

4. 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.

5. Hearing Experts

A technical hearing was organised with the contractors (BfR) of the negotiated procedure NP/EFSA/PREV/2024/03 – Testing approach for the use and reporting of Historical Control

[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

Data (HCD) in regulatory studies'. The Contractor was invited to present draft Final Report and answering questions as needed by the Working Group.

6. Scientific topics for discussion

The contractor for NP/EFSA/PREV/2024/03 presented outcomes from testing the case studies (dichotomous and continuous endpoints) as captured in the draft Final Report and in the data extraction templates. The WG discussed feedback to the tested case studies, needs for Opinion refinement, as well as endpoints to be tested in a next negotiated procedure with BfR (te be initiated in Jan 2025).

Answers to some of the comments received through the Public Consultation and related amended provided to the Opinion/Annexes were discussed. Restructuring of the Opinion was also proposed and agreed. An advanced version of template for presenting HCD on ecotoxicity endpoints was discussed.

Planning for addressing comments from the Public Consultation and amendments to the Opinion/Annexes was agreed and tasks allocated.

7. Any Other Business

None.

8. Next meeting

The next meeting will be held on 30 Jan 2025 (9AM-6PM) as teleconference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

16th Working Group meeting on Historical Control Data

17th (9:00-18:00) 18th (9:00-13:00) Sep 2024

MINUTES – Agreed on 30 Sep 2024

EUROPEAN FOOD SAFETY AUTHORITY

Location: Parma and web-conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
  Carsten Kneuer, Susanne Rudzok, Gyamfi Akyianu
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received by Chiara Perazzolo (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 14th Working Group meeting held 21 Jun, via web-conference

The minutes of the 15th Working Group meeting were agreed by written procedure on 26 Jul 2024.

4. 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.

5. Hearing Experts

A technical hearing was organised with the contractors (BfR) of the negotiated procedure NP/EFSA/PREV/2024/03 – Testing approach for the use and reporting of Historical Control

[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

Data (HCD) in regulatory studies'. The Contractor was invited to present Interim Report 1 and answering questions as needed by the Working Group.

6. Scientific topics for discussion

The Working Group discussed answers to some of the comments received through the Public Consultation and related amended provided to the Opinion/Annexes. Restructuring of the Opinion was also discussed and agreed. An advanced version of a template for presenting HCD on ecotoxicity endpoints was discussed.

The contractor for NP/EFSA/PREV/2024/03 presented outcomes from testing 2 case studies (dichotomous and continuous endpoints) as captured in the Interim Report 1 and the data extraction templates.

Planning for addressing comments from the Public Consultation and amendments to the Opinion/Annexes was agreed and tasks allocated.

7. Any Other Business

None.

8. Next meeting

The next meeting will be held on 13 (9:00-18:00) and 14 (9:00-13:00) November 2024 at EFSA premises.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

15th Working Group meeting on Historical Control Data

11 Jul 2024 (10:00-17:00)

MINUTES – Agreed on 26 Jul 2024

Location: Parma and web-conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received by Chiara Perazzolo (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 14th Working Group meeting held 21 Jun, via web-conference

The minutes of the 14th Working Group meeting were agreed by written procedure on 10 Jul 2024.

4. 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.

5. Scientific topic(s) for discussion

The Working Group discussed comments received through Public Consultation and some changes needed in the Opinion and Annexes. A template for presenting HCD on ecotoxicity endpoints was presented for discussion.

[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

Planning for addressing comments from the Public Consultation and amendments to the Opinion was agreed and tasks allocated.

6. Any Other Business

None.

7. Next meeting

The next meeting will be held on September the 17th (9:00-18:00) and 18th (9:00-13:00) 2024 (online).

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

14th Working Group meeting on Historical Control Data

21 Jun 2024 (10:00-17:00)

MINUTES – Agreed on 10 Jul 2024

EUROPEAN FOOD SAFETY AUTHORITY

Location: Parma and web-conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
  Not Applicable
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received by Chiara Perazzolo (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 12th Working Group meeting held 16 and 24 January 2024, via web-conference

The minutes of the 13th Working Group meeting were agreed by written procedure on 31 May 2024.

4. 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.

5. Scientific topic(s) for discussion

The Working Group discussed amendments to the Decision Scheme, confounders list and templates, based on comments received through Public Consultation, for the finalization of a

[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

revised version of the Opinion and Annexes. Revised Opinion and Annexes will be tested by a competent national authority (German Federal Institute for Risk Assessment, BfR) through an outsourcing project (NP/EFSA/PREV/2024/03). Proposal for case studies selection to be tested was discussed and captured feedback will be shared with BfR at the kick-off (tele)meeting.

Planning for addressing remaining comments from the Public Consultation as well as further amendments to the Opinion was agreed and tasks allocated.

6. Any Other Business

None.

7. Next meeting

The next meeting will be held on 11 Jul 2024 (online).

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI)

CONFLICT OF INTEREST: In the Annual Declaration of Interest submitted by <Mr, Ms, Dr or Prof. please select as appropriate and insert the name of the expert>, the following interest has been declared: <please insert a reference to the interest>. 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 interest above was deemed to represent a Conflict of Interest.

This resulted in the exclusion of the expert from any discussion, voting or other processing of item <XXX> by the concerned scientific group.

CONFLICT OF INTEREST WITH WAIVERS: In the Annual Declaration of Interest filled by <Mr, Ms, Dr or Prof. please select as appropriate and insert the name of the expert/s> the following interest has been declared: <please insert a reference to the interest>, which constitutes a Conflict of Interest (CoI) with the mandate of the EFSA Working Group in hand. In accordance with EFSA's Policy on Independence[6] and the Decision of the Executive Director on Competing Interest Management[7], and taking into account the specific matters discussed at the meeting in question, a waiver was granted in accordance with Article 21 of the Decision of the Executive Director on Competing Interest Management. (you can put the relation to a specific item of the meeting or it can stay general as a new interest declared and related to the mandate, see Article 21 of the Decision of the Executive Director on Competing Interest Management[8]).

Pursuant to Article 21(6) of the above-mentioned Decision, the concerned expert/s was/were allowed to take part in the discussion and in the drafting phase of the EFSA Scientific Report <please insert the title>, and has/have not been allowed to be, or act as, a chairman, a vice-chairman or rapporteur of the Working Group.

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

Annex II

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

NO CONFLICT: With regard to this meeting, <Mr, Ms, Dr or Prof. please select as appropriate and insert the name of the expert> declared the following interest: <please insert a reference to the interest>. In accordance with EFSA's Policy on Independence[9] and the Decision of the Executive Director on Competing Interest Management[10], and taking into account the specific matters discussed at the meeting in question, the interest above was not deemed to represent a Conflict of Interest for the expert concerned.

CONFLICT OF INTEREST: With regard to this meeting, <Mr, Ms, Dr or Prof. please select as appropriate and insert the name of the expert> declared the following interest: <please insert a reference to the interest>. In accordance with EFSA's Policy on Independence[11] and the Decision of the Executive Director on Competing Interest Management[12], and taking into account the specific matters discussed at the meeting in question, the interest above was deemed to represent a Conflict of Interest (CoI).

This results in the exclusion of the expert from any discussion, voting or other processing of item <XXX> by the concerned scientific group.

[9] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[10] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[11] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[12] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

13th Working Group meeting on Historical Control Data

23 May 2024 (10:00-17:00)

MINUTES – Agreed on 31 May 2024

Location: Web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Bertrand Desprez, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
Manon Beekhuijzen, Steven Denham, Donald Stump, Andrea Pelizzari, Diego Lopez
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received by Chiara Perazzolo (ECHA).

2. Adoption of agenda

The agenda was adopted without changes.

3. Agreement of the minutes of the 12th Working Group meeting held 16 and 24 January 2024, via web-conference

The minutes of the 12th Working Group meeting were agreed by written procedure on 30 January 2024.

4. 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.

5. Hearing Expert(s)

[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

Manon Beekhuijzen, Steven Denham, Donald Stump, Andrea Pelizzari and Diego Lopez were invited from Charles River Laboratories to share their experience from testing the approach proposed in the draft Opinion, under agenda item 6.

6. Scientific topic(s) for discussion

The Working Group discussed the main feedback to the draft Opinion received through Public Consultation, conducted in Mar-Apr 2024. An overview of main comments was discussed, and the Working Group agreed on priorities for screening and identifying major comments impacting on the approach proposed in the draft Opinion.

The Working Group was informed that, after the revision of the proposed approach based on the Public Consultation comments, it will be tested through an outsourcing project for its finalization. Based on this, the deadline for the adoption of the Opinion is postponed to Jun 2025.

In the end, the planning of next steps and meeting calendar was also discussed and agreed.

7. Any Other Business

None.

8. Next meeting

The next meeting will be held on 21 Jun 2024 (hybrid).

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

12th Working Group meeting on Historical Control Data

16 (13:00-17:00) and 24 (10:00-17:00) Jan

2024 MINUTES – Agreed on 30 Jan 2024

Location: Web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni
Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received by Chiara Perazzolo (ECHA). Ian Dewhurst attended day 1 (AM and PM) and day 2 (AM).

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[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.

4. Scientific topic(s) for discussion

The Working Group discussed the feedback received from the PPR Panel reviewers (day 1 and day 2). Amendments to the draft Opinion and Annexes were provided, where appropriate, and comments were replied.

Templates for collection of information/data on HCD for reproductive toxicity and developmental toxicity endpoints were presented for discussion (day 2).

The Working Group discussed on the content of the event to be organised at the launch of the Public Consultation (day 2).

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

In the end, the planning of next steps and meeting calendar was also discussed and agreed (day 2).

5. Any Other Business

None.

6. Next meeting

The next meeting will be held via TC on 23 May 2024.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

11th Working Group meeting on Historical Control Data

18 (09:00-18:00) and 19 (09:00-13:00) Oct 2023
MINUTES – Agreed on 27 Oct 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Parma and web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato
- ECHA:
Chiara Perazzolo

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[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.

4. Scientific topic(s) for discussion

The Working Group revised sections drafted in the Scientific Opinion and Annexes. Amendments and pending sections to be drafted were agreed. Moreover, an updated version of the template for presenting HCD was discussed and the Working Group agreed to finalise the template as an Annex, with instructions and filled-in with one example.

Planning of tasks to be addressed for the finalisation of the draft Opinion and Annexes was agreed. The draft documents will be submitted to PPR Panel for review in Dec.

[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

5. Any Other Business

None.

6. Next meeting

The next meeting will be on 24 Jan 2024 via webconference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

10th Working Group meeting on Historical Control Data

5 Oct 2023
10:00-17:00
MINUTES – Agreed on 12 Oct 2023

Location: Web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologises were received by Chiara Perazzolo (ECHA).

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[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.

4. Scientific topic(s) for discussion

The Working Group discussed the feedback received from the Scientific Committee on the proposed methodology (decision tree) presented during the Plenary on 20th Sep. The Working Group discussed on the examples for elucidation of the decision tree. Moreover, an updated version of the template for presenting HCD was presented for discussion.

The status of development of the Opinion was checked and planning for finalisation of the draft, including review by the PPR Panel, was agreed. Tasks to be addressed by the next meeting were assigned.

[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

5. Any Other Business

None.

6. Next meeting

The next meeting will be held in Parma on 18 (full day) and 19 (9:00-13:00) October 2023.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

9th Working Group meeting on Historical Control Data

6 Sep 2023
09:00-18:00
MINUTES – Agreed on 19 Sep 2023

Location: Web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Chiara Perazzolo (ECHA).

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[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.

4. Scientific topic(s) for discussion

The Working Group discussed the updated decision tree with key steps for HCD evaluation and integration with the index study. The decision tree was tested with an example for continuous data. Decision tree will be presented to the Scientific Committee in Sep for collecting feedback on the proposed methodology.

A draft template for presentation of HCD was introduced to the Working Group for discussion. Needed amendments were agreed to be implemented in an updated version of the template.

Tasks for the drafting of pending sections in the Scientific Opinion and Appendices were allocated.

[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

5. Any Other Business

None.

6. Next meeting

The next meeting will be held on 5 October 2023 (10:00 – 17:00) as web conference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

8th Working Group meeting on Historical Control Data

20 July 2023
10:00-17:00
MINUTES – Agreed on 29 Jul 2023

Location: Web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Emily McVey, Martin Wilks (Chair)
- Hearing Expert[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino
- ECHA:
Chiara Perazzolo

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[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. With regard to this meeting, Martin Wilks orally declared the following interest: the Swiss Centre for Applied Human Toxicology is beneficiary of a grant from the Swiss Government in the context of the European Project Partnership for the Assessment of Risks from Chemicals (PARC). In addition, Ian Dewhurst orally declared the new interest with the Food Additives and Flavourings (FAF) Panel, for the assessment of a new food additive which is produced by genetic modification of a microorganism. In accordance with EFSA's Policy on Independence1 and the Decision of the Executive Director on Competing Interest Management[4], and taking into account the specific matters discussed at the meeting in question, the interests were not deemed to represent a Conflict of Interest for the experts concerned.

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

4. Scientific topic(s) for discussion

The Working Group discussed the decision tree with key steps for the collection and use of HCD. Available statistical methods for HCD evaluation and integration with the index study were presented and discussed. Case studies will be developed for the applicability of the decision tree, to be captured in Appendices to the Scientific Opinion.

Tasks for the drafting of sections in the Scientific Opinion and Appendices were allocated.

5. Any Other Business

None.

6. Next meeting

The next meeting will be held on 6 September 2023 (9:00 – 18:00) as web conference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

7th Working Group meeting on Historical Control Data

6-7 June 2023
14:00-18:00 (6 Jun), 9:00-18:00 (7 Jun)
MINUTES – Agreed on 27 Jun 2023

Location: EFSA - Parma (Meeting Room MTG SEAT 00/M04) and web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Emily Mcvey, Martin Wilks (Chair)
- Hearing Expert[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Marco Binaglia, Arianna Chiusolo, Ana-Andreea Cioca, Anna Lanzoni

  Methodology and Scientific Support (MESE) Unit: Laura Martino
- ECHA:
Chiara Perazzolo

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 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

The Working Group developed a flowchart describing the key steps for the collection and use of HCD. The key steps of the flowchart were agreed by the Working Group and preliminary tested against test cases. Each key step was elaborated with details on legal and scientific requirements.

The Working Group agreed to draft the Scientific Opinion on the basis of the flowchart

[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

Further elaboration and discussion in the Working group are needed.

Tasks for the drafting of sections in the Scientific Opinion were allocated.

5. Any Other Business

None.

6. Next meeting

The next meeting will be held on 20 July 2023 (10:00 AM – 5:00 PM) as teleconference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

6th Working Group meeting on Historical Control Data

10 May 2023
10:00-17:00
MINUTES – Agreed on 05 Jun 2023

Location: EFSA - Parma (Meeting Room FMT 00/M17) and web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Martin Wilks (Chair)
- Hearing Expert[1]:
Emily Mcvey
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Ana-Andreea Cioca, Anna Lanzoni

Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato
- ECHA:
Chiara Perazzolo

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[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. With regard to this meeting, Tamara COJA orally declared the following interest: Project Coordinator (on behalf of the Austrian Agency for Health and Food Safety (AGES) as beneficiary) of an EFSA grant (GP/EFSA/FDP/2022/02) on GLP criteria covering different regulatory areas within EFSA's remit. In addition, Ian Dewhurst orally declared the following interest: peer reviewing a scheme for the UK Food Standard Agency on the screening of chemical contaminants found in food of non-animal origin. In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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 expert concerned.

[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

4. Scientific topic(s) for discussion

The Working Group discussed a proposed decision tree on the evaluation of the HCD and their integration in the index study.

The list of possible confounding/covariates aspects related to HCD interpretation were discussed for agreement by the Working Group.

Information on the use of HCD by FDA as well as related data submission were presented and discussed.

Tasks for the drafting of sections in the Scientific Opinion were allocated.

5. Any Other Business

The Working Group updated the calendar of meetings for 2024.

6. Next meeting

The next meeting will be held on 6 (PM) and 7 (full day) July 2023 in Parma.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

5th Working Group meeting on Historical Control Data

15 Mar 2023
10:00-17:00
MINUTES – Agreed on 05/04/2023

Location: EFSA - Parma (Meeting Room FMT 00/M17) and web conference

Attendees:

- Working Group Members:
Tamara Coja, Peter Craig, Ian Dewhurst, Martin Wilks (Chair)
- Hearing Expert[1]:
Emily McVey
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Ana-Andreea Cioca, Anna Lanzoni

Methodology and Scientific Support (MESE) Unit: Laura Martino
- ECHA:
Chiara Perazzolo

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[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.

4. Hearing Expert(s)

Emily McVey, regulatory ecotoxicologist at the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), was invited to share experience on the use of HCD in the context of ecotoxicity studies.

[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

5. Scientific topic(s) for discussion

Statistical considerations applied to two pesticides case studies (continuous and dichotomous data) were presented and discussed by the Working Group. It was agreed to prepare a draft flowchart to start discussing decision-making process on the evaluation and integration of HCD.

The Working Group discussed the main feedback collected during the technical hearing organized in Jan, as well as any follow-up action needed.

A list of possible confounding/covariates aspects related to HCD interpretation were presented and discussed by the Working Group.

Sections drafted in the Scientific Opinion were commented on and tasks were allocated for further development of the output.

In the end, the Working Group was updated on the project planning and the need to postpone the deadline to November 2024 for the adoption of the Scientific Opinion was agreed.

6. Any Other Business

The Working Group agreed the calendar of meetings for 2024.

7. Next meeting

The next meeting will be held on 10 May 2023 (web conference).

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES/PESTICIDE PEER REVIEW UNIT

4th Working Group meeting on Historical Control Data

24 January 2023
09:00-17:30
MINUTES – Agreed on 13/02/2023

Location: EFSA - Parma (Meeting Room FMT 00/M17) and web conference

Attendees:

- Working Group Members:
  Tamara Coja, Peter Craig, Ian Dewhurst, Martin Wilks (Chair)
- Hearing Experts[1]:
  Manon Beekhuijzen, Arjan Polman, Donald Stump, Robert Wally, Emily McVey
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Ana-Andreea Cioca, Anna Lanzoni
  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato
- ECHA:
  Chiara Perazzolo

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[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.

4. Hearing Expert(s)

Manon Beekhuijzen, Arjan Polman, Donald Stump and Robert Wally were invited from Charles River Laboratories to share their experience on HCD availability, requirements, formatting and analysis during agenda item 4.

Emily Mcvey, regulatory ecotoxicologist at the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), was invited to share information on the submission and use of HCD in the context of ecotoxicity studies.

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[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

5. Scientific topic(s) for discussion

The Working Group received information on how HCD are compiled and analysed in a test facility. The Working Group discussed on the level of information that would be needed (individual data, summary data) and on the statistical methods for the evaluation of HCD and their integration in the index study. Statistical considerations applied to a case study (incidence in follicular cell adenoma and other tumours in carcinogenicity study with a pesticide active substance) were presented and discussed.

An overview on the use of HCD in ecotoxicology studies was presented and discussed.

Sections drafted in the Scientific Opinion were commented and tasks were allocated for further development of the output.

6. Any Other Business

The Working Group agreed that the physical meeting in Jun will be organised on the 6th (PM) and 7th (AM -PM).

7. Next meeting

The next meeting will be held on 15 March 2023 (web conference).

PESTICIDE PEER REVIEW UNIT

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES: PESTICIDE PEER REVIEW UNIT

MINUTES OF THE 3RD MEETING OF THE WORKING GROUP ON HISTORICAL CONTROL DATA

Held on 29 November 2022 (teleconference)

(Agreed on 14 December 2022)

Participants

- Working Group Members:

  Tamara Coja, Peter Craig, Ian Dewhurst, Martin Wilks (Chair)

- Hearing Experts[1]:

  Not Applicable

- European Commission and/or Member States representatives:

  Not Applicable

- EFSA:

  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Ana-Andreea Cioca, Anna Lanzoni, Andrea Terron

  Methodology and Scientific Support (MESE) Unit: Laura Martino, Sara Levorato

- Others:

  Not Applicable

[1] As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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[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.

4. Scientific topic(s) for discussion

Examples of historical control data (HCD) integration in the index studies conducted with pesticides and biocides were discussed. A summary was presented on statistical considerations of HCD from relevant literature identified from the grant as well as further literature.

The Working Group agreed on the need to receive information from a test facility on how HCD are compiled, analysed and presented. A technical hearing will be therefore organised in a next Working Group meeting.

Elements to be developed in the Introduction chapter of the Scientific Opinion were discussed. Drafted sections under the Data and Methodology as well as Assessment chapters were commented, and tasks allocated for the next meeting.

5. Next meeting(s)

The next Working Group meeting (teleconference) is scheduled for **24 January 2023**.

[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

PESTICIDE PEER REVIEW UNIT

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

MINUTES OF THE 2ND MEETING OF THE WORKING GROUP ON HISTORICAL CONTROL DATA

Held on 28 October 2022 (teleconference)

(Agreed on 11 November 2022)

Participants

- Working Group Members:

  Tamara Coja, Peter Craig, Ian Dewhurst, Martin Wilks (Chair)

- Hearing Experts[1]:

  Not applicable

- European Commission and/or Member States representatives:

  Not applicable

- ECHA

  Chiara Perazzolo

- EFSA:

  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Ana-Andrea Cioca, Anna Lanzoni, Andrea Terron

  Methodology and Scientific Support (MESE) Unit: Laura Martino

[1] As defined in Article 15 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/sites/default/files/corporate_publications/files/expertselection.pdf

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[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.

4. Scientific topic(s) for discussion

The background information and the terms of reference of the mandate were presented to the new expert, Peter Craig.

Some examples on historical control data (HCD) reporting and use for biocides and pesticides were presented for discussion. The Working Group, supported by these examples, finalised the interpretation of the terms of references as well as the formulation of assessment questions and sub-questions. The methodology to be used for the development of the Scientific Opinion was also discussed and agreed.

The structure of the Scientific Opinion was defined with some tasks allocation for the next meeting.

5. Next meeting

The next Working Group meeting (teleconference) is scheduled for **29 November 2022**.

[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

PESTICIDE PEER REVIEW UNIT

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

MINUTES OF THE 1st MEETING OF THE WORKING GROUP ON HISTORICAL CONTROL DATA

Held on 8 September 2022 (teleconference)

(Agreed on 16 September 2021)

Participants

- Working Group Members:
  Tamara Coja, Ian Dewhurst, Martin Wilks (Chair)

- Hearing Experts:
  Not Applicable

- European Commission and/or Member States representatives:
  Not Applicable

- ECHA:
  Chiara Perazzolo

- EFSA:
  Pesticide Peer Review (PREV) Unit: Arianna Chiusolo, Anna Lanzoni
  Methodology and Scientific Support (MESE) Unit: Laura Martino

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 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. At the beginning of the meeting an interest related to agenda item 5 was declared orally by Tamara Coja, as team member of the beneficiaries for the grant GP/EFSA/ENCO/2020/02. The Chair asked Tamara to disconnect from the web-conference after the presentation of the project outcomes and clarifications requested.

4. Scientific topic(s) for discussion

EFSA introduced the mandate for the Plant Protection Products and their Residues (PPR) Panel to develop a Scientific Opinion on use and reporting of historical control data (HCD) for regulatory studies. The background information and the terms of reference were presented and discussed.

The Working Group was informed about the outcomes from the preparatory tasks (qualitative evaluation of literature on HCD and publicly HCD databases, stakeholders' survey and stakeholders' workshop) performed under the partnering grant GP/EFSA/ENCO/2020/02[3]. The main issues on the reporting, use and interpretation of HCD in (eco)toxicity studies, as captured through the grant, were presented for further consideration in the context of the Scientific Opinion.

The terms of references of the mandate were discussed for interpretation by the Working Group, that also formulated assessment questions and sub-questions.

The planning for the finalisation of the Scientific Opinion (by end November 2023) was presented and agreed by the Working Group.

5. Next meeting(s)

The next Working Group meeting is scheduled for **28 October 2022**.

[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] https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2022.EN-7558