PESTICIDES PEER REVIEW UNIT

10th Working Group meeting on Toxicological properties and MRL of acetamiprid and its metabolites

25 October 2023
9:00-15:00
MINUTES – Agreed on 17 November 2023

EUROPEAN FOOD SAFETY AUTHORITY

Location: Teleconference

Attendees:

- Working Group Members:
Tamara Coja, Antonio Hernández-Jerez, Martin Paparella, Anna Price
- Hearing Experts[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
PREV Unit: Katia Chukwubike, Jochem Louisse, Iris Mangas, Andrea Terron

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with the change that item 13 will be discussed in the next working group (WG) meeting.

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.

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, DoI of Tamara Coja and Antonio Hernandez Jerez were under assessment by EFSA, but still valid at the time of the WG meeting. At the beginning of the meeting, they made an oral statement indicating that they had no interest to declare related to the items of the WG agenda, and EFSA did not identify any conclict of interest.

IV. Scientific topic(s) for discussion

a. ITEM 4. Appraisal of the academic data submitted in extension of the mandate: in vivo and in vitro

The appraisals of the in vitro and in vivo studies were presented, discussed, and agreed upon.

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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

b. ITEM 5. Appraisal of the academic data submitted in extension of the mandate: HOS

The appraisals of the in human observational studies were presented, discussed, and agreed upon.

c. ITEM 6. Uncertainty analysis of the new evidence: EKE

An uncertainty analysis of the new in vitro, in vivo and human observational studies was performed by the WG using an expert knowledge elicitation.

d. ITEM 7. Section 2.1.3.6 Statement. Postulated AOP informed IATA for acetamiprid and uncertainties.

The postulated AOP-informed IATA as described in the statement document was discussed and agreed upon.

e. ITEM 8. Finalization of the new section of the statement containing the additional evidence provided in the extension of the mandate for acetamiprid

Agreements were made regarding the finalization of the section of the statement document describing the assessment of the new in vitro, in vivo and human observational studies.

V. Plan for next steps

The plan proposed by EFSA was presented to the WG, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

PESTICIDES PEER REVIEW UNIT

9th Working Group meeting on Toxicological properties and MRL of acetamiprid and its metabolites

6 July 2023
09:00-13:00

MINUTES – Agreed on 19 July 2023

Location: Hybrid meeting (EFSA, Parma - Teleconference)

Attendees:

- Working Group Members:
Tamara Coja, Jerome Henri, Antonio Hernández-Jerez, Martin Paparella, Anna Price
- Hearing Experts[1]:
Not Applicable
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
PREV Unit: Katia Chukwubike, Jochem Louisse, Iris Mangas, Andrea Terron

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with the change that item 13 will be discussed in the next WG meeting.

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.

IV. Scientific topic(s) for discussion

a. Finalization report

The draft report was presented, discussed and amended upon agreement of the whole WG.

V. Plan for next steps

The plan proposed by EFSA was presented to the working group, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

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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

PESTICIDES PEER REVIEW UNIT

8th Working Group meeting on Toxicological properties and MRL of acetamiprid and its metabolites

26-27 June 2023
26 June: 14:00-18:00, 27 June: 8:00-17:00
MINUTES – Agreed on 19 of July 2023

Location: Hybrid meeting (EFSA, Parma - Teleconference)

Attendees:

- Working Group Members (all attended 26 June: 14:00-18:00 and 27 June: 8:00-17:00): Tamara Coja, Jerome Henri, Antonio Hernández-Jerez (Chair), Martin Paparella, Anna Price
- Hearing Experts[1]:
Kelly Carsten (attended 27 June: 13:30-15:00), Kevin Crofton (attended both days), Mary Gilbert (attended only on 26 June: 14:00-18:00), Marcel Leist (attended 27 June only), Ans Punt (attended 26 June: 14:00-18:00 and 27 June: 8:00-17:00)
- European Commission and/or Member States representatives:
Not Applicable
- EFSA:
PREV Unit: Lucien Ferreira de Costa (attended the first day), Jochem Louisse, Iris Mangas, Andrea Terron

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with the change that item 13 will be discussed in the next working group (WG) meeting.

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.

IV. Scientific topic(s) for discussion

a. ITEM 4: Brief introduction to the meeting and to the Uncertainty Analysis

As introduction to the meeting, the background of the mandate and the interpretation of ToR1 was presented, together with the methodological approach taken. Also, the methodology for data integration and uncertainty analysis were presented. A general overview of the outcome was shown. EFSA explained the expert knowledge elicitation (EKE) procedure that will be followed to come to a conclusion on the in vivo and in vitro evidence made available to the WG.

[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

b. ITEM 5. In vivo DNT: BoE public literature and appraisal summary; Regulatory study appraisal and summary Hearing experts. Other uncertainties on the in vivo data: Positive control and controls variability (hearing experts)

An overview of the available in vivo studies from the open literature and of the available study performed according to EPA OPPTS Guideline 870.6300 (albeit with deviations), as well as the outcomes of the RoB assessment were presented. Hearing experts provided their analysis of the positive control data and Historical Control Data.

c. ITEM 6. Assessment question 2b (in vivo). Based on the in vivo available evidence for DNT hazard characterization and integrated following an AOP-informed IATA conceptual framework, are the current HBGVs for acetamiprid and IM2-1 protective for the most sensitive population (foetus, and children)?

d. ITEM 7. In vivo evidence conclusion and recommendations for filling the gaps.

Item 6 and item 7 were discussed using the EKE methodology. The EKE procedure allowed the WG to conclude on the available in vivo evidence. Final wording of description of the available in vivo evidence and related uncertainties was agreed upon.

e. ITEM 8. WG and hearing expert: What would be in your expert view the minimum dataset to complete the PBK/reverse dosimetry analysis to answer questions 1 and 3?

An overview of the PBK modelling work was presented to the WG. The WG concluded that the available kinetic data are too limited to develop a sufficiently robust PBK model for acetamiprid and IM-2-1. A hearing expert was asked to provide insight into the kinetic data that would be required to develop a sufficiently robust PBK model for this case on acetamiprid and IM-2-1.

f. ITEM 9. In vitro DNT: BoE public literature and appraisal summary, DNT IVB results, Other uncertainties on the in vitro data: relevance of the test systems

The results of the systematic literature search and RoB appraisal for the in vitro DNT studies on acetamiprid were presented. Also, the impact of uncertainty in the presence of functional nAChR subunits in in vitro models for data interpretation was discussed.

g. ITEM 10. DNT IVB from US EPA ToxCast data analysis for neonicotinoids and nicotine (hearing expert)

A hearing expert presented the procedure of DNT IVB data extraction from the CompTox Chemicals Dashboard, and how to evaluate these data for nicotine, acetamiprid, and other neonicotinoids.

h. ITEM 11. Question for the hearing expert: 1. To present the results of Losser (2021a, 2021b) and what would be the recommended figure to be used as PoD, if possible. 2. Which additional tests (appropriate test systems and test methods) would the author recommend for measuring downstream KEs of altered neurodevelopment in vitro.

A hearing expert was asked to provide more insight on the findings reported by Loser et al. (2021a and 2021b) and his view on possible relevant readouts related to downstream key events relevant for nAChR activation, increase in intracellular cellular calcium and nAChR desensitization.

i. ITEM 12. In vitro evidence conclusion and recommendations for filling the gaps.

The EKE procedure was followed to come to a conclusion on the available in vitro evidence. Final wording of description of this evidence and related uncertainties was agreed upon.

V. Plan for next steps

The plan proposed by EFSA was presented to the WG, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

VI. Next meeting

The next meeting (hybrid) will be held on 6 July 2023, from 9:00 to 13:00.

PESTICIDES PEER REVIEW UNIT

7th Working Group meeting on Toxicological properties and MRL of Acetamiprid and its metabolites

12 May 2023
09:00-15:00
MINUTES - Agreed on 23 May 2023

Location: Webconference

Attendees:

- Working Group Members:
  Tamara Coja, Jérôme Henri, Antonio Hernandez (Chair), Martin Paparella, Anna Price
- Hearing Experts[1]:
  Ans Punt
- European Commission and/or Member States representatives:
  Not applicable
- EFSA:
  PREV unit: Katia Chukwubike, Jochem louisse, Iris Mangas, Andrea Terron

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted.

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.

With regard to this meeting, Dr. Tamara COJA 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. It was noted that the EFSA grant falls outside the scope/remit of this Working Group. In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, 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.

[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. Scientific topic(s) for discussion

a. Update In vivo DNT assessment

The appraisal of the in vivo DNT study was presented and discussed. Remaining issues related to the study were identified and related action points defined.

b. nAChR ontogeny

An overview of available scientific knowledge about nAChR expression in rat and human brain (development) was presented and discussed by the WG.

c. DNT IVB nAChR expression

An overview of available scientific knowledge about nAChR expression in in vitro test systems relevant for DNT assessment was presented and discussed by the WG.

d. Progress PBK model development

The progress of PBK development was presented and discussed. It was concluded by the WG that the available kinetic data are too limited to develop a sufficiently robust PBK model to answer the PBK modelling-related questions. This was in line with the view of the hearing expert.

e. Plans reporting PBK modelling

The plans for reporting of the PBK modelling work were presented, discussed and agreed upon.

f. Results of the appraisal and data extraction of kinetic studies

There was no time to discuss the appraisal and data extraction of the kinetic studies. This will be postponed to the next WG meeting.

V. Plan for next steps

The plan proposed by EFSA was presented to the working group, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

VI. Next meeting

The next meeting will be held in EFSA premises on **26 June 14:00-18:00** to **27 June 9:00 – 18:00**.

Annex I

(depending on the interest declared and number of the Annexes adapt numbering)

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 (adapt numbering according to specific situation)

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

PESTICIDES PEER REVIEW UNIT

6th Working Group meeting on Toxicological properties and MRL of acetamiprid and its metabolites

5 May 2023
13:30-17:30
MINUTES – Agreed on 15 May 2023

Location: Hybrid meeting (EFSA - Webconference)

Attendees:

- Working Group Members:
  Tamara Coja, Martin Paparella
- Hearing Experts[1]:
  Not Applicable
- European Commission and/or Member States representatives:
  Not Applicable
- EFSA:
  PREV Unit: Katia Chukwubike, Jochem Louisse, Iris Mangas

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[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.

IV. Scientific topic(s) for discussion

a. Results of the CAT and conflict resolution

The conflicts among experts on the Critical Appraisal Tool were discussed and resolved. The results will be summarized and presented in the next WG 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] 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

V. Plan for next steps

The plan proposed by EFSA was presented to the working group, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

VI. Next meeting

The next meeting will be held on **12 May 2023**, from **9:00** to **15:00**, 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. Tamara COJA 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. It was noted that the EFSA grant falls outside the scope/remit of this Working Group.

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 not deemed to represent a Conflict of Interest for the expert 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

PESTICIDES PEER REVIEW UNIT

5th Working Group meeting on Toxicological properties and MRL of acetamiprid and its metabolites

12 April 2023
09:00-13:00
MINUTES

Location: Webconference

Attendees:

- Working Group Members:
  Tamara Coja, Jerome Henri, Antonio Hernandez (chair), Martin Paparella, Anna Price
- Hearing Experts[1]:
  Anna Beronious, Susanne Hougaard Bennekou
- European Commission and/or Member States representatives:
  Not applicable
- EFSA:
  PREV Unit: Katia Chukwubike, Jochem Louisse, Iris Mangas

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Bertrand Desprez.

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.

IV. Scientific topic(s) for discussion

a. Data collection and extraction kinetic studies

The data collection and extraction of kinetic studies (including their appraisal) to be applied for PBK model development/evaluation were presented and next steps were discussed and agreed on.

b. 4.2 Progress PBK modelling

The progress on PBK modelling was presented and next steps were discussed and agreed on.

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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

c. 4.3 SciRAP tool

The SciRAP tool was presented by Anna Beronious. Questions from the WG members and EFSA about SciRAP were discussed.

d. 4.4 AOP-informed IATA

The AOP-informed IATA on DNT of acetamiprid (OECD case study) was presented by Susanne Hougaard Bennekou. Questions from the WG members and EFSA about the OECD case study were discussed.

V. Plan for next steps

The plan proposed by EFSA was presented to the working group, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

VI. Next meeting

The next meeting will be held online on **12 May 2023** from **9:00** to **15:00**.

PESTICIDES PEER REVIEW UNIT

4th Working Group meeting on Toxicological properties and MRL of acetamiprid and its metabolites

24th March 2023
09:00-13:00
MINUTES – Agreed on 18 April 2023

Location: Webconference

Attendees:

- Working Group Members:
  Jérôme Henri
- Hearing Experts[1]:
  Not Applicable
- European Commission and/or Member States representatives:
  Not applicable
- EFSA:
  PREV Unit (chair): Jochem Louisse, Iris Mangas

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted with small modifications.

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.

IV. Scientific topic(s) for discussion

a. Data collection and extraction kinetic studies

EFSA presented the data collection and extraction to the WG member, who agreed on the approach

b. Appraisal kinetic studies

The plan for appraisal of kinetic studies was discussed and agreed upon.

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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

c. Questions related to PBK modelling in the IATA case study

The WG member presented the questions prepared related to the PBK modelling work of the IATA case study.

d. Progress PBK modelling PK-SIM

The WG member presented the progress made on the PBK modelling work. Further steps to be presented in the next WG meeting were agreed upon.

V. Plan for next steps

Based on the discussions, tasks were defined, deadlines were agreed, which were allocated to the WG member and EFSA Staff.

VI. Next meetings

The next meeting will be held online on **12 April 9:00-13:00** and **13 April 10:00-14:00**

PESTICIDES PEER REVIEW UNIT

3rd Working Group meeting on Toxicological properties and MRL of acetamiprid and its metabolites

23rd March 2023
09:00-13:00
MINUTES – Agreed on 18 April 2023

Location: Webconference

Attendees:

- Working Group Members:
  Tamara Coja
  Martin Paparella

- Hearing Experts[1]:
  Not Applicable

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

- EFSA:
  PREV Unit (Chair): Iris Mangas

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Bertrand Desprez.

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.

IV. Scientific topic(s) for discussion

a. Results of the CAT and conflict resolution

The conflicts among experts on the Critical Appraisal Tool were discussed. There was no time to finalize due to the complexity of the study and the need of checking several documents.

b. Results of the DNT assessment

There was no time to discuss this point and a new ad hoc WG meeting was planned.

[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

V. Plan for next steps

The plan proposed by EFSA was presented to the working group, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

VI. Next meeting

The next meetings will be held online on **24 March 2023** from **9:00 – 13:00**; **12 April 9:00-13:00 and 13 April 10:00-14:00**

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

2nd Working Group meeting on Toxicological properties and MRL of Acetamiprid and its metabolites

27-28 February 2023
14:00-18:00 - 09:00-18:00
MINUTES - Agreed on 14 March 2023

Location: EFSA - Parma

Attendees:

- Working Group Members:
  Antonio F. Hernandez-Jerez (Chair)
  Anna Price
  Tamara Coja
  Jerôme Henri
  Martin Paparella

- Hearing Experts[1]:
  Not Applicable

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

- EFSA:
  PREV Unit: Andrea Terron, Iris Mangas, Katia Chukwubike (only on 27th), Jochem Louisse

I. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Bertrand Desprez.

II. Adoption of agenda

The time schedule of the days was proposed to be slightly modified (first day: 14.00-18.30, second day: 8.30-17.00), which was agreed upon by the working group. An agenda item was added to discuss a suggested amendment of assessment question 1. The agenda was adopted with these changes.

III. 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.

IV. Scientific topic(s) for discussion

4.1 Proposed change assessment question 1

[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

Assessment question 1 in the protocol was slighted modified for more clarity of the translation of the ToRs. All experts agreed.

4.2 Quality assessment of the Biomonitoring data of acetamiprid

All experts agreed with the methodology proposed and results of the appraisal of the human biomonitoring studies

4.3 PBK plan and workflow

All experts agreed with the proposed protocol for the PBK analysis. It was agreed that EFSA should explore the possibility to have an additional expert/hearing expert on PBK to complement the expertise of this critical part of the assessment of the WG.

4.4 Report of the task assigned for in vivo, in vitro and zebrafish BoE: endpoint identification

It was decided to postpone the presentation about expression/ontogeny of nAChR in rodents/humans to the next meeting.

The data extraction for in vivo, in vitro and zebrafish evidence was discussed and agreed. The data set will be included as an appendix of the report as concluded by the WG meeting.

The appraisal of the in vitro and in vivo public literature studies was finalized, discussed and agreed by all the experts. There was no time to finalize the appraisal of the in vivo regulatory study and a new WG meeting will be organized for this purpose. There was no time for finalizing the appraisal of zebrafish studies and it was decided that EFSA staff will do this work.

4.5 Report break-out sessions

Breakout sessions (3) were organized to 1) appraise the in vivo studies, 2) appraise the in vitro and zebrafish studies, and 3) to develop the step-wise approach of PBK model development. At the end of the meeting the different break-out groups reported back to the whole working group.

V. Plan for next steps

The plan proposed by EFSA was presented to the working group, agreed on and accepted. The critical steps that would guide the planned timeframe were defined. In this regard, deadlines were agreed, and new tasks were allocated to the WG members and EFSA Staff.

VI. Next meeting

The next meeting will be held on **23 March 2023** from **09:00** to **13:00**, via webconference.

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

1st Working Group meeting on Toxicological properties and MRL of Acetamiprid and its metabolites

27 January 2023
09:00-13:00
MINUTES - Agreed on 17 February 2023

Location: Web-conference

Attendees:

- Working Group Members:

Antonio Hernández-Jerez (Chair), Anna Price, Tamara Coja, Bertrand Desprez, Jerome Henri, Martin Paparella

- Hearing Experts[1]:

Not Applicable

- European Commission and/or Member States representatives:

Not Applicable

- EFSA:

Iris Mangas, Andrea Terron and Katia Chukwubike

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[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.

IV. Scientific topic(s) for discussion

ToRs and interpretation of the ToRs

The WG agreed on the interpretation of the ToRs and assessment questions.

[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

Protocol for the assessment

The WG agreed with the proposed methodology and protocol for the assessment.

Biomonitoring data and relevance for the risk assessment of acetamiprid

The WG discussed the results of the systematic literature review as conducted by EFSA and the methodology for further relevance and reliability assessment.

Plan for next steps

The critical steps that would guide the planned timeframe were defined. In this line deadlines were agreed, and the new tasks allocated to the WG members and EFSA Staff.

V. Next meeting

The next meeting will be held by teleconference on the 27 February 2023 from 14:00 – 18:00 / 28 February 2023 from 09:00 – 18:00.