

10 June 2025 (09:00-13:00)

MINUTES – Agreed on 18 June 2025

Location: EFSA - Parma Webconference

Attendees:

○ **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Denise Bloch, Francesca Metruccio

○ **Hearing Experts¹:**

Tamara Coja (PPR Panel Chair)

○ **European Commission and/or Member States representatives:**

None

○ **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas

Methodology and Scientific Support (MESE) Unit: Isabelle Delaunois, Justine Dastouet

○ **Others:**

None

I. Welcome and apologies for absence

The Chair welcomed the WG members and Tamara Coja, who, in her capacity as Chair of the PPR Panel, contributed to the discussion on the eligibility criteria and search string for the second phase of the Mandate.

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 and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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



In October 2024, the Acting Executive Director of EFSA granted a DoI waiver to Denise Bloch as regards her participation as Member of the PPR Panel WG on Methodologies in assessing long-term toxicity and carcinogenicity of plant protection products.

IV. General update

a. Outcome of the 131st PPR Panel plenary (29-30 April 2025)

An update on the progress of the mandate and an overview of the statement and annexes were presented to the Panel for possible endorsement.

To further investigate the whole-mixture approach, EFSA formally requested an extension in December 2024. On 9 April, the Parliament officially agreed to extend the deadline for this mandate to the end of April 2026.

Given the expanded scope, the work has been split into two phases:

- The first phase focuses on the component-based approach, including interactions between different components within plant protection products.
- The second phase will concentrate on the whole-mixture approach.

At the 131st PPR Panel plenary, the current draft statement and annexes related to the first phase were discussed and endorsed by the Panel. The final statement will be proposed for adoption and published upon completion of the second phase in April 2026.

b. Indicative timeline for the second phase of the EP Mandate

After the 11th WG meeting, the next step will be dedicated to the screening and data extraction exercise that would be addressed separately by external experts and EFSA. Beginning of 2026, the WG will discuss the results and update the statement and annexes accordingly.

V. Revised version of the protocol

The WG discussed the search strategy, eligibility criteria, variables and values that will be used for the data extraction related to the whole-mixture approach. Revisions were made directly within the shared file, and changes are reflected in the new version of protocol.

VI. Any Other Business

Action points for completing the revised protocol were identified and distributed to the WG members.

VII. Next steps

An overview of the second phase for this mandate will be provided to the Panel at the 132nd PPR Panel plenary (25-26 June 2025).

The screening and data extraction exercise will be carried out by EFSA and external experts. The Working group members may be consulted on specific questions.

The next WG meeting is scheduled for 7 January 2026.

3 April 2025

09:00-13:00

MINUTES - Agreed on 29 April 2025

Location: EFSA – Parma Web conference

Attendees:

○ **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Denise Bloch, Francesca Metruccio

○ **Hearing Experts¹:**

Not Applicable

○ **European Commission and/or Member States representatives:**

Not applicable

○ **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas

Methodology and Scientific Support (MESE) Unit: Laura Ciccolallo, Justine Dastouet

○ **Others:**

Not applicable

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 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.

In October 2024, the Acting Executive Director of EFSA granted a DoI waiver to Denise Bloch as regards her participation as Member of the PPR Panel WG on Methodologies in assessing long-term toxicity and carcinogenicity of plant protection products.

¹ As defined in Article 34 of the document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups":
<https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf>

² 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. General update

Post-meeting note: on 9 April 2025, the European Parliament formally agreed to extend the deadline to the end of April 2026. As a result, the work will continue with the whole-mixture approach (second phase), and the draft statement will be updated to reflect the outcomes of the second phase of the Mandate. The present statement under discussion reflects the outcome of the first phase of this Mandate (component-based approach).

The EFSA request and Parliament's reply are available on Open EFSA, in the supporting documents: <https://open.efsa.europa.eu/question/EFSA-Q-2024-00432>

V. Draft Statement and Annexes: comments following review

Revisions were made to specifically address the comments raised in the draft statement and Annexes by the PPR Panel and internal reviewers. The draft statement and Annexes were amended live based on the discussion.

VI. Any Other Business

The WG was invited to address remaining open points with the aim of providing a clean version of the draft statement and Annexes in view of the endorsement by the PPR Panel end of April 2025.

VII. Next meeting

The 131st PPR Panel plenary is scheduled from 29-30 April 2025 where the draft statement and Annexes will be proposed for endorsement.



**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
9th Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



6 March 2025 (09:00-13:00)
MINUTES – Agreed on 19 March 2025

Location: Teleconference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Denise Bloch, Francesca Metruccio

- **Hearing Experts¹:**

None.

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Elisa Aiassa, Laura Ciccolallo, Justine Dastouet

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the WG members.

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 and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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



In October 2024, the Acting Executive Director of EFSA granted a DoI waiver to Denise Bloch as regards her participation as Member of the PPR Panel WG on Methodologies in assessing long-term toxicity and carcinogenicity of plant protection products.

4. Assessment and drafting of the output

The Working Group reviewed the methodologies identified through primary and secondary research studies, discussing their inclusion and exclusion based on eligibility criteria. A description of the general principles of the selected methodologies were refined and incorporated into the draft statement.

Additionally, the Working Group evaluated the revised visuals and determined which ones to retain in the draft statement. Outstanding points in the draft were reviewed, and the remaining sections were assigned for further drafting.

5. Other Business

The PPR Panel reviewers will review the draft statement and background documents by 20 March. The comments will be discussed at the 10th Working Group meeting on 3 April 2025.



**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
8th Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



27 February 2025 (14:00-18:00)
MINUTES – Agreed on 7 March 2025

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Denise Bloch, Francesca Metruccio

- **Hearing Experts¹:**

None.

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Elisa Aiassa, Laura Ciccolallo, Justine Dastouet

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the WG members.

2. Adoption of agenda

The agenda was adopted without changes. Apologies were received from Denise Bloch.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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In October 2024, the Acting Executive Director of EFSA granted a DoI waiver to Denise Bloch as regards her participation as Member of the PPR Panel WG on Methodologies in assessing long-term toxicity and carcinogenicity of plant protection products.

4. Discussion

Outcome of the data extraction exercise and secondary search studies

EFSA provided an update on the data extraction exercise. During the full text screening phase, publications were categorised into four lines of evidence. The majority of the studies fall under the in vitro and in vivo lines of evidence. Some publications were classified under multiple lines of evidence based on the methods used in the studies.

A quality control on the data extracted is underway and is expected to be finalised by the next WG meeting. Following data extraction, new methodologies identified from the primary and secondary research studies will be evaluated by the Working Group.

Structure of the visual

The Working Group discussed and agreed on structure of the visuals, opting for tables and pie charts. Legends and footnotes will be added to guide the reader through the visuals. The finalised visuals will be prepared for review by the next WG meeting.

Draft statement

The WG reviewed the draft statement and assigned sections for further drafting.

5. Other Business

The 9th WG meeting is scheduled for 6 March 2025. The WG will review the visuals and address open points in the draft statement.



**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
7th Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



7 February 2025 (10:00-17:00)
MINUTES – Agreed on 17 February 2025

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Denise Bloch, Francesca Metruccio

- **Hearing Experts¹:**

None.

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Laura Ciccolallo, Justine Dastouet

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the WG members.

2. Adoption of agenda

The agenda was adopted without changes. Apologies were received from Denise Bloch.

3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, 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.

In October 2024, the Acting Executive Director of EFSA granted a DoI waiver to Denise Bloch as regards her participation as Member of the PPR Panel WG on Methodologies in assessing long-term toxicity and carcinogenicity of plant protection products.

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>



4. Outcome of the data extraction exercise and secondary search studies

A preliminary trial of the data extraction process was conducted over the past two weeks, during which each line of evidence was examined. The Working Group discussed and agreed upon the variables, values to be extracted, and the required level of detail. To ensure consistency, the data extraction will be repeated based on these agreements.

Additionally, the WG has identified various methodologies from the secondary search studies. The principles of these methodologies will be outlined in the draft statement.

5. Development of the visual

An example of the visual based on an actual sample was presented to the Working group. The interactive matrix includes the list of references at the bottom of the table where available, enabling direct access to full publications. The WG explored different approaches for structuring the data.

6. Other Business

6.1. Draft statement and Annexes

Annex A (i.e., protocol) and Annex B (i.e., outcome of the public consultation) have been created and proofread. Specific sections have been assigned to WG members to begin drafting.

6.2. WG meetings planning

An update on the progress of this Mandate will be presented to the Panel at the 130th PPR Panel Plenary meeting on 26 and 27 February 2025.

The next WG meeting is scheduled for 27 February (hybrid meeting).



**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
6th Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



22 January 2025 (10:00-17:00)
MINUTES – Agreed on 29 January 2025

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Denise Bloch, Francesca Metruccio

- **Hearing Experts¹:**

None.

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Justine Dastouet, Laura Ciccolallo

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the WG members.

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 and the Decision of the Executive Director on Competing Interest Management, 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.

In October 2024, the Acting Executive Director of EFSA granted a DoI waiver to Denise Bloch as regards her participation as Member of the PPR Panel WG on Methodologies in assessing long-term toxicity and carcinogenicity of plant protection products.

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>



4. Screening and data extraction exercise

Based on the protocol, circa 16 000 studies were collected from the selected data sources. The screening exercise started at the end of December and continued until mid-January. Three external experts and EFSA participated in this exercise.

The full text screening and data extraction phases are currently underway. The full texts of around 30 publications have yet to be collected. A number of studies have already been identified for inclusion and distributed into the lines of evidence in vivo, in vitro, in silico and human. A review of included studies will be carried out in parallel to ensure quality.

Secondary search studies have been collected. These studies represent the state of the art, a summary of the 'digested data' describing the available methodologies. The secondary search studies were distributed to the Working Group members in order to identify methodologies relevant to this work.

The Working Group also discussed the section on data visualization. The template described in the protocol in Section 3.5. was used as an example. EFSA has started testing the implementation in Power BI, a collaborative and interactive tool.

5. Draft statement

The WG discussed the structure of the draft statement and proposed ideas for the content of each section.

6. Any Other Business

Action points were distributed to the Working Group members. An update on the Mandate will be provided to the Panel at the 130th PPR Panel Plenary (26-27 February 2025).

The next WG meeting is scheduled for 7 February 2025 by teleconference.



**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
5th Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



27 November 2024 (14:00-18:00)
MINUTES – Agreed on 4 December 2024

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Francesca Metruccio

- **Hearing Experts¹:**

None.

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Justine Dastouet

- **Others:**

External experts (Observers): Selam Alemu, Anastasia Repouskou

1. Welcome and apologies for absence

The Chair welcomed the WG members. Apologies were received from Denise Bloch. The Chair welcomed the three external experts, Selam Alemu, Anastasia Repouskou, Stefano Ubbiali, that will support the Working Group with the screening and data extraction phase.

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 and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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4. Outcome of the public consultation

The WG members discussed the remaining comments submitted during the public consultation on the draft protocol.

5. Any Other Business

5.1. Agreement on action points

Comments have been allocated to WG members for a last revision. The WG members were invited to finalise the protocol in line with the replies to the comments.

5.2. Next steps

External experts and EFSA started the pilot exercise on a set of 500 publications. This aims to familiarize reviewers with the protocol. Divergent opinions during this pilot will be discussed to ensure alignment. If needed, WG members may be consulted for clarification.

The next WG meeting will be held on 22 January 2026 to begin the assessment and drafting of the final output.



**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
4th Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



22 November 2024 (13:00-17:00)
MINUTES – Agreed on 4 December 2024

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Francesca Metruccio

- **Hearing Experts¹:**

None.

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas, Manuela Tiramani
Methodology and Scientific Support (MESE) Unit: Elisa Aiassa, Laura Ciccolallo, Justine Dastouet, Isabelle Delaunois

- **Others:**

External experts (Observers): Selam Alemu, Anastasia Repouskou, Stefano Ubbiali

1. Welcome and apologies for absence

The Chair welcomed the WG members. Apologies were received from Denise Bloch and Susanne Bennekou. The Chair welcomed the three external experts, Selam Alemu, Anastasia Repouskou, Stefano Ubbiali, that will support the Working Group with the screening and data extraction phase.

Stefano Ubbiali, Anastasia Repouskou, and Selam Alemu have been invited to observe the deliberations and decisions of the Working group. As part of a pilot project, the external experts will contribute to addressing the initial literature screening and data extraction based on the revised protocol over the next few weeks.

The Chair also welcomed Manuela Tiramani, Head of Unit of PREV.

2. Adoption of agenda

The agenda was adopted without changes.

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>



3. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence and the Decision of the Executive Director on Competing Interest Management, 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. Outcome of the public consultation

During the public consultation, a total of 98 comments were received from various stakeholders, including NGOs, academia, Member States, and industries.

The Working Group members addressed part of the comments. Specifically, the inclusion of methodologies based on studies performed with the PPP alone have been extensively discussed. The aim of the Mandate is to provide comprehensive inventory of all existing methodologies, including both component-based approach and whole-mixture approach. In response to this request, the Working Group agreed to consider available methodologies that rely solely on data from the formulation itself (the whole-mixture approach concept), in addition to the proposed investigations (additivity, synergism). Furthermore, the Working group agreed with the broader definition of 'long term toxicity' potential as 'toxicity over chronic exposure, i.e., covering toxicological properties such as reproductive toxicity or neurotoxicity.

Further comments were addressed, and the protocol was amended accordingly.

5. Any Other Business

5.1. Agreement on action points

Due to the limited number of WG members, discussions on comments will continue at the next WG meeting.

5.2. Next steps

External experts and EFSA will conduct a pilot exercise for screening and data extraction from end of November to beginning of December (2 weeks) on a set of publications to test and get familiar with the protocol. Dedicated meetings with the external experts and EFSA are foreseen to guide them in the process.

The 5th WG meeting will be held on 27 November from 2 to 6 pm.



**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
3rd Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



22 October 2024 (10:00-17:00)
MINUTES – Agreed on 30 October 2024

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Francesca Metruccio

- **Hearing Experts¹:**

Denise Bloch (BfR) (10:00-17:00)

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Isabelle Delaunois, Elisa Aiassa

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the WG members and the hearing expert, Denise Bloch. Meeting participants briefly introduced themselves.

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 and the Decision of the Executive Director on Competing Interest Management, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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



4. Hearing expert

Denise Bloch was invited as hearing expert to share her expertise and comments on the draft protocol. Denise Bloch is employed in the German Federal Institute for Risk Assessment (BfR) and has recognised expertise and is the author of several publications in the field of regulatory toxicology, pesticide risk assessment and New Approach Methodologies-based risk assessment, in particular in the area of mixtures and coformulants. Based on her expertise in regulatory toxicity and pesticide risk assessment, as well as her relevant publications on the topic, Denise Bloch was invited to provide comments on the draft protocol.

5. Protocol finalisation and approval

The Working Group conducted a live review and modification of each section of the draft protocol, taking into account the discussion and feedback received. These revisions were made to specifically address the comments and concerns raised by the PPR Panel reviewers.

6. Any Other Business

6.1. Agreement on WG meeting dates

The 4th WG meeting is scheduled for **22 November 2024**. Comments from the public consultation will be discussed and systematic literature search will be conducted based on the final version of the protocol.

6.2. Agreement on action points

The WG was invited to address remaining open points with the aim of providing a clean version of the draft protocol in view of the endorsement by the PPR Panel.

6.3. Next steps

From 24 October to 28 October, to be confirmed: endorsement of the draft protocol by the PPR Panel via written procedure.

From 31 October to 21 November, to be confirmed: 3-week public consultation on the draft protocol for the systematic literature search. The public consultation will be opened for 3 weeks on Connect EFSA: <https://connect.efsa.europa.eu/RM/a0ITk000002f6WY>

It was noted that comments will be limited to the draft protocol itself; no data submissions will be requested.

**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
2nd Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



30 September 2024 (14:00-18:00)
MINUTES – Agreed on 18 October 2024

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Francesca Metruccio

- **Hearing Experts¹:**

Denise Bloch (BfR) (14:00-18:00)

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Isabelle Delaunois, Elisa Aiassa

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the WG members and the hearing expert, Denise Bloch. Meeting participants briefly introduced themselves.

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 and the Decision of the Executive Director on Competing Interest Management, 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.

The ADoI of Susanne Bennekou has been resubmitted for a new interest and is under assessment at EFSA level.

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>



4. Hearing expert

Denise Bloch was invited as hearing expert to share her expertise and comments on the draft protocol. Denise Bloch is employed in the German Federal Institute for Risk Assessment (BfR) and has recognised expertise and is the author of several publications in the field of regulatory toxicology, pesticide risk assessment and New Approach Methodologies-based risk assessment, in particular in the area of mixtures and coformulants. Based on her expertise in regulatory toxicity and pesticide risk assessment, as well as her relevant publications on the topic, Denise Bloch was invited to provide comments on the draft protocol.

5. Protocol refinement

The draft protocol was updated in real-time based on the working group's discussion.

The WG revisited the discussion on the problem formulation, specifically the types of components present in PPP to be included in the scope.

Furthermore, an overview of the search results was presented to the WG, detailing the number of studies retrieved using the following search terms.

The WG also refined the list of relevant endpoints, grouped by lines of evidence.

Finally, discussions focused on the data model and creation of the systematic evidence map. The proposed data model would serve as the foundation for creating an evidence map (i.e., a dynamic, interactive database of studies). The map will be structured in a table format, with selected variables used to classify the studies. For example, a key variable might be the lines of evidence with attributes such as in vitro, in vivo, etc.

6. Any Other Business

6.1. Agreement on action points

Action points were distributed among the WG experts with the aim of providing a clean version of the draft protocol by 11 October.

The protocol will then be shared with the PPR Panel reviewers for 1-week proof reading. Comments from PPR Panel reviewers will then be available to the WG for the third WG meeting.

6.2. Next WG meeting

Next WG meeting is planned on 22 October 2024 by teleconference.

**SCIENTIFIC PANEL ON
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**
1st Working Group meeting on methodologies in
assessing PPP long-term toxicity and carcinogenicity.



20 September 2024 (11:00-18:00)
MINUTES – Agreed on 4 October 2024

Location: Web-conference

Attendees:

- **Working Group Members:**

Martin Wilks (Chair), Susanne Bennekou, Francesca Metruccio

- **Hearing Experts¹:**

Denise Bloch (BfR) (11:00-18:00)

- **European Commission and/or Member States representatives:**

None

- **EFSA:**

Pesticides Peer Review (PREV) Unit: Mathilde Colas
Methodology and Scientific Support (MESE) Unit: Isabelle Delaunois, Elisa Aiassa

- **Others:**

None

1. Welcome and apologies for absence

The Chair welcomed the WG members and the hearing expert, Denise Bloch. Meeting participants briefly introduced themselves.

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 and the Decision of the Executive Director on Competing Interest Management, 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.

The ADoI of Susanne Bennekou has been resubmitted for a new interest and is under assessment at EFSA level.

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>



4. Hearing expert

Denise Bloch was invited as hearing expert to share her expertise and comments on the draft protocol. Denise Bloch is employed in the German Federal Institute for Risk Assessment (BfR) and has recognised expertise and is the author of several publications in the field of regulatory toxicology, pesticide risk assessment and New Approach Methodologies-based risk assessment, in particular in the area of mixtures and coformulants.

5. Presentation on mandate's ToRs and draft protocol

EFSA introduced the mandate from the European Parliament to conduct a scientific literature review of the available methodologies to assess the long-term toxicity and carcinogenicity of pesticide products, including those resulting from interactions in the product. The background information and the terms of references (ToRs) were presented to the experts. More specifically, the regulatory context, the work already carried out by EFSA and an overview of the timeline and steps applicable to this mandate were outlined.

6. Discussion on problem formulation & interpretation of ToRs

The WG reviewed the draft protocol, updating the document in real-time based on the discussion.

The discussion focused on several key aspects, including the interpretation of the mandate's terms of reference, which encompasses the inclusion of both primary and secondary research studies. Additionally, the WG examined the scope of the mandate, addressing factors such as the type of area, assessment methods, endpoints, target population, and exposure. Lastly, the WG delved into the problem formulation at hand.

The WG also reviewed the eligibility criteria for study selection for each line of evidence, as well as the criteria for selecting relevant studies. Additionally, the experts discussed the methodology for evidence retrieval and the search strategy.

It was noted that data collection will be outsourced to external experts. The use of tools such as Distiller SR and Distiller AI (for screening titles and abstracts, followed by human validation) was proposed.

7. Agreement of WG meeting minutes

The WG meeting minutes have been agreed.

8. Any Other Business

8.1. Agreement on WG meeting dates

The planning for the next WG meeting was shared and discussed with the Working Group. Next WG meeting is planned on the 30th of September 2024 by teleconference.