

**SCIENTIFIC PANEL ON  
PLANT PROTECTION PRODUCTS AND THEIR RESIDUES**  
5<sup>th</sup> 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 Experts<sup>1</sup>:**

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.

---

<sup>1</sup> 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 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**  
4<sup>th</sup> 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 Experts<sup>1</sup>:**

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.

---

<sup>1</sup> 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**  
3<sup>rd</sup> 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 Experts<sup>1</sup>:**

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.

---

<sup>1</sup> 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 4<sup>th</sup> 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**  
2<sup>nd</sup> 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 Experts<sup>1</sup>:**

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.

---

<sup>1</sup> 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**  
1<sup>st</sup> 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 Experts<sup>1</sup>:**

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.

---

<sup>1</sup> 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 30<sup>th</sup> of September 2024 by teleconference.