# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 13<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



29 October 2025 9:00-13:00 MINUTES - Agreed on 5 November 2025

Location: Webconference

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o EFSA:

Jochem Louisse (PREV; chair), Alicia Paini (MESE)

o Observer:

Muhammad Waqar Ashraf (ECHA)

## 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Discuss comments PPR Panel reviewers

The comments made by the PPR Panel reviewers were discussed and agreements were reached on how to tackle them. Only limited textual updates of the draft Scientific Opinion were considered necessary.

#### b. Next steps, task division

Further steps were identified to finalise the draft Scientific Opinion for submission to the PPR Panel for adoption and tasks were allocated among the WG members.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

## MEETING MINUTES – 29 October 2025 13<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

This is the final meeting of this WG.

# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 12<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



3 October 2025 9:00-13:00 MINUTES - Agreed on 13 October 2025

Location: Webconference

#### Attendees:

Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o EFSA:

Jean-Lou Dorne (CSO), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

o Observer:

None

## 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Discuss replies comments public consultation and updates document

The responses to the comments made during the public consultation were finalised and related updates of the Scientific Opinion were agreed.

#### b. Next steps, task division

Further steps were identified to finalise the draft Scientific Opinion for review by the PPR Panel and tasks were allocated among the WG members.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES – 3 October 2025 12<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

The next meeting will be held on 29 October 2025 (webconference).

# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 11<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



28-29 August 2025 13:00-18:00 / 9.00-16.00 MINUTES - Agreed on 8 September 2025

**Location**: EFSA - Parma (Meeting Room 00/M03)

#### Attendees:

Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o FFSA:

Jean-Lou Dorne (CSO), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

Observer:

Muhammad Waqar Ashraf (ECHA)

## 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Discuss comments public consultation and draft answers

The comments received during the public consultation were discussed by the WG. General agreements were reached by the WG members on how to reply to the comments received and whether adjustments of the draft Scientific Opinion were considered necessary.

#### b. Update PPR Panel

The WG discussed what information will be presented to the PPR Panel in the upcoming plenary meeting in September regarding the comments made in the public consultation and the related adjustments in the draft Scientific Opinion.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES – 28-29 August 2025 11<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



#### c. Planning, next steps, task division

The planning was discussed, and next steps were agreed. Tasks were allocated among the WG members.

## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

The next meeting will be held on 3 October (9.00-13.00) via web conference.

# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 10<sup>th</sup> Working Group meeting on QIVIVE DNT IVB

efsa EUROPEAN FOOD SAFETY AUTHOPITY

6 June 2025 9:00-13:00 MINUTES - Agreed on 23 June 2025

Location: Webconference

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o EFSA:

Jochem Louisse (PREV; chair)

o Observer:

None

## 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Discuss updates draft Scientific Opinion

The updates made in the draft Scientific Opinion based on the comments provided by the PPR Panel reviewers were discussed. Agreements were made to finalise the draft Scientific Opinion for evaluation of the PPR Panel for endorsement for public consultation.

#### b. Next steps, task division

Further steps were identified to finalise the draft Scientific Opinion and tasks were allocated among the WG members.

 $<sup>^{1}\,\</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf}$ 

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

## MEETING MINUTES – 6 June 2025 10<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

The next meeting will be held on 28-29 August 2025 at EFSA premises.

# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 9<sup>th</sup> Working Group meeting on QIVIVE DNT IVB

efsa EUROPEAN FOOD SAFETY AUTHORITY

23 May 2025 13:00-18:00 MINUTES - Agreed on 6 June 2025

Location: Webconference

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o EFSA:

Jean-Lou Dorne (ED Team Chief Scientist Office), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

Observer:

None

### 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Discuss comments reviewers PPR Panel

The comments provided for by the PPR Panel reviewers were discussed. Based on the comments some amendments of the document were agreed by the WG members.

#### b. Next steps, task division

Further steps were identified and tasks for the next meeting were allocated among the WG members.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

## MEETING MINUTES – 23 May 2025 9th Working Group meeting on QIVIVE DNT IVB



## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

The next meeting will be held on 6 June 2025 (9.00-15.00), via web conference.

# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 8<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



7 April 2025 13:00-18:00 MINUTES - Agreed on 22 April 2025

Location: Webconference

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

EFSA:

Jean-Lou Dorne (ED Team Chief Scientist Office), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

Observer:

None

### 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Overview kinetic data collection

Kinetic data collected on paired maternal/fetal exposure was discussed. Overview figures will be added to the Scientific Opinion and extracted data will be added as Appendix to the Scientific Opinion.

#### b. Discuss draft Scientific Opinion

The draft Scientific Opinion was discussed and adjusted with specific attention to the chapter on uncertainty analysis.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES – 7 April 2025 8<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



#### c. Next steps, task division

Further steps were identified and tasks for the next meeting were divided among the WG members.

## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

The next meeting will be held on 23 May 2025 (13.00-18.00), via web conference.

# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 7<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



28 February 2025 13:00-18:00 MINUTES - Agreed on 11 March 2025

Location: Webconference

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o FFSA:

Jean-Lou Dorne (ED Team Chief Scientist Office), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

Observer:

Muhammad Waqar Ashraf (ECHA)

## 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Exposure via lactation

Aspects related to chemical exposure of infants via lactating mothers were discussed and the implications for QIVIVE of data from the DNT IVB assays.

#### b. Assessment uncertainties

Uncertainties related to the QIVIVE of DNT IVB were discussed, with specific attention to uncertainties related to PBK modelling and the in vitro dose metrics for QIVIVE.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate publications/files/competing interest management 17.pdf

## MEETING MINUTES - 28 February 2025 7<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



#### c. Next steps, task division

Further steps were identified and tasks for the next meeting were divided among the WG members.

## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

The next meeting will be held on 7 April 2025 (13.00-18.00), via web conference.

# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 6<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



20 - 21 January 2025 13:00-18:00 / 09:00-17:00 MINUTES - Agreed on 3 February 2025

**Location**: EFSA - Parma (Meeting Room 00/001)

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o EFSA:

Jean-Lou Dorne (ED Team Chief Scientist Office), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

## Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Iris Mangas.

### 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2</sup>, EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting and the preparatory meetings listed under agenda item "Preparatory meeting/s". No Conflicts of Interest related to the issues discussed in these meetings have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

## IV. Scientific topic(s) for discussion

#### a. Methods for chemical parameter values

Methods to obtain chemical-specific PBK model parameters were presented and discussed. An overview of methods will be included in the Scientific Opinion.

## b. Linking of in vitro dose metric to internal dose metric and tiered PBK modelling strategy

Approaches were presented and discussed on how an in vitro dose metric can be linked to an in vivo internal dose metric for the QIVIVE. Also, a tiered PBK modelling strategy for the QIVIVE was presented and discussed. Recommended approaches will be included in the Scientific Opinion.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES - 20 - 21 January 2021 6<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



#### c. Step-wise QIVIVE approach and uncertainty analysis

A step-wise QIVIVE approach was discussed using the tiered PBK modelling strategy. Scenarios were discussed when application of the higher tier modelling-based QIVIVE is recommended based on the outcomes of the lower tier modelling-based QIVIVE.

The topic on uncertainty analysis was postponed to the next meeting.

#### d. Next steps, task division

Further steps were identified and tasks for the next meeting were divided among the WG members.

## V. Preparatory Meeting/s

No preparatory meetings were held.

## VI. Next meeting

The next meeting will be held on 28 February 2025 (13.00-18.00), via web conference.

## SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 5<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



18 December 2024 9:00-16:00 MINUTES - Agreed on 16 January 2025

Location: Webconference

#### Attendees:

Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer

o FFSA staff:

Jochem Louisse (PREV; chair), Alicia Paini (MESE)

Hearing Expert:
 Alessandra Roncaglioni

Observer:

Muhammad Waqar Ashraf (ECHA)

## Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Emanuela Testai, Andrea Terron, Iris Mangas, and Jean-Lou Dorne.

## 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2,</sup> 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 (EFSA-Q-2024-00299)

#### a. QSAR models for kinetic parameters

Before the meeting, questions were formulated by the WG for the hearing expert related to in silico modelling, i.e., quantitative structure activity relationship (QSAR) and molecular dynamic modelling. The hearing expert presented her answers to the WG, and aspects of in silico modelling and related reporting were further discussed.

#### b. Methods for chemical parameter values

Methods to obtain chemical-specific PBK model parameters were presented and discussed. An overview of methods will be included in the Scientific Opinion.

#### c. QIVIVE approach

 $<sup>^{1}\,\</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf}$ 

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES - 18 December 2024 5<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



Given time constraints, the discussion on a preferred QIVIVE approach was postponed to the next WG meeting.

#### d. Next steps and task division

Further steps were identified and tasks for the next meeting were divided among the WG members.

## V. Next meeting

The next meeting will be held on 20-21 January 2025, at EFSA in Parma.

## SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 4<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



15 November 2024 8:30-13:30 MINUTES - Agreed on 4 December 2024

Location: Webconference

#### Attendees:

Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o EFSA:

Jochem Louisse (PREV; chair), Alicia Paini (MESE)

Hearing Expert:André Dallmann

## Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Andrea Terron (PREV), Iris Mangas (PREV), and Jean-Lou Dorne (MESE).

### 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 Independence¹ and the Decision of the Executive Director on Competing Interest Management², 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 (EFSA-Q-2024-00299)

#### a. PBK modelling of fetal exposure

Before the meeting, questions were formulated by the WG for the hearing expert related to pregnancy PBK modelling and related prediction of fetal exposure. The hearing expert presented his answers to the WG, and aspects of pregnancy PBK modelling and fetal exposure were further discussed.

#### b. Methods for chemical parameter values

Methods to obtain chemical-specific PBK model parameters were presented and discussed. Further information will be collected for discussion in the next meeting (point c).

#### c. Next steps and task division

 $<sup>^{1}\,\</sup>underline{\text{http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf}$ 

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES - 15 November 2024 4<sup>th</sup> Working Group meeting on QIVIVE DNT IVB



Further steps were identified and tasks for the next meeting were divided among the WG members.

## V. Next meeting

The next meeting	ı will be l	held on	18 December	2024 (	(9.00-16.00)	), via web	conference.
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## SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 3rd Working Group meeting on QIVIVE DNT IVB



09 October 2024 13:00-18:00 MINUTES - Agreed on 25 October 2024

Location: Webconference

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Francesca Metruccio, Nynke Kramer, Emanuela Testai

o EFSA:

Jochem Louisse (PREV; chair), Alicia Paini (MESE)

### I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Andrea Terron (PREV), Iris Mangas (PREV).

### 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2,</sup> EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process.

With regard to this meeting, Antonio Hernández Jerez declared the following interest: participation to an international expert group of the Danish Ministry of Environment and Gender Equality aimed to evaluate if the parametric value for nitrate in drinking water is sufficiently protective for the public with respect to the risk of developing colorectal cancer. 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.

## IV. Scientific topics for discussion (EFSA-Q-2024-00299)

#### a. Cases literature QIVIVE DNT

Two case studies described in the literature on the QIVIVE of in vitro DNT data were presented. Critical aspects relevant for regulatory application were discussed.

#### b. Methods input parameters

An initial draft overview of methods to obtain chemical-specific model parameters was presented and discussed. Further information will be collected (point d).

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES - 09 October 2024 3<sup>rd</sup> Working Group meeting on QIVIVE DNT IVB



#### c. In vitro distribution kinetics - chemical characteristics

In silico predictions of in vitro distribution kinetics in test systems of the DNT IVB were presented and discussed. Although currently available methods have large uncertainties (given the lack of test system specific information needs as input for the in silico models), insight can be obtained in the relation of chemical characteristics and expected in vitro biokinetics (and related in vitro exposure).

#### d. Discussion next steps and task division

Further steps were identified and tasks for the next meeting were divided among the WG members.

## V. Next meeting

The next meeting will be held on 15 November 2024 (8.30-13.30), via web conference.

## SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR)

2<sup>nd</sup> Working Group meeting on QIVIVE DNT IVB



05 September 2024 13:00-18:00 / 09:00-13:00 MINUTES - Agreed on 25 September 2024

Location: Webconference

#### Attendees:

Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Nynke Kramer

Jean-Lou Dorne (MESE), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

### Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Francesca Metruccio, Emanuela Testai, Andrea Terron (PREV), Iris Mangas (PREV).

#### 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<sup>1</sup> and the Decision of the Executive Director on Competing Interest Management<sup>2,</sup> 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 (EFSA-Q-2024-00299)

#### a. Finalisation protocol and interpretation of the ToRs

The updated protocol, including the assessment questions, was discussed and agreed.

#### b. Previous EFSA evaluations QIVIVE DNT IVB

DNT IVB QIVIVE cases previously evaluated by EFSA were presented and discussed.

#### c. PBK model parameters and methods

An overview on chemical-specific input parameters for PBK models was presented and discussed. Methods used to obtain values for such parameters will be identified.

#### d. Structure Scientific Opinion and task division

The first draft structure of the Scientific Opinion was discussed and tasks were allocated to EFSA staff and WG members.

<sup>&</sup>lt;sup>1</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES - 5 September 2024 2<sup>nd</sup> Working Group meeting on QIVIVE DNT IVB



## V. Next meeting

The next meeting will be held on 9 October 2024 (13.00-18.00), via web conference.	The next meeting will be he	eld on 9 October 2024	(13.00-18.00), via	web conference.
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# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 1st Working Group meeting on QIVIVE DNT IVB



04-05 July 2024 09:00-18:00 / 09:00-13:00 MINUTES - Agreed on 24 July 2024

**Location**: EFSA - Parma (Meeting Room 00/06b)/Webconference

#### Attendees:

o Working Group Members:

Keyvin Darney, Antonio Hernández Jerez, Nynke Kramer, Francesca Metruccio, Emanuela Testai

Hearing Experts<sup>1</sup>:

Ellen Fritsche (present only on 4 July)

o EFSA:

Jean-Lou Dorne (MESE), Jochem Louisse (PREV; chair), Alicia Paini (MESE)

## Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Andrea Terron (PREV) and Iris Mangas (PREV).

Jean-Lou Dorne (MESE) participated online.

Ellen Fritsche participated as a hearing expert on the first day of the meeting.

### II. Adoption of agenda

The agenda was adopted without changes.

## III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence<sup>2</sup> and the Decision of the Executive Director on Competing Interest Management<sup>3,</sup> 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. Introduction, ToRs and interpretation of the ToRs

Background information on the DNT IVB was presented. The terms of reference and interpretation of terms of reference were discussed. Based on the discussion, the text on the interpretation of the terms of reference will be updated by EFSA staff to be evaluated by WG members.

## V. Scientific topic(s) for discussion (EFSA-Q-2024-00299)

#### a. Protocol for the assessment, translation ToRs into assessment questions

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: <a href="http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf">http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf</a>

<sup>&</sup>lt;sup>2</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/policy\_independence.pdf

<sup>&</sup>lt;sup>3</sup> http://www.efsa.europa.eu/sites/default/files/corporate\_publications/files/competing\_interest\_management\_17.pdf

## MEETING MINUTES - 4-5 July 2024 1st Working Group meeting on QIVIVE DNT IVB



The draft protocol, including the assessment questions, were discussed and adjustments were proposed. Based on the discussion, the assessment questions will be updated by EFSA staff to be evaluated by WG members.

#### b. Overview DNT IVB assays

The hearing expert provided a detailed overview of the 17 test methods that comprise the DNT IVB.

#### c. Considerations PBK model - input parameters

An overview was presented on PBK models and their input parameters of relevance for QIVIVE of DNT IVB data, and critical aspects were discussed.

#### d. Considerations in vitro/in vivo TK studies

An overview was presented on toxicokinetic studies for derivation of chemical-specific input parameter values, and critical aspects were discussed.

#### e. Considerations in vitro biokinetics/dose metrics

An overview was presented on the importance of consideration of in vitro chemical distribution kinetics for determining the in vitro dose metric to be applied for the QIVIVE.

#### f. Considerations on analytical methods for human biomonitoring (HBM) of pesticides

Principles of analytical methods and the importance of quality criteria relevant for analysis of HBM samples, but also for other kinetic studies were presented, and critical aspects were discussed.

#### g. In vitro and in vivo TK data in pesticide dossiers

An overview was presented on the typical in vitro and in vivo ADME/TK data available in the pesticide dossiers, and their possible use for PBK model parameterisation were discussed.

#### h. Previous EFSA evaluations QIVIVE DNT IVB

Due to time constraints, this agenda item has moved to the next WG meeting.

#### i. Definition and division of tasks, timeline of work

The draft timeline was presented and discussed. Based on the discussion the meeting schedule will be updated by EFSA staff. Tasks were defined for the next WG meeting.

## VI. Next meeting

The next meeting will be held on 5 September 2024 (13.00-18.00), via web conference.