



# SCIENTIFIC PANEL ON Plant Protection Products and their Residues (PPR) 133<sup>rd</sup> Plenary meeting

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30 September/1 October 2025  
14:00-18:00/9:00-13:00  
MINUTES - Agreed on 17 October 2025

**Location:** EFSA premises, Parma

Attendees:

- Panel Members: Pauline Adriaanse, Tamara Coja, Judy Choi, Antonio Finizio, Maeva Giraudo, Thomas Kuhl, Francesca Metruccio, Martin Paparella, Emily McVey, Silvia Pieper, Eugenio Scanziani, Ivana Teodorovic, Martin Wilks
- Hearing Experts: Not applicable
- European Commission and/or Member States representatives: Not applicable
- EFSA:

PREV UNIT: Dionysia Athanasiou, Sofia Batista-Leite, Marco Binaglia, Anna Castoldi, Arianna Chiusolo, Mathilde Colas, Federica Crivellente, Rafaela De Jesus, Dimitra Kardassi, Frederique Istace, Anna Lanzoni, Mariano Lopez Romano, Jochem Louisse, Galini Mavriou, Martina Panzarea, Juan Parra Morte, Miguel Santos, Scattareggia Marchese Adriana, Anne Theobald, Manuela Tiramani, Giorgia Vianello

PLANTS Unit: Maria Arena, Fernando Alvarez, Domenica Auteri, Gabriella Fait, Alessio Ippolito, Christopher Lythgo, Alberto Linguadoca, Laura Padovani, Vincenzo Padricello, Rachel Sharp, Laura Villamar Bouza

MESE Unit: Dastouet Justine, Georgiadis Marios

Observers: see Annex I

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received by Paul van der Brink.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Declarations of Interest of Panel 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.

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<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/policy_independence.pdf)

<sup>2</sup> [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf)



## **4. Agreement of the minutes of the 132<sup>nd</sup> PPR Plenary held on 25 June 2025, via web-conference**

The minutes of the 132<sup>nd</sup> PPR Plenary were agreed by the Panel members via written procedure on 11<sup>th</sup> July.

## **5. Brief introduction of Panel members**

The Panel members introduced themselves to the observers.

## **6. Presentation of EFSA guideline for observers**

EFSA presented the guidelines for observers for open plenary meetings.

## **7. Update from Scientific Committee**

The chair reported the main scientific highlights from the last meeting of the Scientific Committee, as follow:

- Guidance on read-across
- Statement on the Margin of Exposure
- Draft guidance on evidence appraisal
- Update Guidance on weight of evidence and Guidance on biological relevance
- Genotoxicity guidance (revision)
- Benchmark dose approach
- Consideration on length and readability of Panel/Scientific Committee opinions.

## **8. Scientific topics for discussion**

### **8.1. Reviewing the literature on the methodologies available to study the long-term toxic and/or carcinogenic effects of PPP, in particular those resulting from interactions between components mixed in these products ([EFSA-Q-2024-00432](#))**

The Panel and observers were updated on the scope of the mandate, deadlines, status and next steps. The Working Group (WG) dealing with this mandate had no meeting from the last plenary meeting.

### **8.2. Metabolites common to several active substances ([EFSA-Q-2024-00560](#))**

The Panel was informed on progress made since the last plenary. Feedback was asked to the Panel on some specific aspects. Planning and milestones were discussed.

### **8.3. Application of PBK modelling for the QIVIVE of DNT IVB data for pesticide active substances ([EFSA-Q-2024-00299](#))**

Main comments received during the public consultation were reported and discussed. The draft opinion, after review (Maeva, Judy and Martin P), will be presented for possible adoption at the next plenary.



#### **8.4. Waiving the dog studies in the regulatory process for agrochemical approval ([EFSA-Q-2024-00199](#))**

The draft opinion was submitted to the reviewers (Eugenio, Thomas and Emily) for comments before the possible endorsement for the launching of the public consultation and the organization of a stakeholder workshop in November. Following presentation and discussion on the main comments received from the reviewers, the draft opinion was unanimously endorsed.

#### **8.5. Request for revision of Terrestrial Ecotoxicology Guidance ([EFSA-Q-2024-00463](#) and [EFSA-Q-2024-464](#))**

The Panel was informed on the progress made by the WG in addressing the 2 mandates, i.e. the one related to the revision of the guidance documents on the risk assessment for non-target arthropods, in-soil organisms and non-target terrestrial plants and the one on a methodology for addressing indirect effects resulting from trophic interactions. Planning and next milestones were presented.

### **9. Update on new mandates**

#### **9.1. Update of the guidance on Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 ([EFSA-Q-2024-00585](#))**

The Panel was informed about the mandate from the European Commission. It was clarified that the first term of reference of the mandate requested a guidance on critical appraisal tools for the appraisal of the evidence and is being addressed by the MESE Unit. The second terms of reference requests EFSA to update the EFSA guidance on open literature review in the context of the Regulation (EC) No 1107/2009 by considering the outcome of terms of reference 1 (ToR1) and was assigned to the PPR Panel. It was noted that a new WG is needed since the existing ones do not cover the required expertise to carrying this mandate over. Emily McVey was appointed as chair of the WG.

### **10. Other mandates**

#### **10.1. FAIR principles for mechanistic effect models in ERA ([EFSA-Q-2025-00205](#))**

The statement on the FAIR principle for mechanistic effect model was unanimously endorsed by the Panel for its publication.

### **11. Q&A sessions**

Two Q/A sessions for addressing questions received from observers were foreseen at the end of each day. Questions posed by the observers during the meeting were answered by the Panel and EFSA. See Annex II.

### **12. AOB**

The Panel was informed on the expert survey which will be launched around mid-October for gathers insights into the level of satisfaction among Panel experts regarding their collaboration with EFSA.

The checklist for reviewers was presented following the comments collected. Guidelines on how the checklist should be filled were also drafted and presented.



### **13. Next meeting**

The next meeting will be held as teleconference on 19 and 20 November 2025.

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**Annex I List of Observers attending the meeting**

Last Name	First Name	Affiliation
Novakova	Nadezda	Central Institute for Supervising and Testing in Agriculture
Azzali	Alessandra	Universidad de Granada
Renahan	Tess	PETA Science Consortium International e.V.
Foil	Daniel	BfR (German Federal Institute for Risk Assessment)
CEBALLOS	Michael Warren Gonzales	Universidad Católica de Valencia San Vicente Mártir
Herrmann	Kristin	German Federal Institute for Risk Assessment
Heise	Tanja	Federal Institute for Risk Assessment
Rodrigues	Maria Augusta	Anvisa
Boahene	Nana	Norwegian Scientific Committee for Food and Environment (VKM)
RIME	Soyub	German Federal Institute for Risk Assessment (BfR)
Meng	Helene	LVMH
Eleftheriadou	Dimitra	Bundesinstitut für Risikobewertung
Kneuer	Carsten	BfR - German Federal Institute for Risk Assessment
Guillen	Laura	Pompadour Ibérica, S.A.
Cafiero	Giulia	Wageningen University and Research
Pieper	Christina	German Federal Institute for Risk Assessment
Giaki	Katerina	Technical University of Denmark
Perez	Mariana	Rifcon
Stenrød	Marianne	NIBIO
SCHMITT	Anne	German Federal Institute for Risk Assessment
Azzali	Alessandra	Universidad de Granada
Chan	Yu Suen	Chinese Medicine Regulatory Office, Department of Health, Hong Kong SAR
Huska	Kirsten	Federal Institut for Risk Assessemnt

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**Annex II List of questions from observers and answers**

	OBSERVER	QUESTION	ANSWER
<b>General</b>			
1	<b>Ms. Maria August Rodrigues</b>  Anvisa, Brazil	Are there any limitations on the use of BMD to determine reference values for pesticides?	EFSA recommends the benchmark dose (BMD) approach as a scientifically more advanced method compared to the no-observed-adverse-effect-level (NOAEL) approach for deriving Reference Points to for the establishment of Health-Based Guidance Values. While the use of the BMD approach is not yet the standard in the pesticide area, it is increasingly proposed in application dossiers (often to support the NOAEL selection) and considered in the assessment. From a technical standpoint, the limitations are not specific to pesticides and are not dissimilar from those present in other domains of chemical risk assessment, including i.e., the availability of data suitable for BMD modelling, and for certain endpoints the availability of a scientific rationale to establish a relevant effect size to be used as Benchmark Response.
2	<b>Ms. Maria August Rodrigues</b>  Anvisa, Brazil	How do you assess the cumulative risk exposure of pesticide residues in the diet?	The first step consists in defining toxicological effects of pesticides, unambiguous in terms of nature and/or site of occurrence, which may result from a combined action of pesticides. Pesticides causing these effects are identified based on their toxicological data and



	OBSERVER	QUESTION	ANSWER
			<p>grouped into cumulative assessment groups. The cumulative exposure is then calculated under the assumption of dose-addition by probabilistic modelling in populations of consumers of different age and countries. These calculations use individual consumption data collected in food consumption surveys and occurrence data in food commodities collected under official monitoring programs. After an uncertainty analysis, the cumulative risk is finally characterised in each consumer population in the form of a distribution. The focus is on percentile 99.9 of the distribution, in other words on the consumers who are the most at risk. In case of interest for all the details of the methodology, the EFSA report on the retrospective cumulative dietary risk assessment of craniofacial alterations by residues of pesticides published in 2022 can be consulted:</p> <p><a href="https://www.efsa.europa.eu/en/efsajournal/pub/7550">https://www.efsa.europa.eu/en/efsajournal/pub/7550</a></p>

**Questions related to item 8.2**

	<b>Mr. Carsten Kneuer</b>  German Federal Institute for Risk Assessment (BfR)	Can you clarify why new Excel data extraction templates are used instead of IUCLID, which has been introduced in PPP assessment for study summary. Thank you.	<p>Dose-response tables are not currently available in most of the IUCLID - OHT templates. Therefore, templates for extracting these dose response data were created.</p> <p>Please noted that the report generator in IUCLID does not allow currently extracting all the data as needed in excel. However, robust study summaries can indeed generated in word. These have been generated.</p>
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	OBSERVER	QUESTION	ANSWER
			<p>Data extraction from IUCLID in excel via indirect way, by using the OECD QSAR toolbox could be also done. Again, that data extraction is without considering dose response tables.</p> <p>Please also noted that the quality depends on how the applicant filled in the information.</p>

**Questions related to item 8.3-**

	<b>Ms. Maria August Rodrigues</b>  Anvisa, Brazil	What are the requirements for the use of PBK modelling for the QIVIVE for different endpoints, for example, carcinogenicity, mutagenicity, reprotoxicity?	The (draft) Scientific Opinion is tailored to QIVIVE of data from the developmental neurotoxicity in vitro battery (DNT IVB), and the document does not cover other toxicity endpoints. Regarding the PBK modelling requirements, the Scientific Opinion provides some minimal data requirements for PBK model parameterisation and refers to the OECD guidance document on <i>the characterisation, validation and reporting of Physiologically Based Kinetic (PBK) models for regulatory purposes</i> (OECD Series on Testing and Assessment No. 331) for PBK model evaluation.
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