Management Board
11 December 2025

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES (PPR)

Tamara Coja - Chair of the PPR Panel

EUROPEAN FOOD SAFETY AUTHORITY

PPR PANEL 2024 - 2029

Composition: 14 members, the smallest EFSA Panel in the period 2024 – 2029

PPR PANEL – REMIT

- Ecotoxicology (non-target terrestrial and aquatic organism)
- Fate and behaviour in environment
- Mammalian toxicology (e.g., carcinogenicity, developmental and reproductive toxicity, neurotoxicity, genotoxicity, ADME, immunotoxicology)
- NAMs (e.g., in vitro testing, in silico methods, AOP)
- Residue and consumer safety
- Dietary/non-dietary and environmental exposure assessment
- Chemical and microbial risk assessment

PPR PANEL & UNITS ROLES

PPR

Provision of *ad hoc* scientific advice ('generic mandates')

Specific support in the assessment of Applications

Provision of sectoral guidance documents

- Not involved in the peer review
- *Ad hoc* support on specific scientific questions related to Applications

UNITS

PREV Unit:
- Mammalian tox
- Residues
- Scientific coordination

PLANTS Unit:
- Ecotox
- Chemical & envir exposure

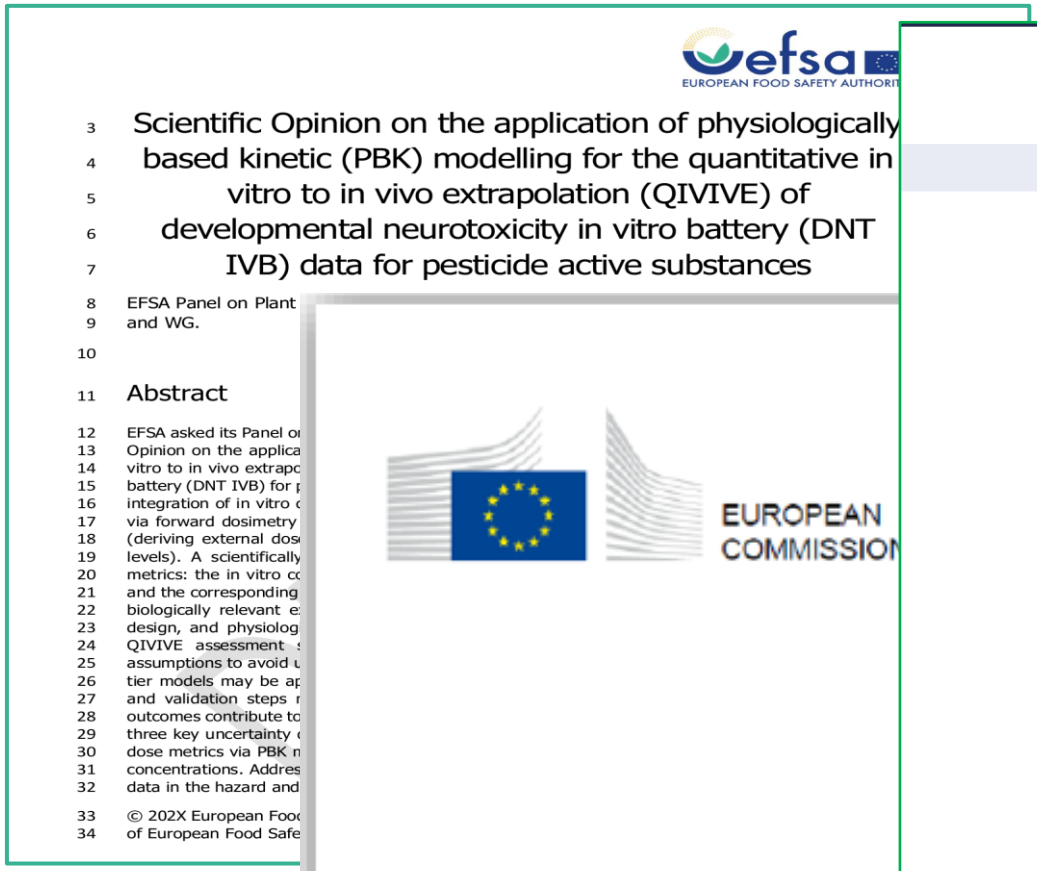
Coordinate the Peer Review of active substances

Pesticides Steering Network

Maximum Residue Levels & Consumers risks

- **Conclusions**
- **Technical reports**
- **Guidance development**
- **MRL Reasoned Opinions**

GENERIC MANDATES (1) - NEW APPROACH METHODOLOGIES (NAMS)



Scientific Opinion on the application of physiologically based kinetic (PBK) modelling for the quantitative in vitro to in vivo extrapolation (QIVIVE) of developmental neurotoxicity in vitro battery (DNT IVB) data for pesticide active substances

EFSA Panel on Plant and WG.

Abstract

EFSA asked its Panel o Opinion on the applica vitro to in vivo extrapo battery (DNT IVB) for p integration of in vitro via forward dosimetry (deriving external dos levels). A scientifically metrics: the in vitro c and the corresponding biologically relevant e design, and physiolog QIVIVE assessment assumptions to avoid u tier models may be ap and validation steps outcomes contribute to three key uncertainty dose metrics via PBK concentrations. Addres data in the hazard and

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On the roadmap towards phasing out an

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Workshop on waiving the dog studies

6 November 2025, 15:00 - 18:00 (CET);
7 November 2025, 15:00 - 18:00 (CET)
Online

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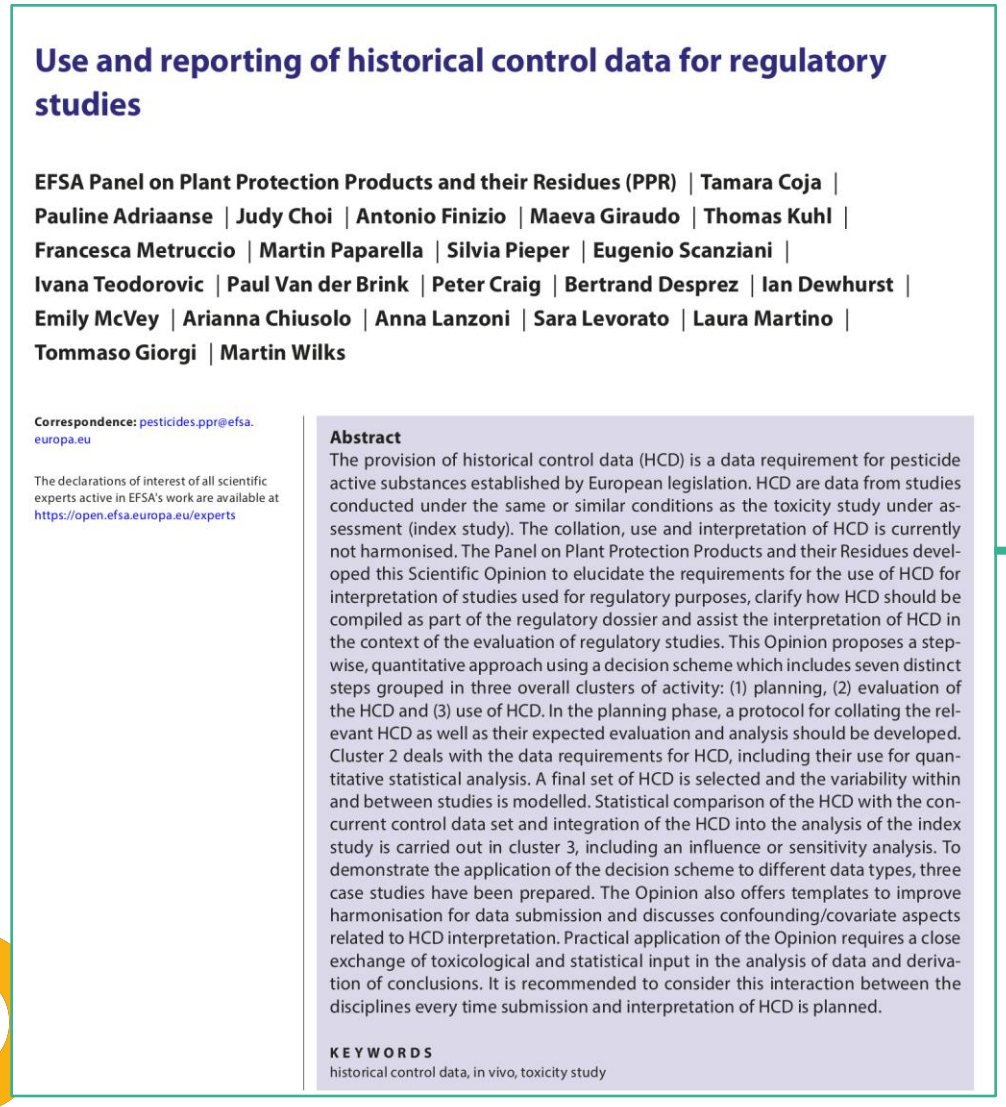
Contents
Documents
Related topics

Background

EFSA is organising a workshop with relevant stakeholders in the framework of the self-task mandate of the Panel on Plant Protection Products and their Residues (PPR Panel) for the development of a scientific opinion on waiving the dog studies in the regulatory process of agrochemicals approval.

Under Regulation (EU) No. 283/2013 of setting out the data requirements for pesticidal active substances, short-term oral toxicity testing in rodents (90-day rat study) and in non-rodents (90-day dog study) are required (among others) to address hazard identification and human safety of plant protection products (PPPs), and to inform the approval of active substances in the European Union (EU). A retrospective analysis of the active substance approval process, previously conducted by EFSA, underlined that in 95% of the cases among 101 reviewed active substances, the dog was not the most sensitive species used for setting the Health-Based Guidance Values (HBGVs). The purpose of the scientific opinion is to review and update the abovementioned retrospective analysis with a broader

GENERIC MANDATES (2): NEW METHODOLOGY



Use and reporting of historical control data for regulatory studies

EFSA Panel on Plant Protection Products and their Residues (PPR) | Tamara Coja | Pauline Adriaanse | Judy Choi | Antonio Finizio | Maeva Giraudo | Thomas Kuhl | Francesca Metruccio | Martin Paparella | Silvia Pieper | Eugenio Scanziani | Ivana Teodorovic | Paul Van der Brink | Peter Craig | Bertrand Desprez | Ian Dewhurst | Emily McVey | Arianna Chiusolo | Anna Lanzoni | Sara Levorato | Laura Martino | Tommaso Giorgi | Martin Wilks

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

The provision of historical control data (HCD) is a data requirement for pesticide active substances established by European legislation. HCD are data from studies conducted under the same or similar conditions as the toxicity study under assessment (index study). The collation, use and interpretation of HCD is currently not harmonised. The Panel on Plant Protection Products and their Residues developed this Scientific Opinion to elucidate the requirements for the use of HCD for interpretation of studies used for regulatory purposes, clarify how HCD should be compiled as part of the regulatory dossier and assist the interpretation of HCD in the context of the evaluation of regulatory studies. This Opinion proposes a stepwise, quantitative approach using a decision scheme which includes seven distinct steps grouped in three overall clusters of activity: (1) planning, (2) evaluation of the HCD and (3) use of HCD. In the planning phase, a protocol for collating the relevant HCD as well as their expected evaluation and analysis should be developed. Cluster 2 deals with the data requirements for HCD, including their use for quantitative statistical analysis. A final set of HCD is selected and the variability within and between studies is modelled. Statistical comparison of the HCD with the concurrent control data set and integration of the HCD into the analysis of the index study is carried out in cluster 3, including an influence or sensitivity analysis. To demonstrate the application of the decision scheme to different data types, three case studies have been prepared. The Opinion also offers templates to improve harmonisation for data submission and discusses confounding/covariate aspects related to HCD interpretation. Practical application of the Opinion requires a close exchange of toxicological and statistical input in the analysis of data and derivation of conclusions. It is recommended to consider this interaction between the disciplines every time submission and interpretation of HCD is planned.

KEYWORDS

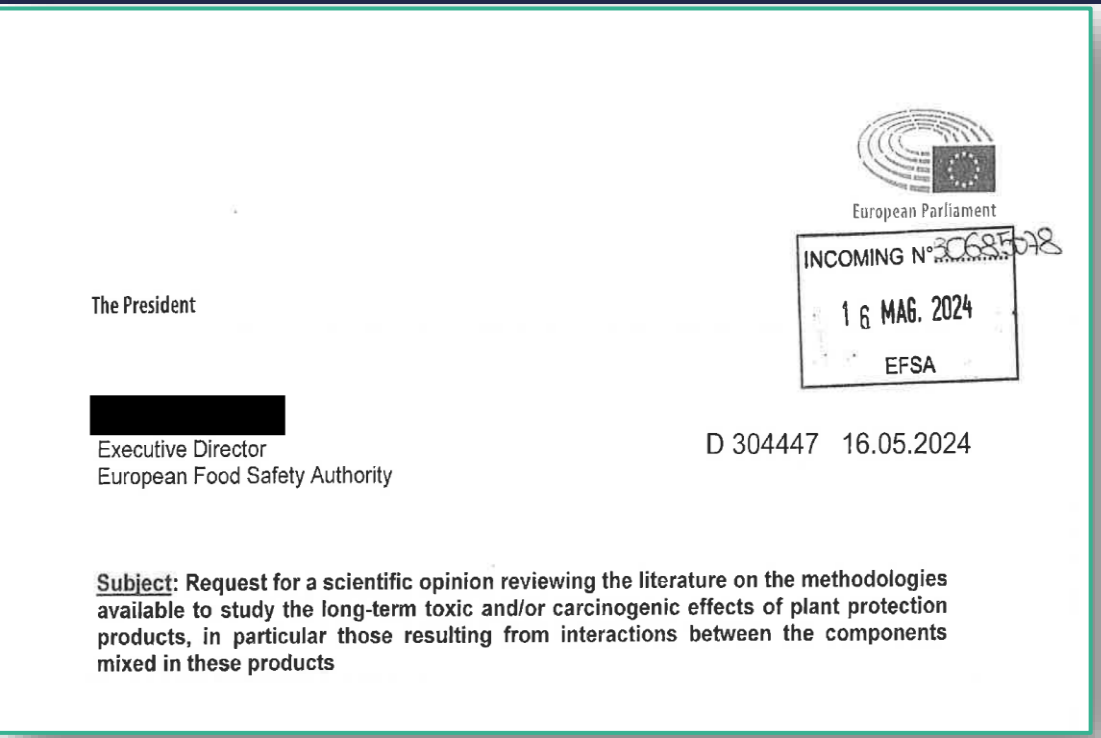
historical control data, in vivo, toxicity study

Interdisciplinary methodology: mammalian toxicology/ ecotoxicology & statistics)

Stakeholders' communication & engagement:

- Webinar held on 9th October 2025 https://www.efsa.europa.eu/en/events/webinar-historical-control-data-regulatory-studies
- Trainings in 2026
- Possibly, tool development

GENERIC MANDATES (3) – MANDATE FROM THE EU PARLIAMENT



European Parliament

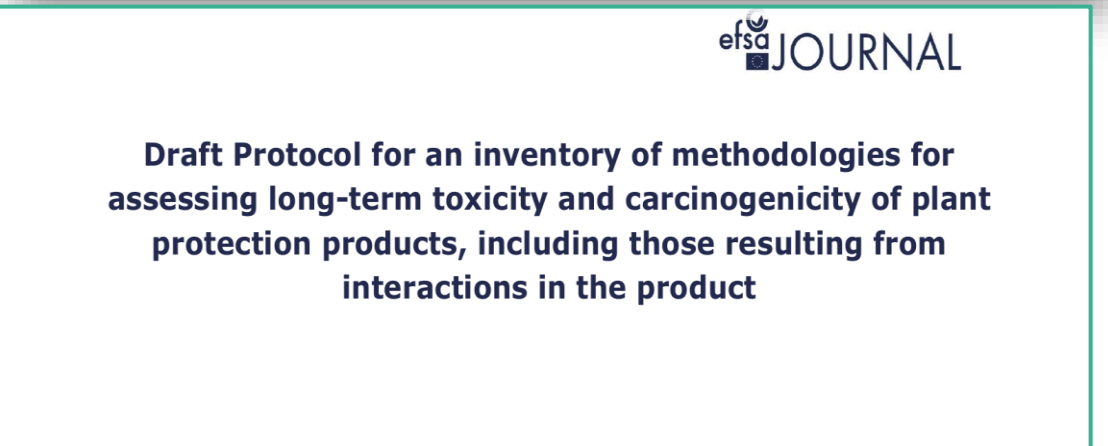
INCOMING N° 3068508
16 MAG. 2024
EFSA

The President

[redacted]
Executive Director
European Food Safety Authority

D 304447 16.05.2024

Subject: Request for a scientific opinion reviewing the literature on the methodologies available to study the long-term toxic and/or carcinogenic effects of plant protection products, in particular those resulting from interactions between the components mixed in these products

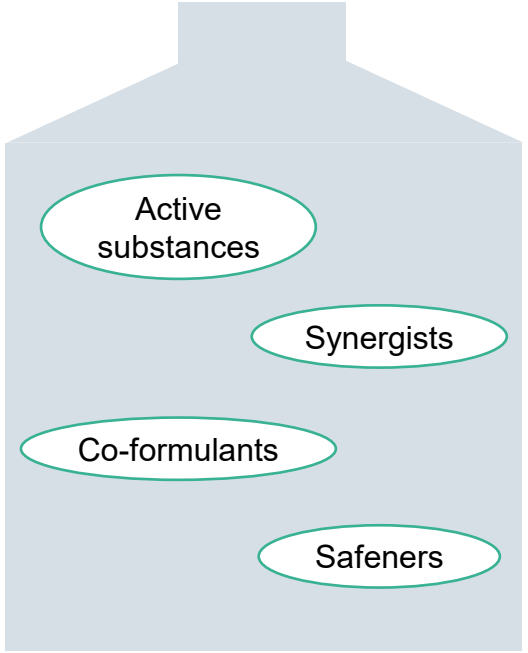


efsa JOURNAL

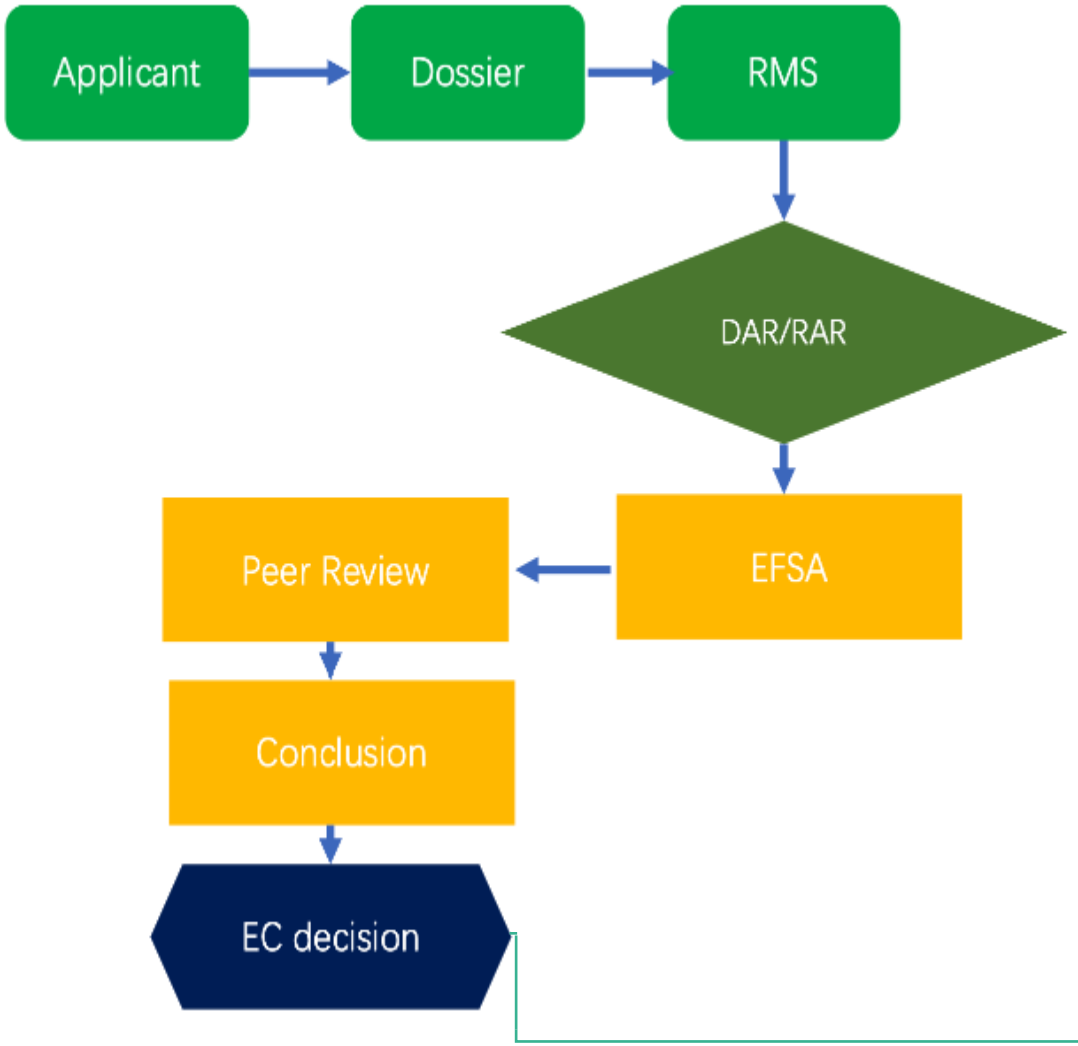
Draft Protocol for an inventory of methodologies for assessing long-term toxicity and carcinogenicity of plant protection products, including those resulting from interactions in the product

- **Component-based approach and possible interaction (additive and synergistic effects):** Statement endorsed in Apr 2025
- **Whole mixture approach:** ongoing

Adoption by PPR Panel: April 2026



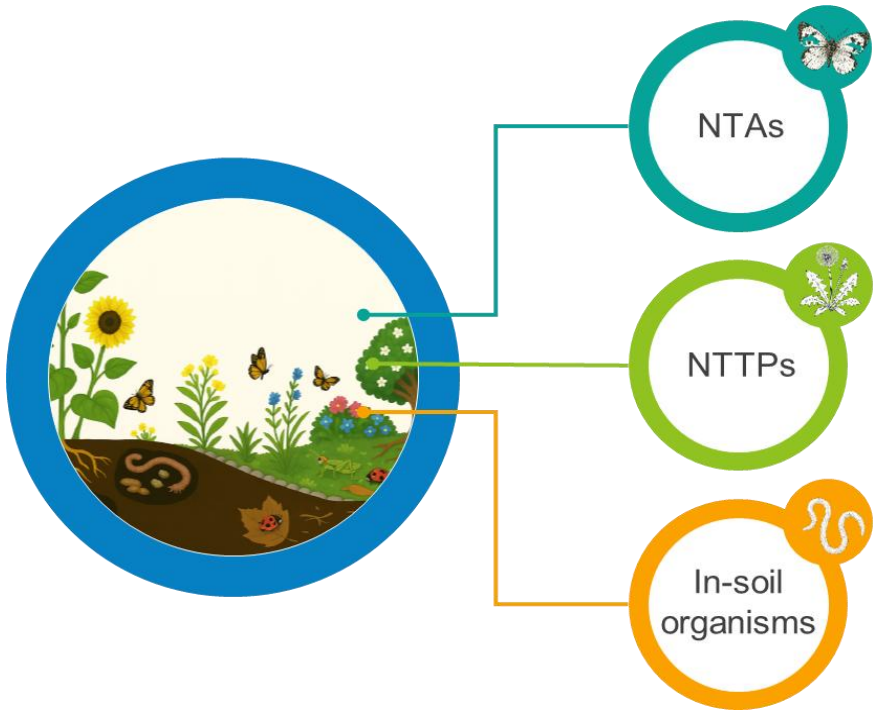
SUPPORT TO APPLICATIONS



Following approval, additional data may become available challenging the EC decision on approval, e.g., mandate on acetamiprid, flupyradifurone, chitosan or the need for a harmonised assessment, i.e. common metabolites to various substances may arise

EC may mandate the PPR Panel to support with the evaluation or additional data or to provide a harmonised toxicological assessment

DEVELOPMENT OF SECTORAL GUIDANCE



M-2024-00086: Request to EFSA to review the Guidance document on Terrestrial Ecotoxicology on Plant Protection Products (PPPs) (i.e. on non-target arthropods (NTAs), non-target terrestrial plants (NTTPs) and in soil organisms)

M-2024-00101: Request to EFSA to develop a Guidance document to assess the potential indirect effects on biodiversity via trophic interactions under agro-environmental conditions

Outline with the planning:
https://www.efsa.europa.eu/en/supporting/pub/en-9216

BENEFITS OF MULTIDISCIPLINARY COMPOSITION

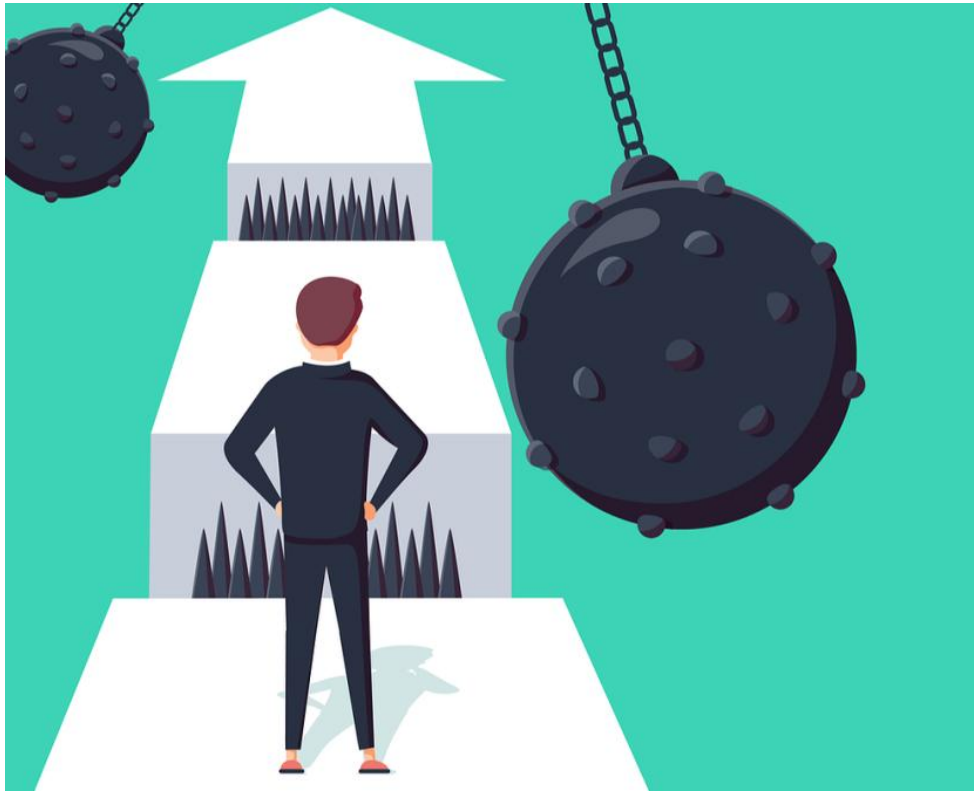
Heterogeneity of the expertise in the Panel :

- Helps breaking silos and generate innovative approaches
- Experts with expertise outside the specific domain of a mandate may help improving readability of outputs for external readers
- Encourage holistic analysis

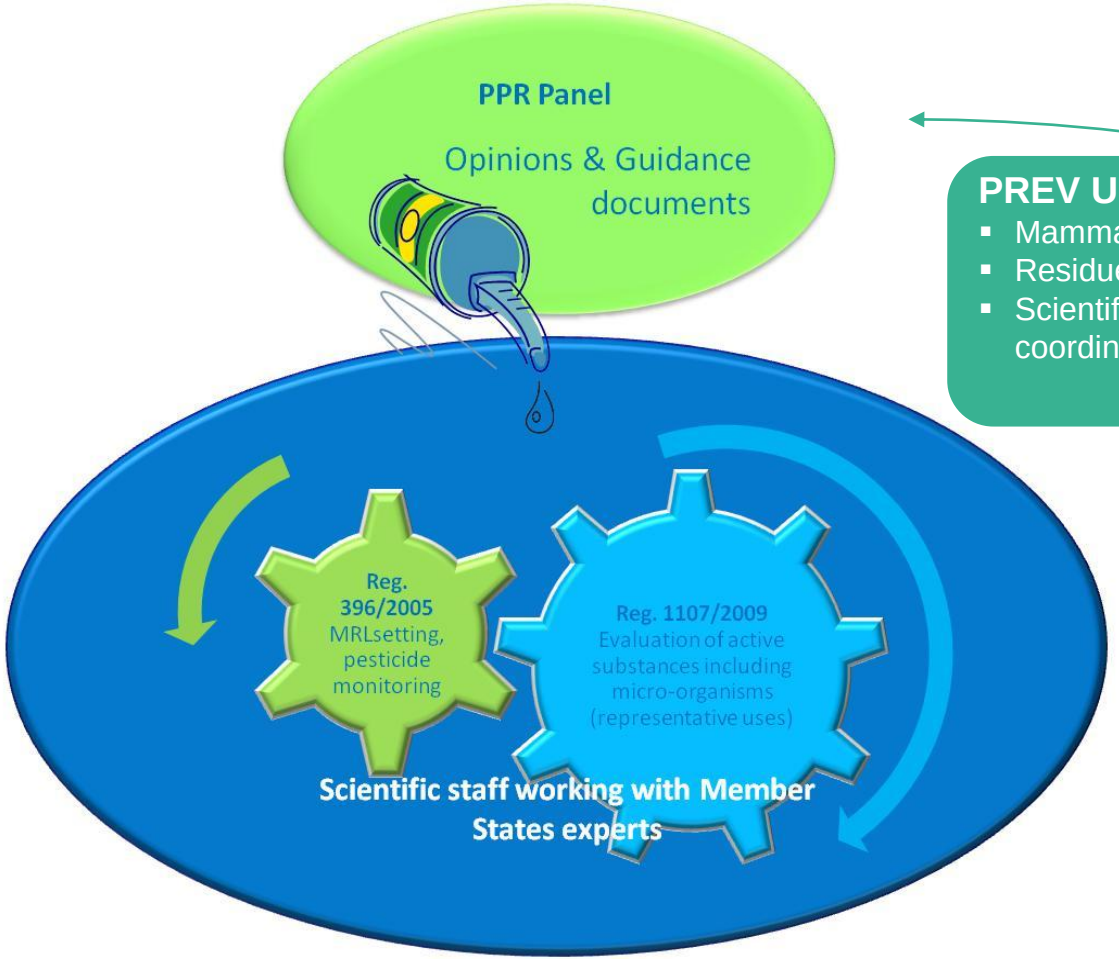
CHALLENGES OF MULTIDISCIPLINARY COMPOSITION

Based on specificity of the mandates, multidisciplinary composition of the Panel may lead to:

- Limited input: experts whose fields are not directly aligned with the mandate may have fewer opportunities to contribute
- Disciplinary balance: this can lead to feelings of undervaluation and the marginalisation of certain disciplines



LIMITING FACTORS



PREV Unit:
- Mammalian tox
- Residues
- Scientific coordination

PLANTS Unit:
- Ecotox
- Chemical & envir exposure

Limited **time resources** in the Units to support self-task mandates of the Panel

Business as usual (BAU) – high priority
Most of internal resources are therefore allocated to BAU