

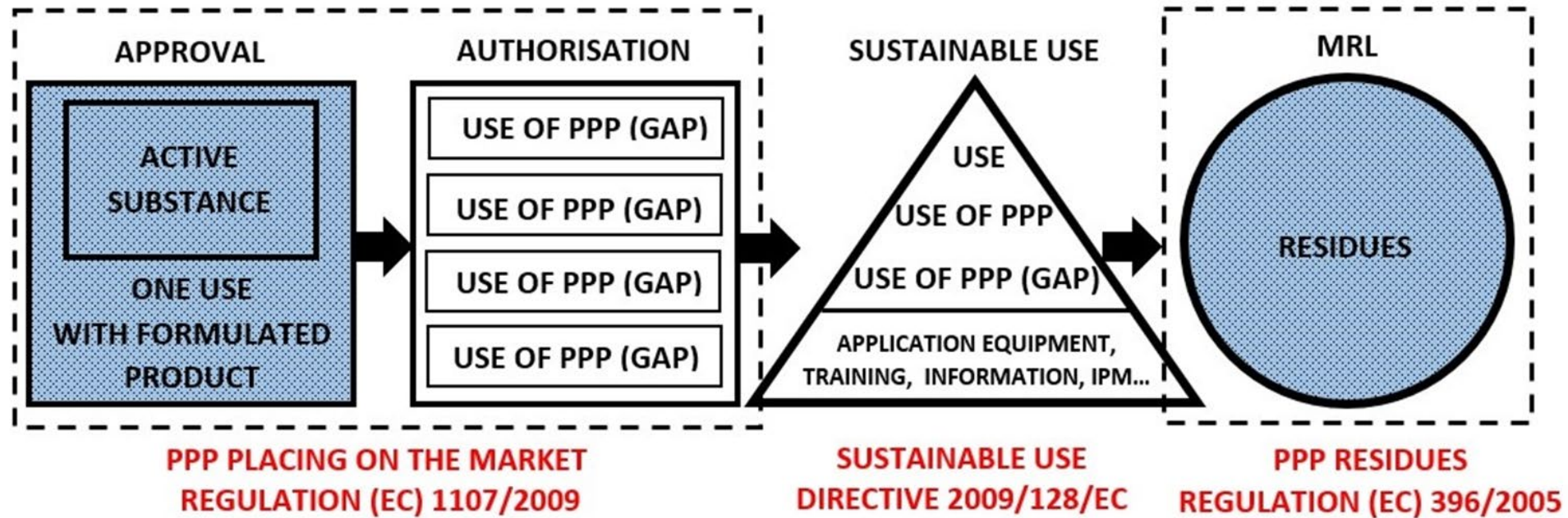


Plant protection products – update and ongoing developments

PLENARY MEETING
ADVISORY GROUP ON SUSTAINABILITY OF FOOD SYSTEMS
8 MAY 2024,

Karin Nienstedt - DG SANTE

Legal framework for pesticides





**CLIMATE
PACT AND CLIMATE
LAW**

**PROMOTING
CLEAN
ENERGY**

**INVESTING IN
SMARTER, MORE
SUSTAINABLE
TRANSPORT**

PROTECTING NATURE

**STRIVING
FOR GREENER
INDUSTRY**

**FROM FARM
TO FORK**

The European Green Deal

**ELIMINATING
POLLUTION**

**LEADING THE
GREEN CHANGE
GLOBALLY**

**ENSURING
A JUST TRANSITION
FOR ALL**

**MAKING
HOMES ENERGY
EFFICIENT**

**FINANCING
GREEN
PROJECTS**

Outline

- Biologicals used as active substances in PPPs
- Chemical AS: safeners and synergists, data requirements, uniform principles,
- PPP: labelling, assessment & co-formulants
- Guidance Documents & mandates to EFSA
- Delays

Biologicals: Activities on micro-organisms

New Regulations and guidance documents on MO

- Guidance document on Metabolites of Concern (Oct 2020)
- Guidance document on AMR (May 2021)
- Four implementing Regulations (applicable as from Nov 2022)

Two Communications from the European Commission

- List recommended test methods/guidance documents
- Support dossier-preparation
- Not legally binding
- Endorsed in March 2023
- Additional database of useful guidance documents

Explanatory notes + dRR

- Support understanding of the new EU Reg
- Support dossier-preparation
- Harmonise risk assessment and risk management
- Not legally binding
- Endorsed at PAFF October
- dRR also endorsed

Tools

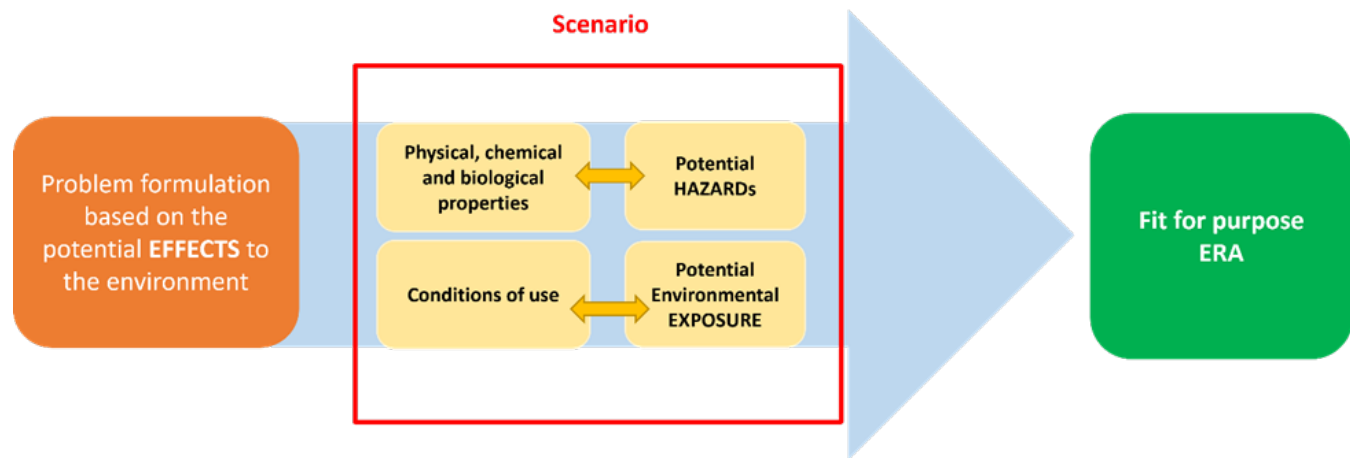
- IUCLID
- New test methods (OECD)
- Consensus documents on MO species
- Background level on MO species

Completed/available

On-going

Biologicals: activities for other biocontrol agents

- **Pheromones**: amended **GD on semiochemicals** extending the group of pheromones beyond the SCLP group – Adopted in January 2024
- **Others (e.g., iRNA, peptides)**: based on need-to-know approach (e.g. via point 1.5 introduction data requirements) and along the “**Problem Formulation**” document adopted in January 2024



- **Baculovirus/bacteriophages**: ongoing revision of guidance document

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Commission Regulation on Safeners and Synergists

New requirements:

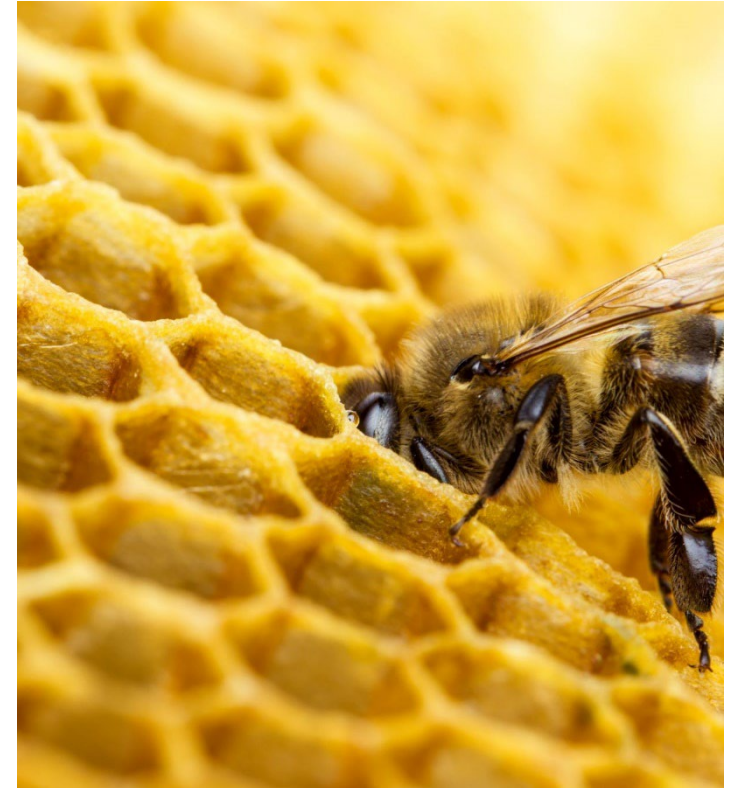
- Setting data requirements (Art 25)
- Establishing the work programme (Art 26)
- Publication: ~ end of May 2024
- Entry into force: the twentieth day following that of publication
- Adoption of the work programme: 18 months from the date of entry into force

Dates to keep in mind:

- First dossier submissions: 48 months from the date of entry into force
- Transitional period for products already on the market: until five years of the adoption of that work programme.

Update of the uniform principles and data requirements

- Which Regulations?
 - Regulation (EU) No 546/2011 on the uniform principles
 - Regulations (EU) No 283 and 284/2013 setting data requirements for active substances and plant protection products respectively
- Why?
 - To adapt to technical and scientific progress to take account of updated guidance (bees and water treatment GD)
- Procedure?
 - Public consultation (feedback mechanism)
 - Regulatory procedure with scrutiny



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Amendment Regulation (EU) No 547/2011: Labelling requirements for Plant Protection Products (PPP)

Content of the proposal :

- **Annex I:** Information on the PPP identification and conditions of use
- **Annex II:** Standard phrases for safe disposal of the PPP
- **Annex III:** Standard phrase and pictogram for hazard communication of PPP containing chemicals: hazard for bees
- **Annex IV:** Standard phrase for hazard communication of PPP containing micro-organisms: sensitising effects
- **Annex V:** Standard phrases for risk mitigation measures: human health and environment
- **Annex VI:** Coloured scheme

In few days ➡ **Interservice consultation will be launched**

Before summer ➡ **Stakeholder consultation**

Recent progress on co-formulants in PPPs:

3 objectives:

1. To develop a guidance to harmonise the assessment of PPPs;
2. To establish an EU database of co-formulants (need for sharing data and assessments of co-formulants and products in view of ensuring efficient use of resources);
3. To improve a clear communication on the legal framework and on ongoing activities.



actions

- updates on website: [The Assessment of Plant Protection Products \(PPPs\) \(europa.eu\)](https://europa.eu)
- continuous discussions on the database and guidance (ScoPAFF, PAI, ZAPID workshop (4-7 December 2023))
- Regulation 383/2021: 11 notifications received so far for additional unacceptable substances to be listed in Annex III (carc cat 1, PBT/vPvB, POP, or no more BPR). Amendment of Annex III will be initiated.
- Art 27 (3) applies for unacceptable coformulants which are already on the market.

Guidance to harmonise how PPPs are assessed

Input: outcome of the report of the June Technical Workshop (available at EFSA website)

What is needed?

- To describe a harmonised process for the assessment of PPPs, including a process to narrow down the scope of the in-depth risk assessment to some particular situations (flow-chart)
- Preparatory work (e.g. literature search, existing databases - see outcome of the report of the June Technical Workshop)
- To be decided if there will be a new guidance or some existing guidance will be updated

How to work?

COM is in contact with MS (PAFF, PAI WG) and EFSA, ECHA , stakeholders will be consulted asap

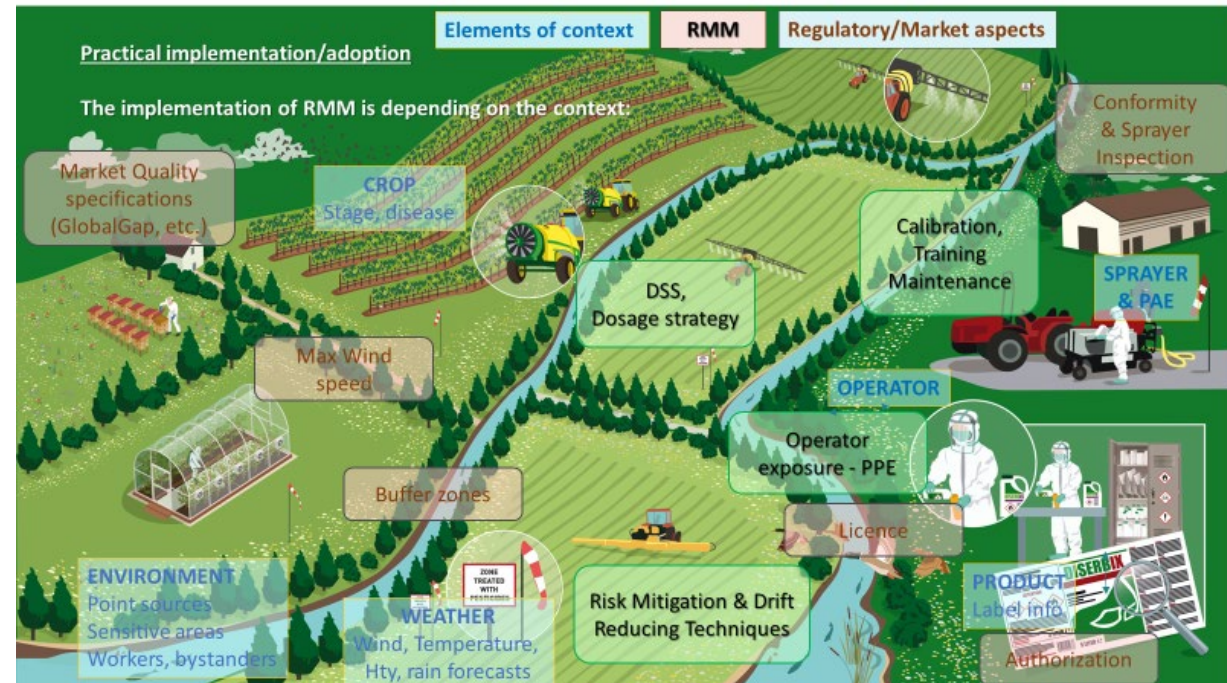
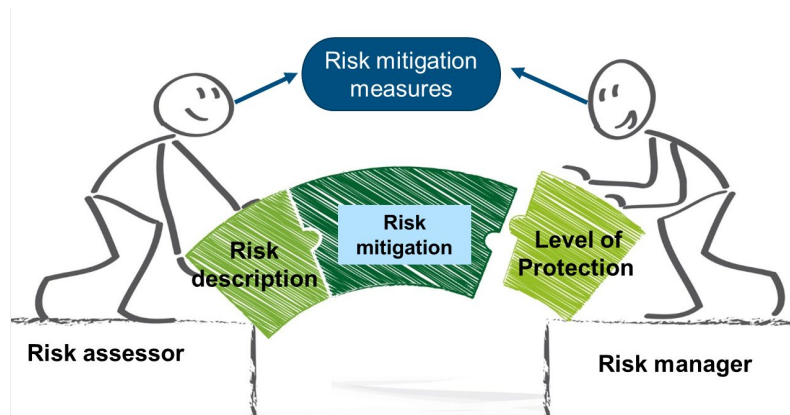
- COM presented a draft flowchart at PAI in March 2024
- **Workshop on guidance document and database for the assessment of PPP including co-formulants** (with the participation of MS authorities, EFSA, ECHA and Commission) – 20 June 2024 on line - Agenda to follow

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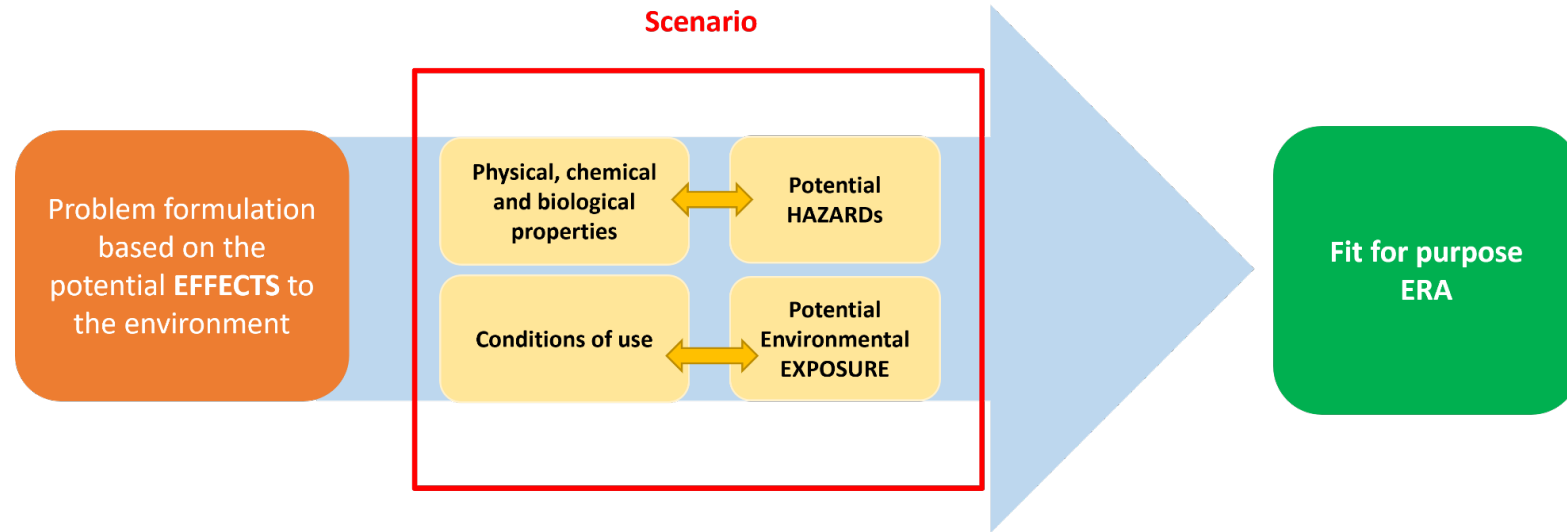
Horizontal Guidance: Compendium conditions of use to reduce exposure and risk from PPPs

- Could be relevant for your pesticide use scenario (GAP)



https://food.ec.europa.eu/document/download/cdd9b6c4-29dc-4077-a118-3e51c0abeb80_en?filename=pesticides_ppp_app-proc_guide_horiz_comp-cond.pdf

Horizontal Guidance: Problem Formulation for Environmental Risk Assessment



To provide justifications as referred to 1.5 of the introduction of the Data Requirements: in cases where **experimental data would not be necessary owing to:**

- 1) the **nature** of the active substance
- 2) or the **representative uses** of the plant protection product containing it.

When comparing to a scenario in which a chemical pesticide is applied with a conventional sprayer in the open field, **lower environmental effects** may be expected for:

- 1) microorganisms, pheromones, botanicals, plant extracts,
- 2) application methods such as indoor uses (permanent greenhouses or storage rooms), precision application techniques, localised applications (e.g., burrows, drip irrigation)

Guidance document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water

- Endorsed by SCoPAFF
- Update data requirements and the Uniform Principles (stakeholder consultation via the feedback mechanism)
- Submission of confirmatory information for a number of active substances is pending implementation of the GD

GD currently under preparation/revision or discussion in PAFF

Under preparation/revision:

- Updated guidance on emergency authorisations
- Negligible exposure
- Assessment of PPPs and co-formulants

Under discussion for endorsement in SCoPAFF:

- Revised guidance on bees
- Revised guidance for birds and mammals

Database of guidance and supporting documents

[Home](#) > [Food Safety](#) > [Plants](#) > [Guidelines and supporting documents on Active Substances and Plant Protection Products](#)

Guidelines and supporting documents on Active Substances and Plant Protection Products

This database contains guidance documents, test methods and supporting documents relevant for the risk assessment processes for the (renewal) of approvals of chemical and microbiological active substances and for authorisations of chemical and microbiological plant protection products.

The database contains more documents than those currently contained in Commission Communications [2023/C 344/02](#) and [2023/C 344/01](#) (as regards chemical active substances and plant protection products), and the Commission Communications [2023/C 202/03](#) and [2023/C 202/02](#) (as regards microbiological active substances and plant protection products). These four Commission Communications are related to data requirements set out in Commission Regulation (EU) 283/2013 and 284/2013.

Procedural Guidance documents are also listed.

Documents other than those listed in the above Communications have been included in the database following suggestions by Member States or interested stakeholders during the consultations for the ongoing revision of the above Communications – **they are included for information purposes only**.

Click one of the following buttons to access the database content

List by Section ▾

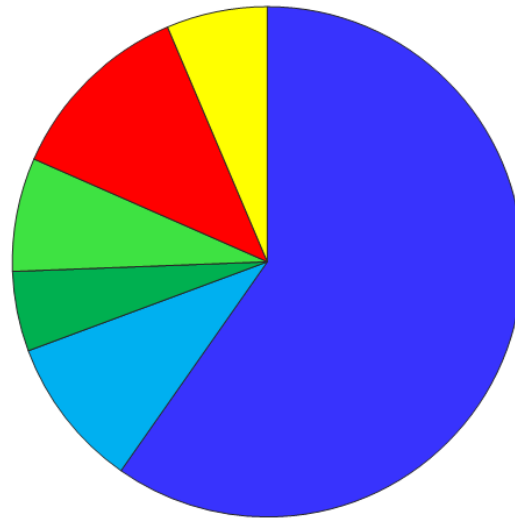
List by Documents

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Approved active substances - overview

Approved active substances
1 February 2024



■ Active Substances

■ Low-risk Active Substances

■ CfS Active Substances

■ Active Substances - microbial

■ Low-risk Active Substances - microbial

■ Basic Substances

Particular actions to reduce delays and to increase availability of (low risk) PPPs (1)

- Grants “SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA”
 - Priorities:
 - to reduce delays in approval and authorisations
 - to increase number of experts in microorganisms
 - to ring fence the fees for the authorities actually carrying out the work
 - Hiring additional staff
 - all grants signed, started as of 1 January 2024
 - €5 Million of total budget of 6 MS (AT, EE, ES, LT, LV, and SK)- € 3,4M EC contribution.
- Better Training for Safer Food – Risk Assessment on Micro-organisms
 - since July 2021
 - target: risk assessors
 - as of today, 11 sessions held and about 350 officers were trained
 - training session still ongoing until March 2025

Particular actions to reduce delays and to increase availability of (low risk) PPPs (2)

ZAPID workshop, Braunschweig, DE, 4-7 December 2023:

- 5 sessions:
 - Meeting legal requirements – Tackling delays
 - Harmonising zonal decision making – Special focus on Mutual Recognition, minor uses, and assessment of co-formulants
 - Work sharing on digital platforms
 - Implementation of new scientific and technical knowledge - Guidance Documents
 - Authorisation of ppp in the light of the Green Deal - Low risk, biocontrol and non-chemical ppp
- Report of ZAPID will be available asap: [Workshops/events - European Commission \(europa.eu\)](https://ec.europa.eu/workshops/events/)
- Part of the follow up activities identified at ZAPID to improve the zonal system could be considered by MS in the framework of PAI (Working Group on Post Approval Issues of SCoPAFF) where Commission is present and in the inter-zonal committees

Thank you for your attention !

For further information:

https://ec.europa.eu/food/plant/pesticides/refit_en

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