

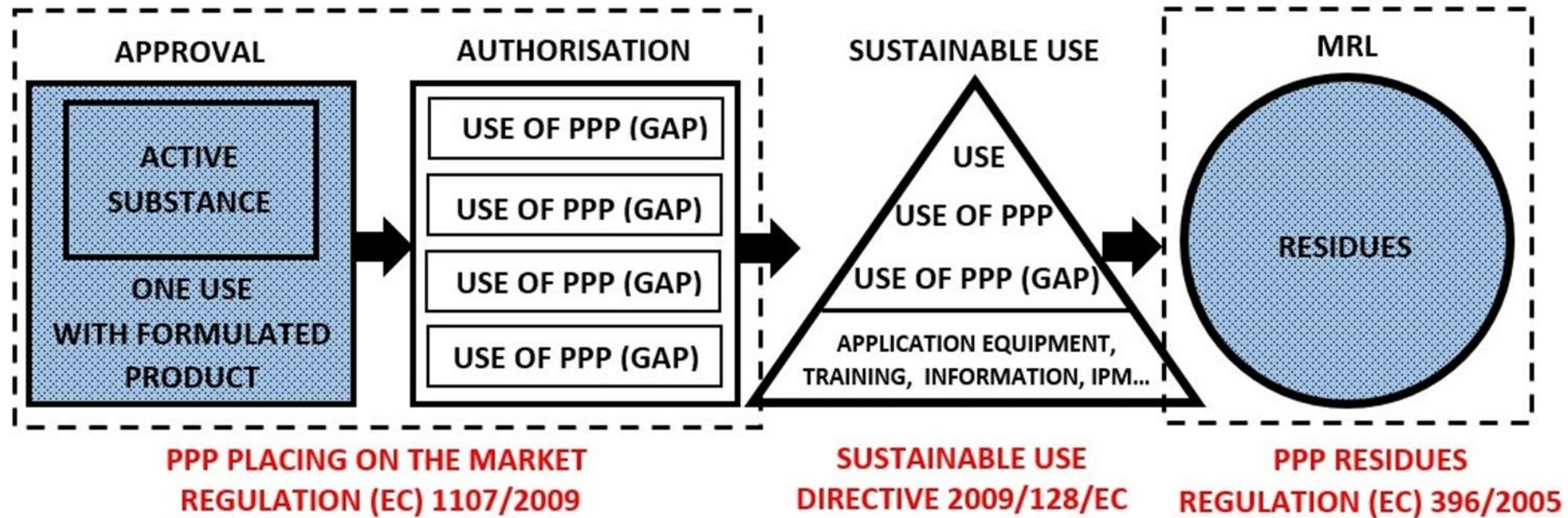


Plant protection products – update and ongoing developments

PLENARY MEETING
ADVISORY GROUP ON SUSTAINABILITY OF FOOD SYSTEMS
17 NOVEMBER 2023,

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: data requirements, uniform principles, safeners and synergists
- PPP: labelling, assessment & co-formulants
- Guidance Documents & mandates to EFSA
- Delays

Activities on micro-organisms used in PPP

New Regulations on MO

- 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

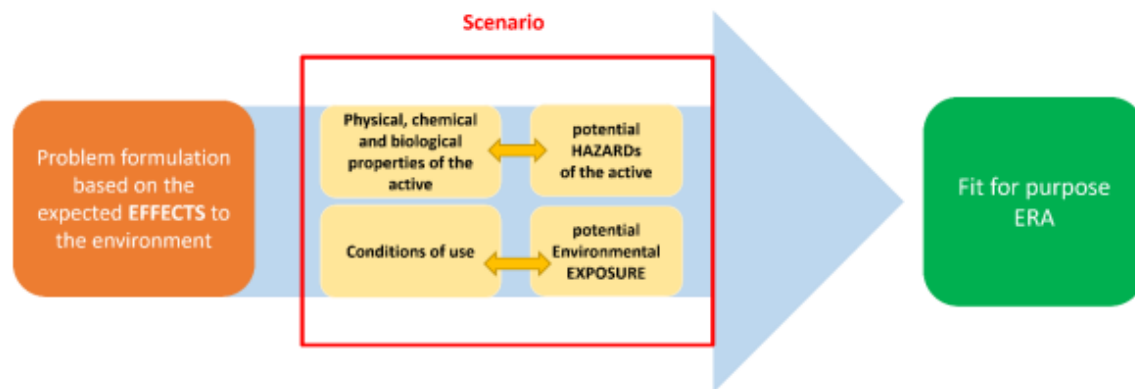
- IUCLID
- New test methods (OECD)
- Consensus documents on MO species
- Background level on MO species

Completed/available

On-going

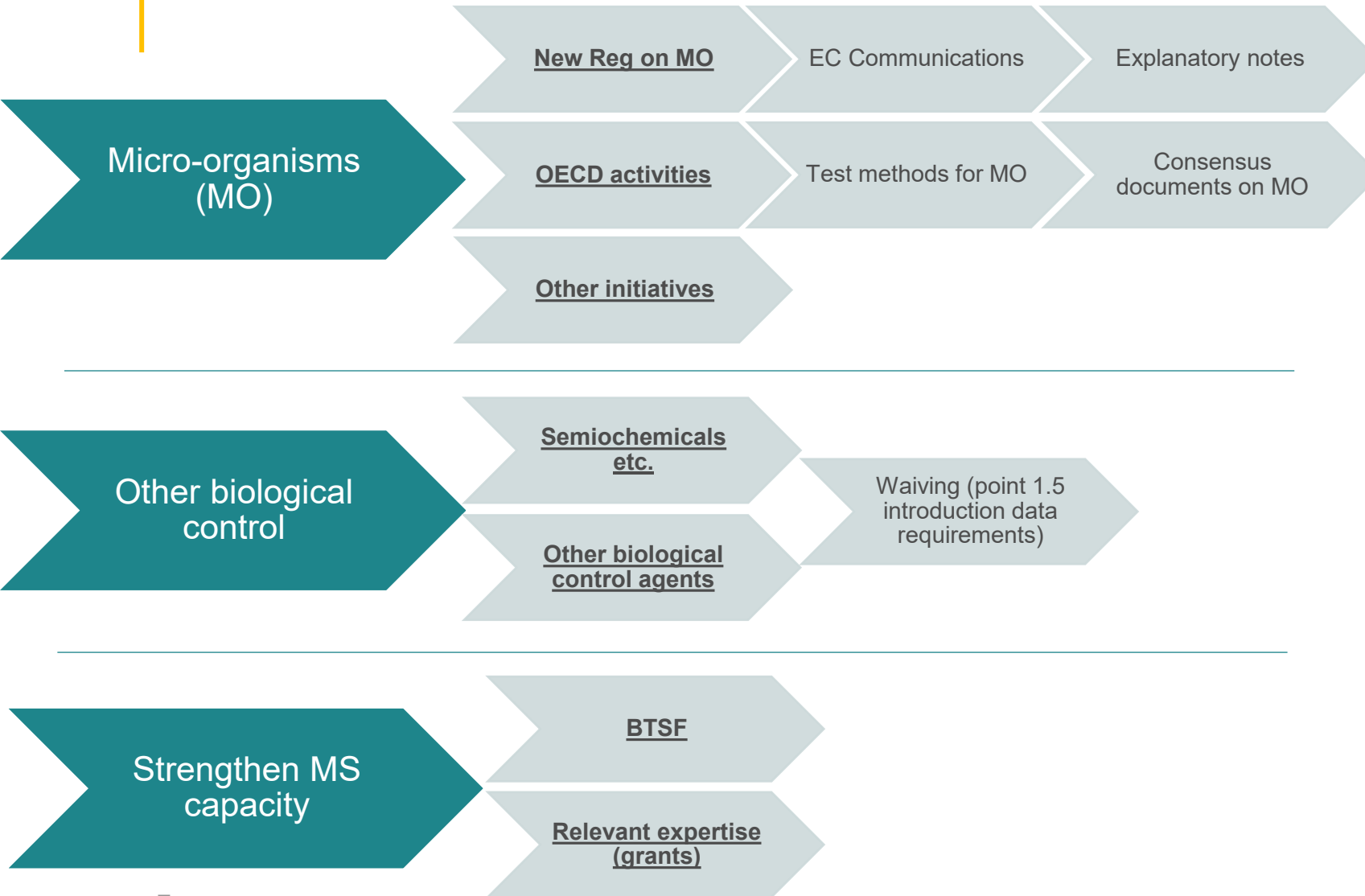
Main ongoing activities for other biocontrol agents

- **Pheromones:** amendment of the GD on semiochemicals to extend the group of pheromones beyond the SCLP group – Discussion with stakeholders at Biopesticides WG on 14-15 November
- **Others (e.g., iRNA, peptides):** based on need-to-know approach (e.g. via point 1.5 introduction data requirements) and along the draft “Problem Formulation” document



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

Road to 2030!



Reduce by 50% the overall use and risk of **chemical pesticides** and reduce use by 50% of more hazardous **pesticides**



Achieve at least 25% of the EU's agricultural land under **organic farming** and a significant increase in **organic aquaculture**

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Draft Commission Regulation on Safeners and Synergists

Current status

- Setting data requirements (Art 25)
- Establishing the work programme (Art 26)
- CIS almost finalised

Next steps

- TBT notification and feedback mechanism
- Vote in SCoPAFF (early 2024)
- Scrutiny EP and Council
- Publication

Point of interest

- First dossier submissions in 5 years
- Transitional period for products already on the market

Communications 283/2013 and 284/2013 – Part A and upcoming database of guidance and supporting documents

Communications- Part A

- Published in September 2023: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2023:344:TOC>
- Your comments were considered (please see the excel table that contains the comments from MS and stakeholders and our replies)

Database of guidance and supporting documents - Under preparation

- Guidance documents and test methods in all the four Communications (Part A and B) and supporting documents
- You will be soon consulted to check the content (mainly weblinks) and report mistakes (thanks for comments on the structure)
- Then, it will be publicly available

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 and new methodologies for assessing hazards and risks of substances and products, and new criteria for endocrine disrupting properties
- Procedure?
 - Public consultation (feedback mechanism)
 - Regulatory procedure with scrutiny



New hazard classes for CLP Regulation: impact on PPP (1)

On 31 March 2023, Commission Delegated Regulation (EU) 2023/707 formally implemented the new hazard classes for

- (i) endocrine disruptors;
- (ii) persistent, bioaccumulative, and toxic/very persistent and very bioaccumulative (PBT/vPvB) substances; and
- (iii) persistent, mobile, and toxic/very persistent and very mobile (PMT/vPvM)

It applies to all chemical substances and mixtures placed on the EU market under REACH, and includes active substances in biocidal and plant protection products, which are normally prioritised for harmonised classification in the EU.

New hazard classes for CLP Regulation: impact on PPP (2)

Technical guidance are currently in preparation by ECHA WGs

Direct impact on PPP dossiers:

- Harmonised template for PPP/CLH submission needs to be adapted
- New ED criteria for hazard class 2 (no direct regulatory consequence for PPP)
- All active substances already identified as endocrine disruptors under Reg 1107/2009 will be listed as classified - hazard class 1 (under Co-Decision)
- Some updating of the Annex II for PPPs will be needed in the future in order to align some criteria (e.g. persistency) or for introducing some of the new end points to be addressed (e.g. mobility)

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

Content of the proposal

- **Annex I:** Information on the plant protection product identification and conditions of use
(Proposal for digital label still under discussion)
- **Annex II:** Standard phrases for safe disposal of the plant protection products
- **Annex III:** Standard phrase and pictogram for hazard communication of plant protection products containing chemicals: hazard for bees (Under discussion)
- **Annex IV:** Standard phrase for hazard communication of plant protection products containing micro-organisms: sensitising effects
- **Annex V:** Standard phrases for risk mitigation measures: human health and environment
- **Annex VI:** Coloured scheme (Under discussion)

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

What has been done?

- **Revision of the current sentences** to protect operators and workers, the environment, bees, to avoid resistance. **Modular sentences** to provide flexibility to MS according to their local conditions:

TO PROTECT (specify environmental compartment, group of organisms or species) KEEP AN UNTREATED BUFFER ZONE/ VEGETATED FIELD MARGIN(S) OF (width to be specified) TO (for instance surface water, field margins).

- **Inclusion of sentences:**

- for safe disposal of tank residues and containers
- to communicate the potential sensitising effects of micro-organisms.
- For seed treatment uses (including the use and sowing of treated seeds)



**Foreseen for the Q1/Q2 of 2024:
Informative meeting with the main stakeholders + Stakeholder consultation**

Recent progress on co-formulants in PPPs (1):

- List of unacceptable co-formulants (Annex III): Regulation 383/2021
- Implementing regulation for identifying other unacceptable co-formulants: Regulation 574/2023
- EFSA technical report (based on products submitted for representative uses in the dossiers for active substances since 2019):

<https://www.efsa.europa.eu/en/supporting/pub/en-7547>

Recent progress on co-formulants in PPPs (2):

-1st Workshop (23 May 2023): setting the scene with stakeholders and mapping of issues for the next technical workshop preparing an action plan.

-2nd Workshop (21-22 June 2023): technical workshop discussing with risk assessors. EFSA Technical report available



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

-new website: [The Assessment of Plant Protection Products \(PPPs\) \(europa.eu\)](https://europa.eu)

-discussions on the data base and guidance (ScoPAFF, PAI, PSN network etc.)

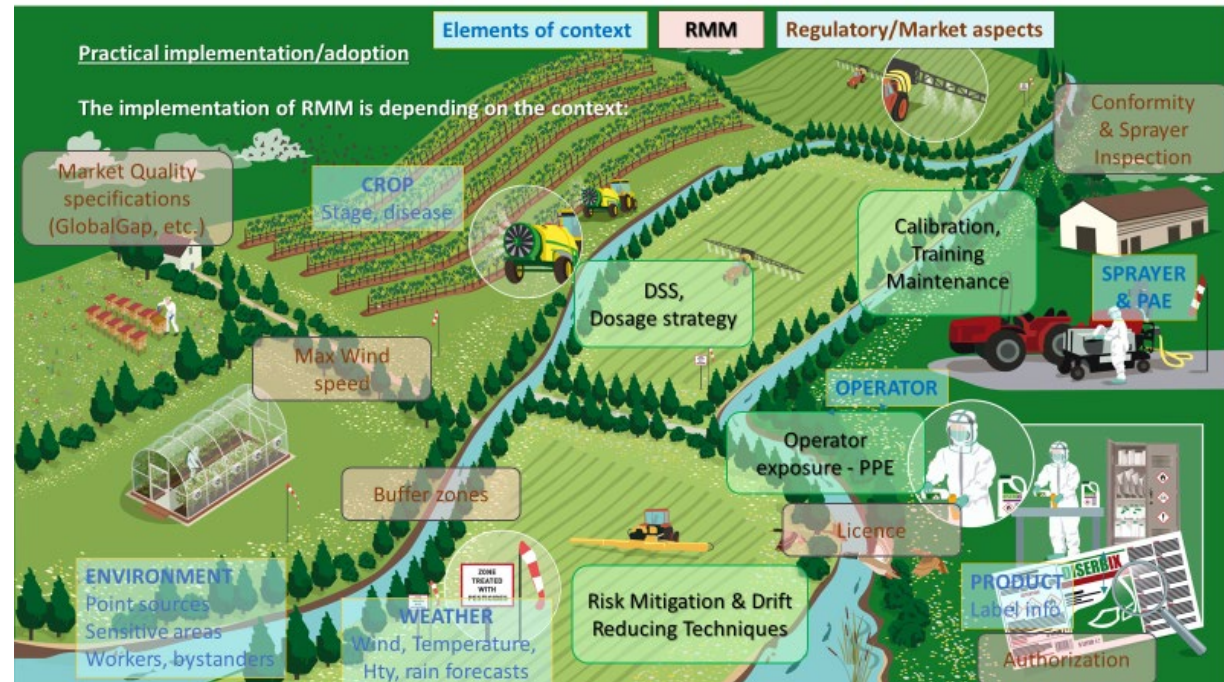
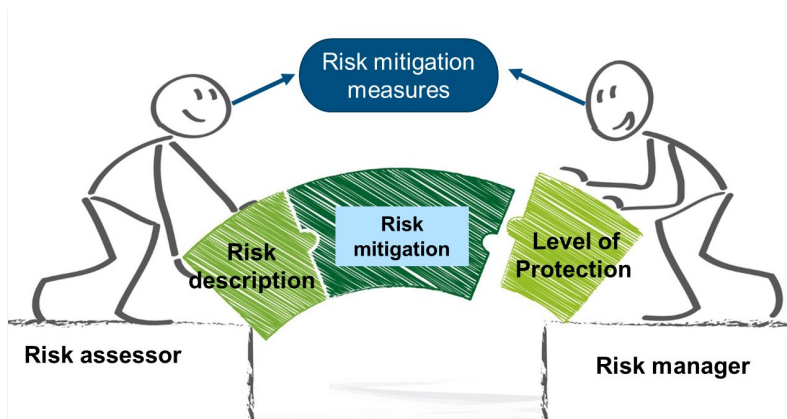
-Next: ZAPID workshop (4-7 December 2023)

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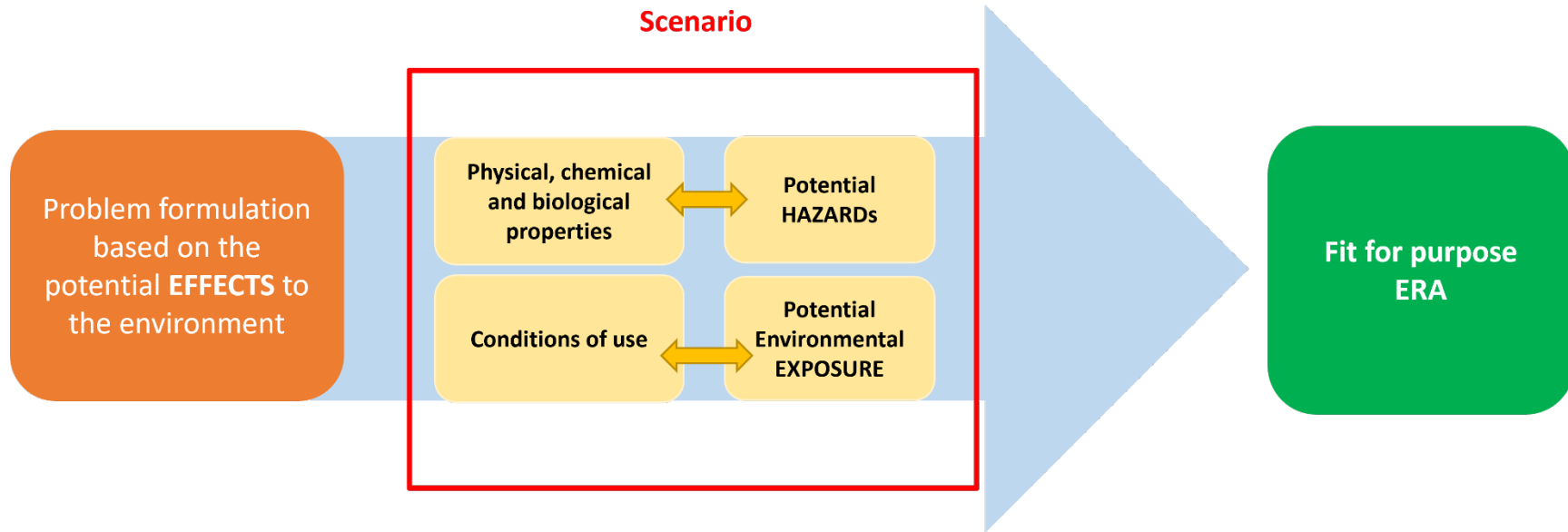
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“Horizontal work”: compendium conditions of use/RMM

- Compendium on conditions of use/risk mitigation measures : could be relevant for your pesticide use scenario (GAP)



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)

Draft consulted with stakeholders and amended based on 23 submitted case studies

New / updated GD endorsed by PAFF...

- GD on time dependent sorption of pesticides in soil (Aged sorption for groundwater leaching)
- *GD on relevance of groundwater metabolites (updated to align genotox part, major update planned later)*
- *GD bees*
- *GD birds and mammals*

Under preparation:

- *Updated guidance on emergency authorisations*
- *Negligible exposure*

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

- Mandate to EFSA and ECHA to develop GD on impact of water treatment processes to residues of AS or metabolites
- GD published on 28 August 2023 by EFSA
- SCoPAFF now discussing how to implement the GD
- Need to amend the 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

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

- Grants “SMP-FOOD-2022-BIOCIDES-PESTICIDES-IBA”
 - to 6 Member States in PPP (and 9 in biocide)
 - to reduce the delays; to establish full cost recovery system
 - in case of PPP: to increase expertise in microorganisms.
 - Total of 10 M€, contracts are to be signed soon
- BTSF trainings (e.g. on MO or ED)
- Workshop on possibilities to increase availability of PPPs (26 October 2023, Webex)
- ZAPID workshop (Braunschweig, DE, 4-7 December 2023)

Thank you for your attention !

For further information:

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

Disclaimer

All views expressed are purely personal and should not be considered as representative of the European Commission's official position. Neither the European Commission nor any person acting on behalf of the Commission is responsible for the use which might be made of the information provided.