



# Biopesticides specificities in the PPP framework – European Commission state of play

**CropLife Europe Annual Conference**  
**6 March 2024**

*Domenico Deserio*  
*EU Commission, SANTE E.4*

# Farm to Fork and pesticides

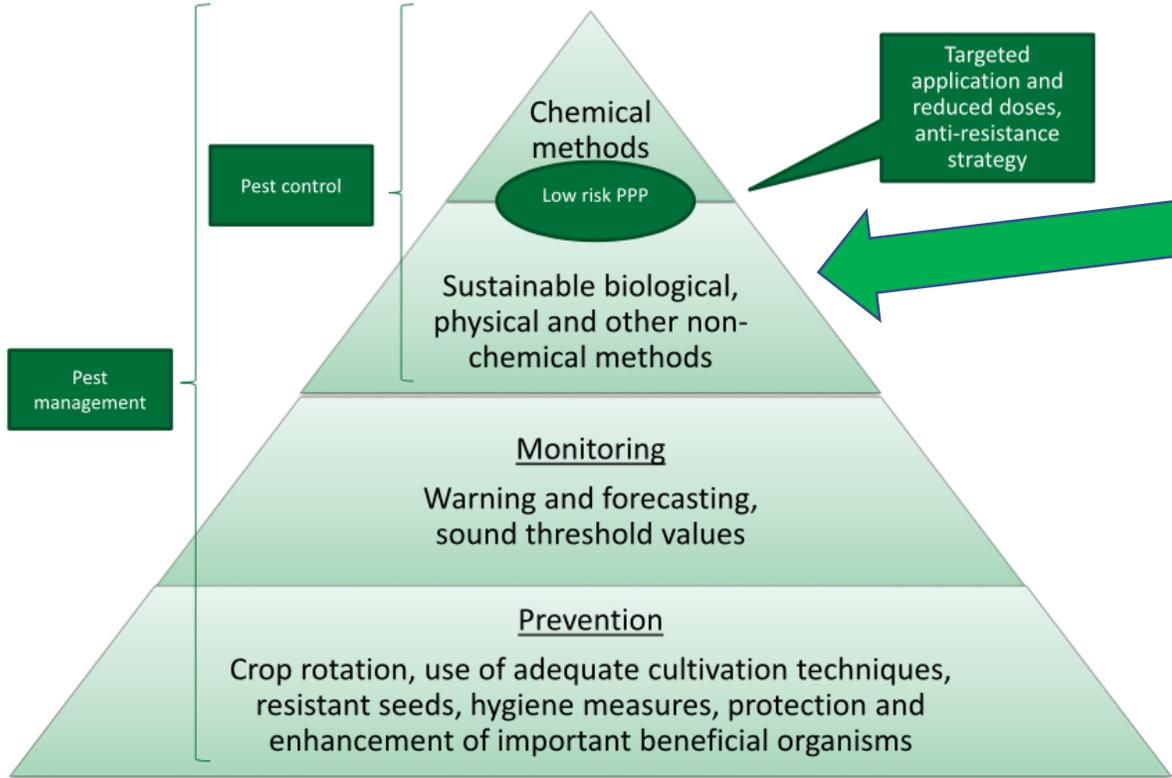


**The use of pesticides in agriculture** contributes to pollution of soil, water and air. The Commission will take actions to:

- ✓ **reduce by 50%** the use and risk of chemical pesticides by 2030.
- ✓ **reduce by 50%** the use of more hazardous pesticides by 2030.

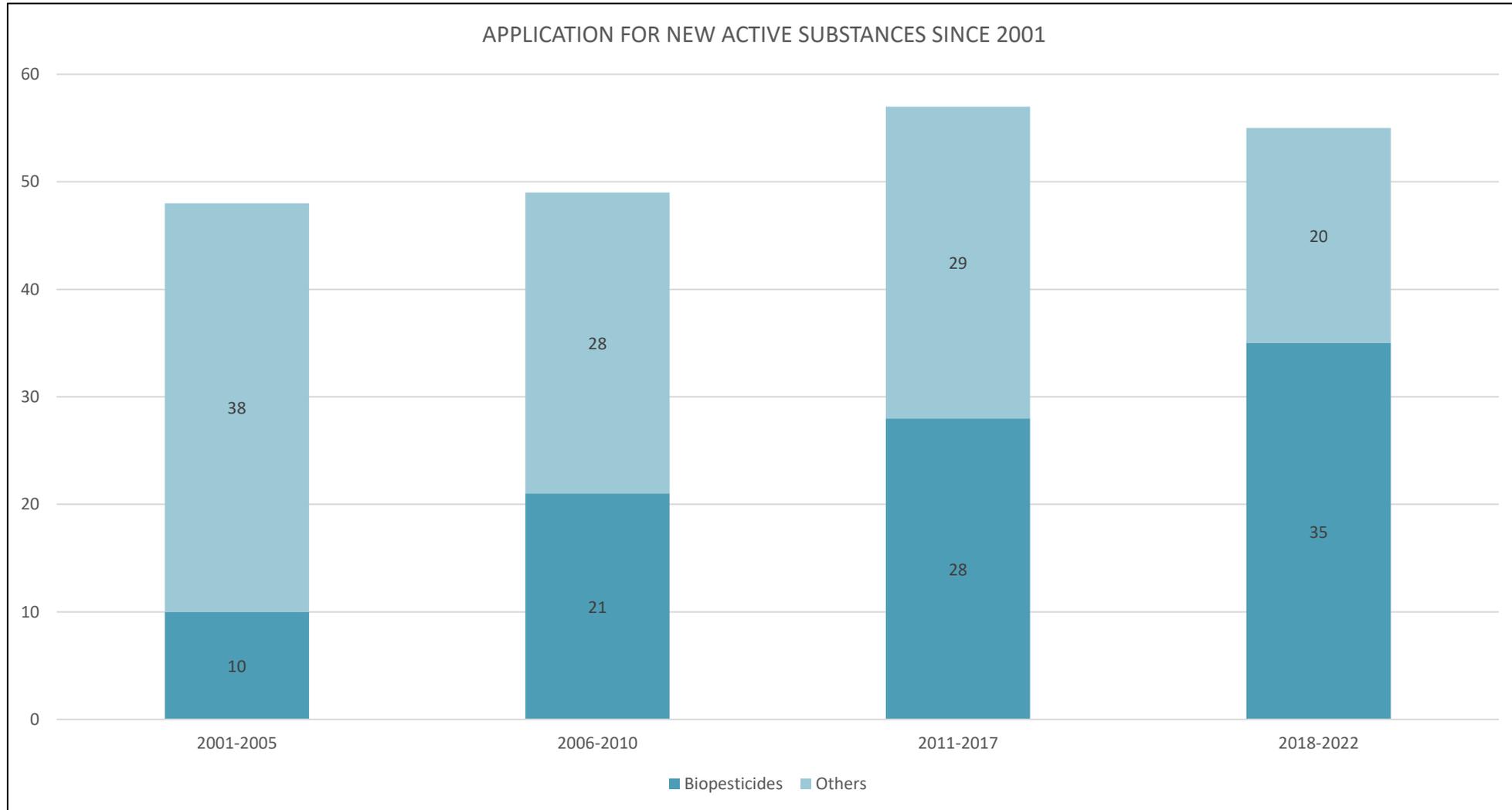


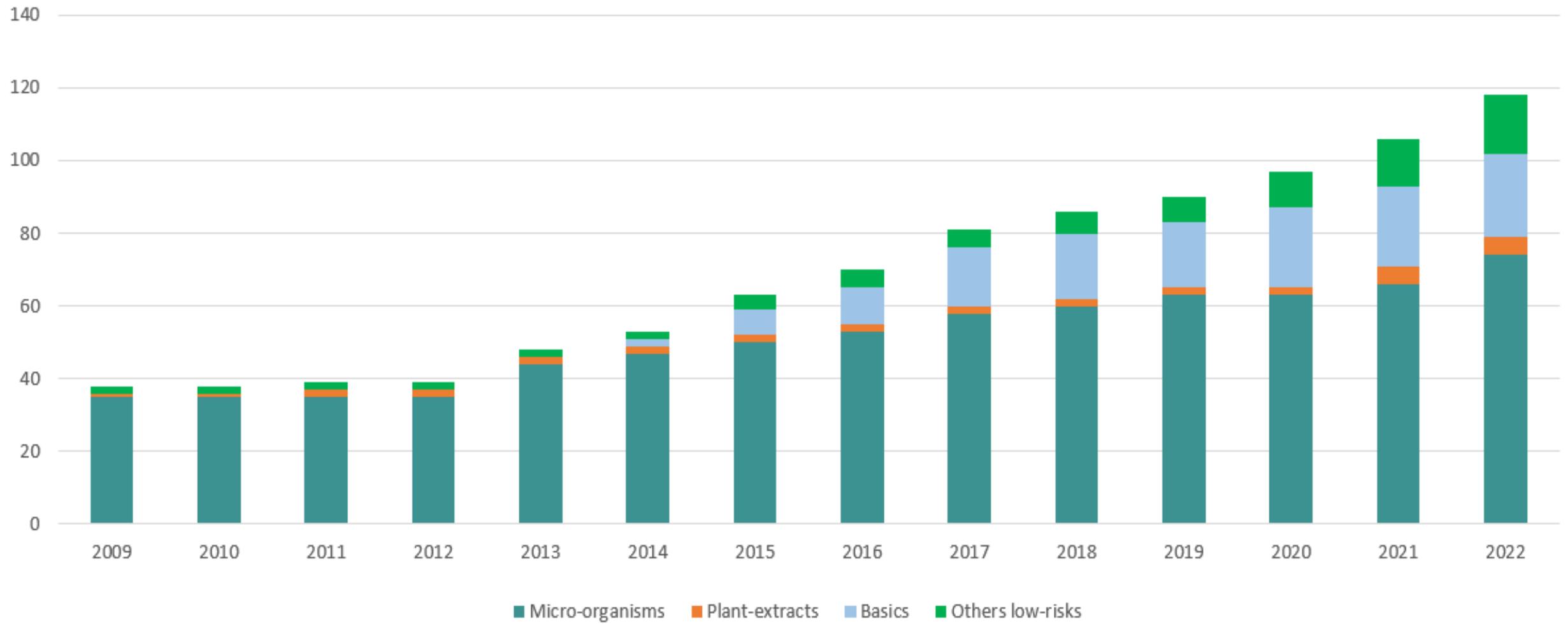
**Organic farming** is an environmentally-friendly practice that needs to be further developed. The Commission will boost the development of EU organic farming area with the aim to achieve **25% of total farmland under organic farming by 2030**.



**SUSTAINABLE USE OF PESTICIDES – IPM**

# Trends in applications for new active substances





# Activities on micro-organisms used in PPP

## 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 recommend methods/ guidance documents
- Support dossier
- Not legally binding
- Endorsed in March 2023
- Additional database of useful guidance documents

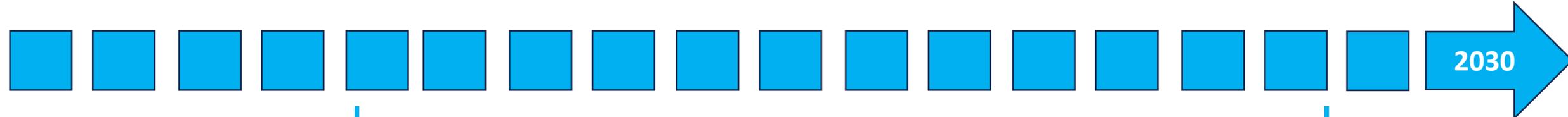
## Explanatory notes + dRR

- Understanding of the new
- Comparison
- Assessment and risk
- Not legally binding
- Endorsed at PAFF October 2023

## Others

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

**“Need to know” approach**



CLE conference 2023

CLE conference 2024

# Activities on micro-organisms used in PPP

## 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

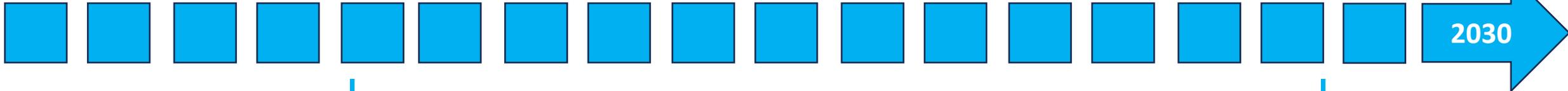
## New database

- Will include both references included in the Commission Communications + others
- Support dossier-preparation (Not legally binding)
- List by section, or by document

### Active Substances

#### Active Substance Part B (micro-organisms)

+ 0: General Guidance	6 documents
+ 1: Identity of the applicant, identity of the active substance and manufacturing information	2 documents
- 2: Biological properties of the micro-organism	4 documents
<b>2.7: Genetic stability and factors affecting it</b>	
<ul style="list-style-type: none"> <li>• EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506) <a href="#">website</a></li> </ul>	
<b>2.8: Information on metabolites of concern</b>	
<ul style="list-style-type: none"> <li>• EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506) <a href="#">website</a></li> <li>• EU Guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258) <a href="#">website</a></li> </ul>	



CLF conference 2023

CLF conference 2024

# Activities on micro-organisms used in PPP

## New Regulatory guidance documents MO

- Guidance document on Microbial Metabolites of Fungicides (Oct 2020)
- Guidance document on Microbial AMR (May 2021)
- Four implementation measures for Regulations (as from Nov 2021)



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY  
Food Safety, Sustainability, and Innovation  
Pesticides and Biocides

PAFF-PPL-October 2023-Doc.A.07.01  
12 October 2023

**Explanatory notes**

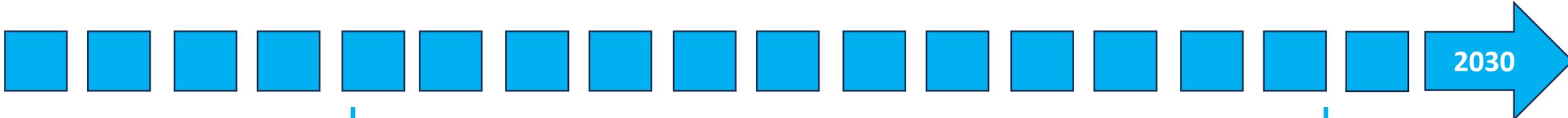
**for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of Reg. (EC) No 1107/2009**

## 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 2023

## Others

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



CLF conference 2023

CLF conference 2024

# Activities on micro-organisms used in PPP

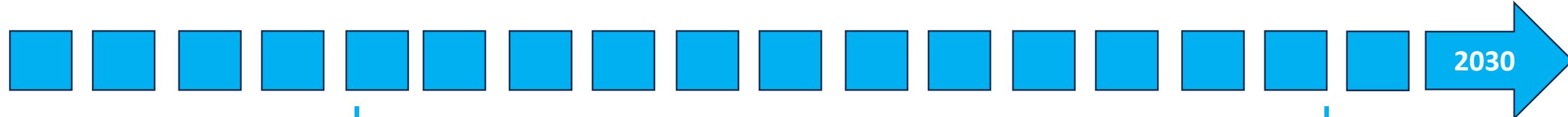
On-going



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

- “Literature review on the occurrence and population levels in soil of micro-organism species used in plant protection”.*  
 ✓ Duration: 12 months (Q3 2023 to Q3 2024)
- “Review of biology and ecology of micro-organism species used in plant protection”.*  
 ✓ Duration: 18 months (Q3 2023 to Q2 2025)

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

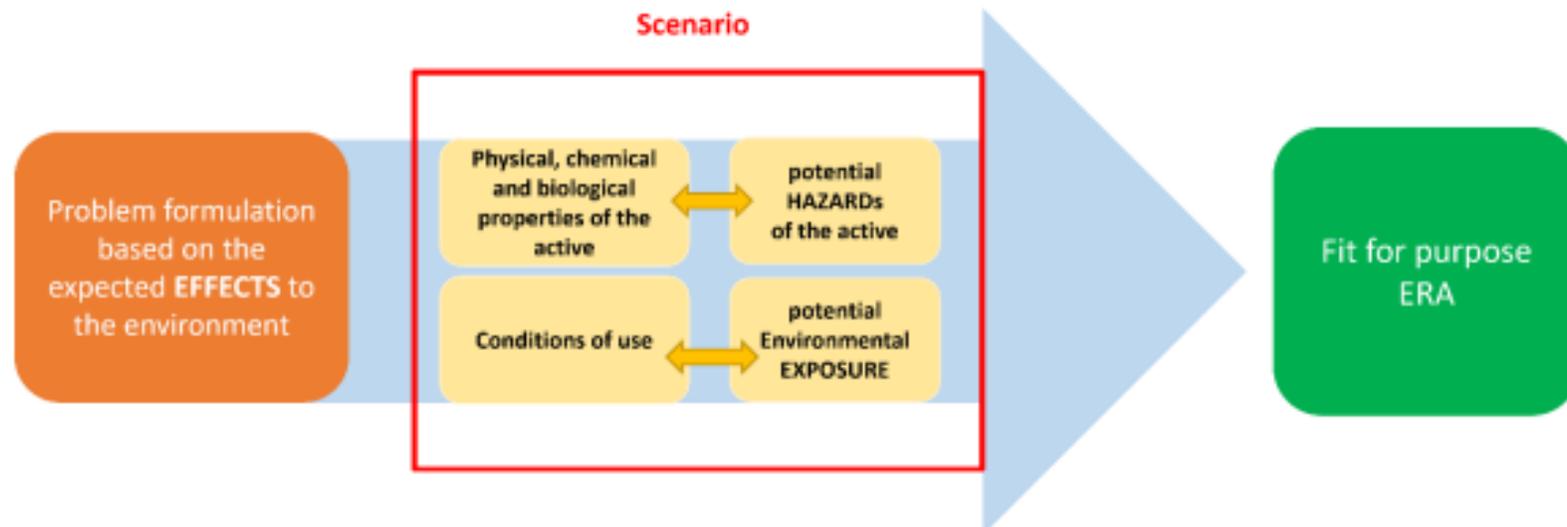


CLÉ conference 2023

CLÉ conference 2024

# Other biocontrol agents

- **Pheromones:** amendment of the GD on semiochemicals to extend the group of pheromones beyond the SCLP group – (Endorsed in Jan 2024)
- **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 (Endorsed in Jan 2024)



# Strengthening Member States capacity

- ❑ 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
  
- ❑ Grants for MS to assess plant protection products
  - ✓ allocated to 6 MS (AT, EE, ES, LT, LV, and SK).
  - ✓ focusing on priority review of biocontrol

# Keep in touch



[ec.europa.eu/](https://ec.europa.eu/)



[europa.eu/](https://europa.eu/)



[@EU Commission](https://twitter.com/EU_Commission)



[@EuropeanCommission](https://www.facebook.com/EuropeanCommission)



[European Commission](https://www.linkedin.com/company/european-commission)



[europeancommission](https://www.instagram.com/europeancommission)



[@EuropeanCommission](https://www.youtube.com/@EuropeanCommission)



[EUTube](https://www.youtube.com/EUTube)



[EU Spotify](https://open.spotify.com/playlist/37i9dQZF1DX0XUf1h2tJ5i)

# Thank you



© European Union 2020

Unless otherwise noted the reuse of this presentation is authorised under the [CC BY 4.0](https://creativecommons.org/licenses/by/4.0/) license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.

Slide xx: [element concerned](#), source: e.g. [Fotolia.com](#); Slide xx: [element concerned](#), source: e.g. [iStock.com](#)