



# Regulation of PPP – ensuring access to new and innovative low-hazard PPPs

SANTE E4

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Improving knowledge, skills and capacity building to ensure plant health in more sustainable agricultural systems

# Farm to Fork and Sustainable use of pesticides

## From Farm to Fork:

Our food, our health, our planet, our future

The European Green Deal



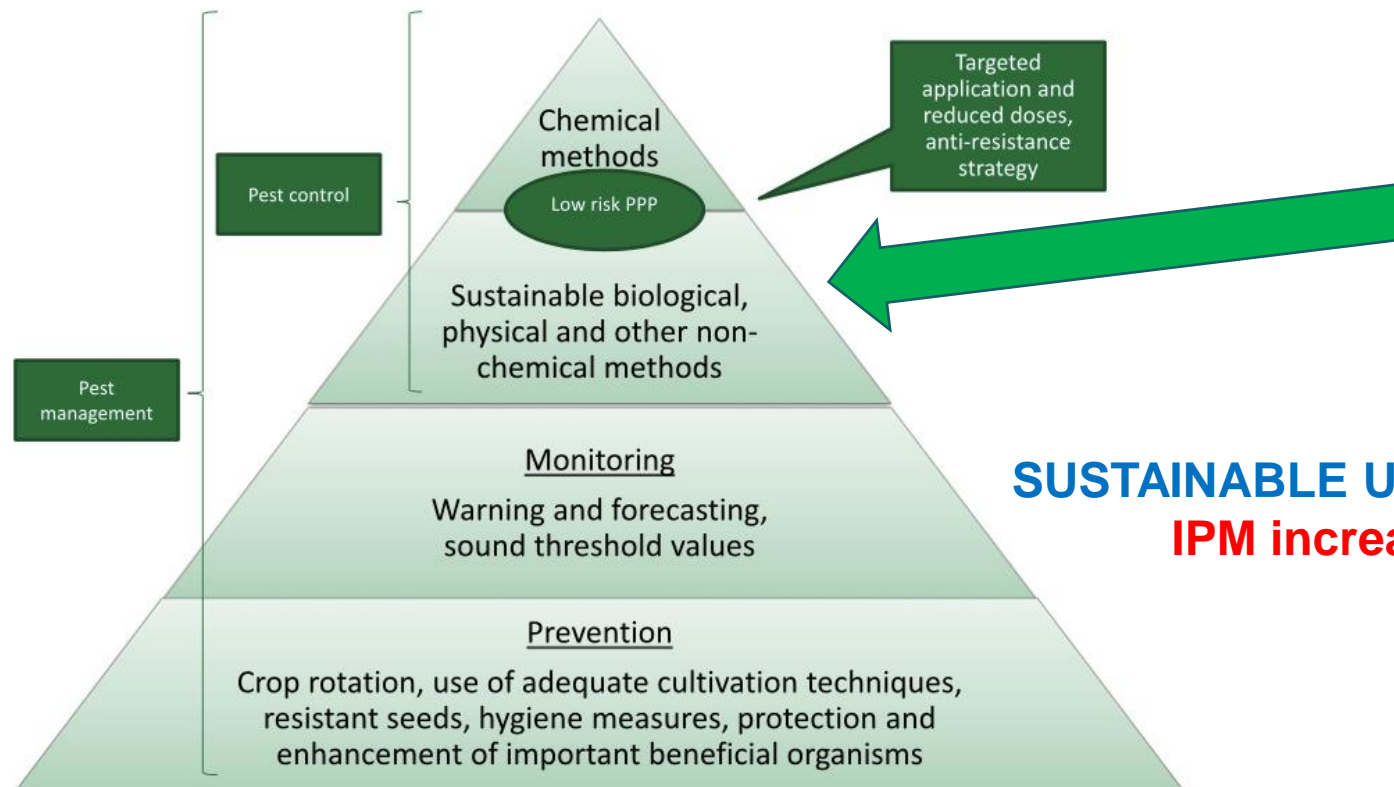
The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

✓ 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**.

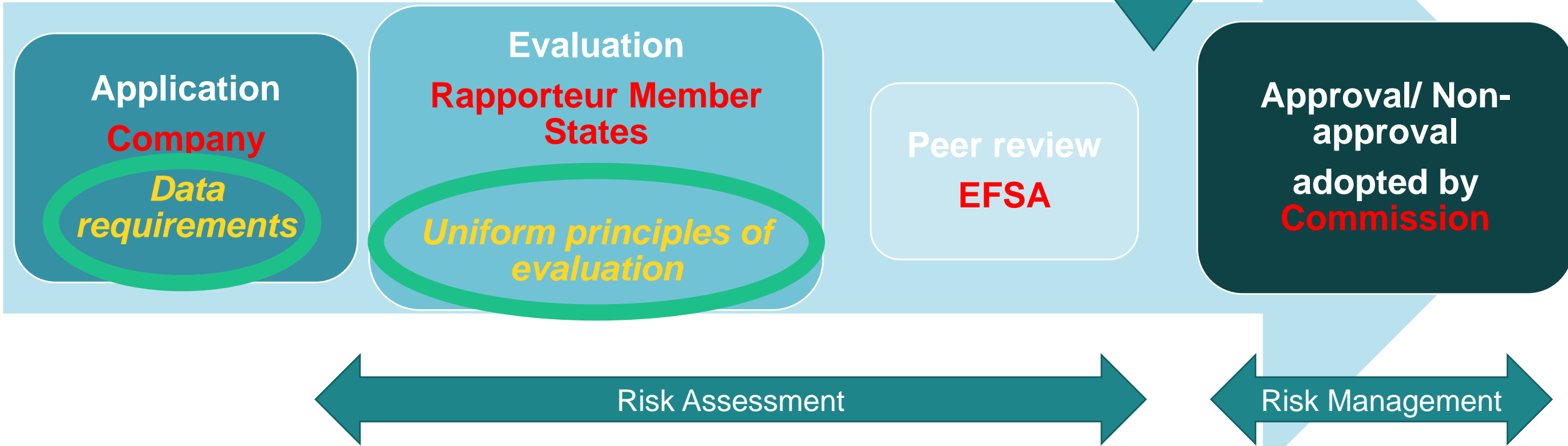


**SUSTAINABLE USE OF PESTICIDES –  
IPM increasingly central**

# Regulation 1107/2009

## Active substances (EU level)

- Standing Committee for Plants Animals Food and Feed (PAFF, 27 MS)
- Restrictions of use and/or risk mitigations could be set



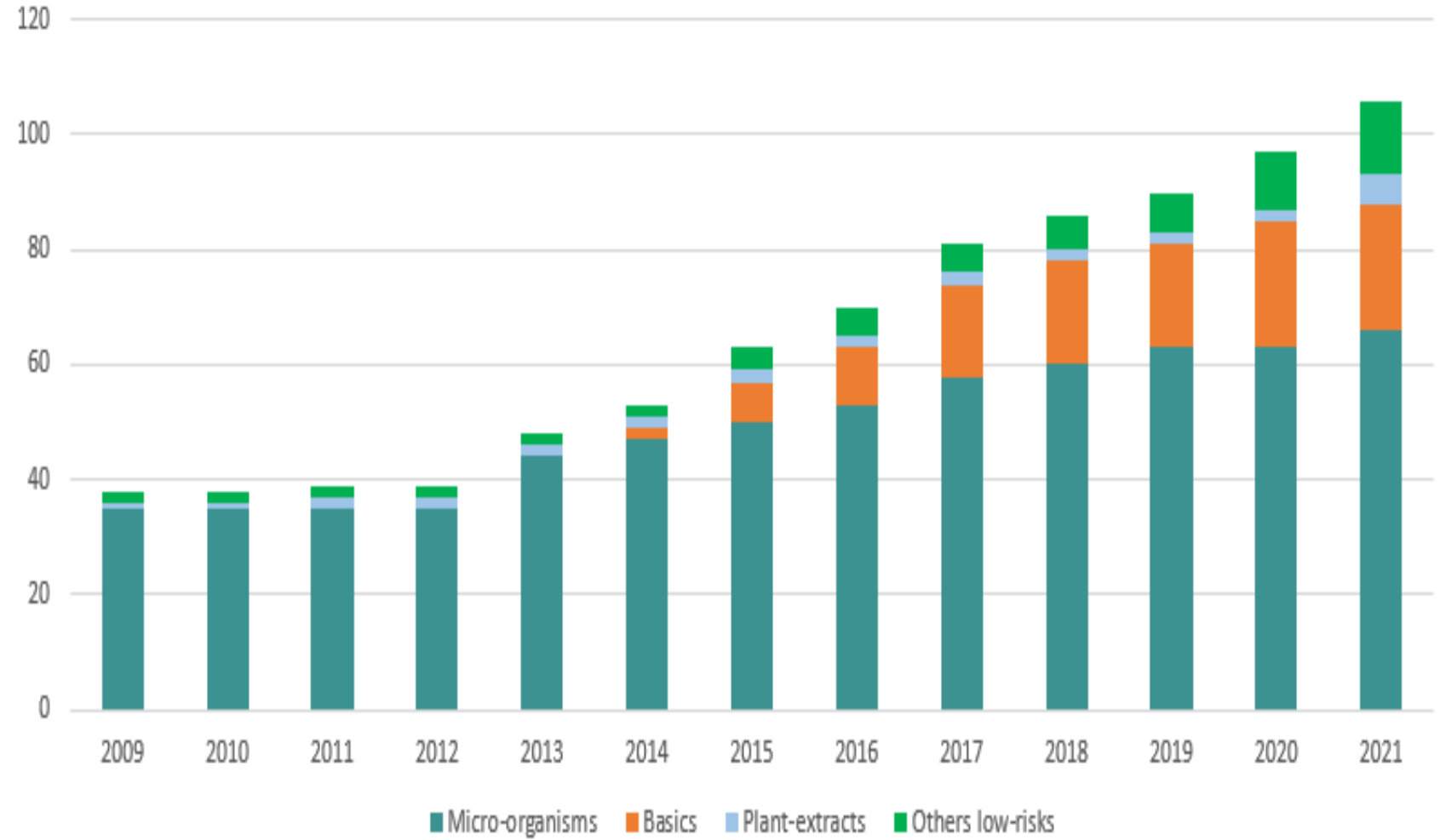
# Amendment of Regulations on micro-organisms:

- ❑ **Reg. 283/2013** (data requirements AS): «*which data are needed to an applicant to submit a dossier of an AS?*»
- ❑ **Reg. 284/2013** (data requirements PPP): «*which data are needed to an applicant to submit a dossier of a PPP?*»
- ❑ **Reg. 546/2011** (Uniform Principles) + **Annex II Reg 1107/2009**: «*evaluation of AS and PPP, decision making criteria, low-risk status?*»

**New Regulations applicable since 21 November 2022!!!**

# Revision of EU framework: why focusing on micro-organisms?

Low hazard active substances approved in EU



“Low risk” substances?  
Organic farming?

# Activities on micro-organisms (I)

## 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

- Support understanding of the new EU Reg
- Support dossier-preparation
- Harmonise risk assessment and risk management
- Not legally binding
- Stakeholders under consultation
- Endorsment planned in Q2-Q3

Completed/available

On-going

Under planning

# Activities on micro-organisms (II)

## OECD activities

## Test methods for MO

## Consensus documents on MO

- ❑ EU BPWG experts involved in OECD activities (e.g. Conference on Innovating Microbial Pesticide Testing, consensus documents on *B. amyloliquefaciens* and *B. bassiana*)

## Other initiatives on MO

- ❑ Exploring further improvement for speeding up access to market of new isolates of already-approved viruses (e.g. baculoviruses and bacteriophages)
- ❑ Compile horizontal information on natural background levels and MO species (species review) – public procurement

Completed/available

On-going

Under planning



# Other biopesticides

## Other biological control agents: semiochemicals, botanicals / other innovative AS (e.g. peptides, RNAi)

- Current regulatory framework already allows applications for other BCA to be submitted
- Point 1.5 of the introduction to Reg (EU) No 283/2013 and 284/2013
  - Problem Formulation Document (ERA) (in preparation)
  - RA is flexible: Importance of pre-submission meetings!
- On pheromones**: Exploring possible extension of SCLP definition
- On other innovative substances (e.g., RNAi): Need of case-studies to build experience



# Strengthen MS capacity

## Training on Risk Assessment on Micro-Organisms (BTSF)

- ❑ Aim: improving expertise in MS authority on assessing micro-organisms
- ❑ Intended benefits: Reducing bottlenecks and fostering harmonisation in risk assessment
- ❑ On going since 2 years

## Provision of specific grants for MS

- ❑ call for proposals for financial grants (10 million Euros over 5 years)
- ❑ Aim: to reduce delays and to increase expertise and capacities on assessment of alternatives to conventional chemicals (particularly micro-organisms).

Completed/available

On-going

Under planning

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# Thank you



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