



# Peptides as biological control agents under Reg (EC) 1107/2009

EU, European Commission, SANTE E4

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*ABIM, workshop peptides regulation*

21 Oct 2025

# Farm to Fork, a Vision for Agriculture and food, and biological control



2020



2025

→ Accelerating access to biocontrol

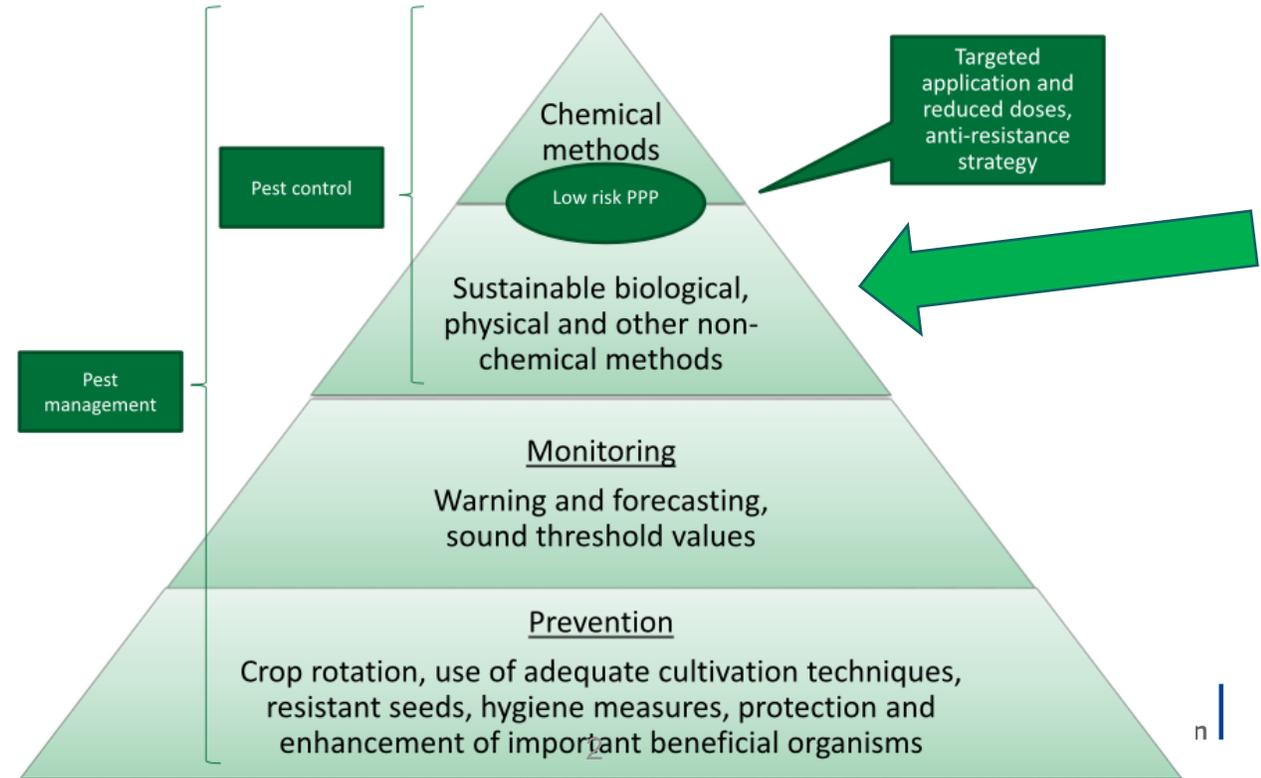


The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

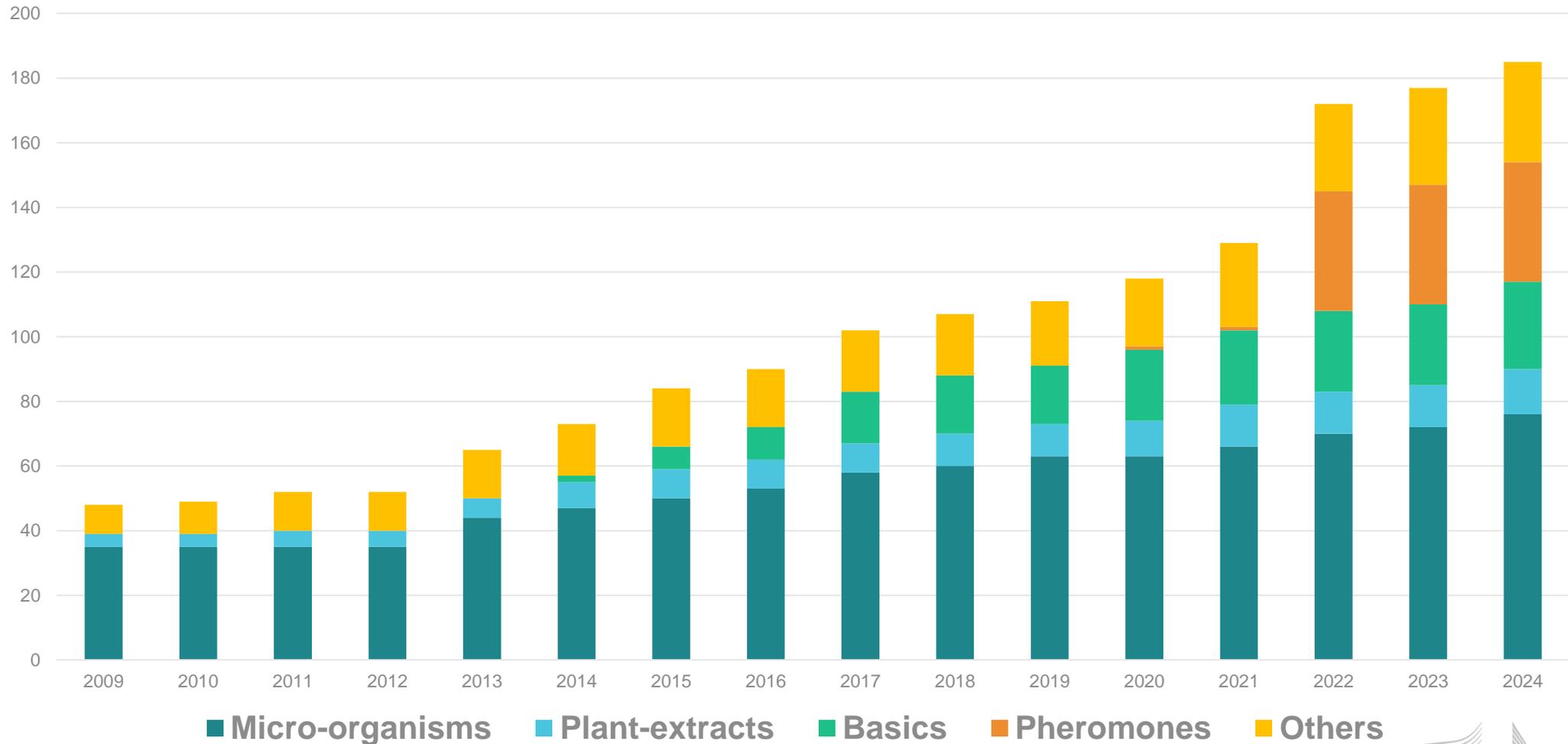
- ✓ reduce by 50% the use and risk of chemical pesticides by 2030.
- ✓ reduce by 50% the use of more hazardous pesticides by 2030.



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.**



# Availability of biocontrol active substances in the EU



# Regulation 1107/2009

Active substances (EU level)

Process:

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

Application  
**Company**

*Data requirements*

Evaluation

**Rapporteur Member States**

*Uniform principles of evaluation*

Peer review

**EFSA**

Approval/ Non-approval  
adopted by  
**Commission**

# Is the EU legal framework ready for peptides?

- Already possible to take peptides to the EU market as biocontrol agents!
- Under data requirements and uniform principles\* Part A



*“certainty of specific requirements” VS “openness to innovation”*

*“regulating tightly” VS “flexibility of legal framework”*

Ideally, we need to find the right balance for such innovative active substances!!!

\* Reg (EU) No 283/2013, Reg (EU) No 284/2013, Reg (EU) No 546/2011

# Facilitating access to market of peptides (I)

- Data requirements and uniform principles\* Part A currently into force and current amendments (*public consultation concluded on 9 Oct 2025*)

Introduction point 1.5:

(...) the information shall not be required, **where a scientific justification** is provided showing that the information is not necessary because:

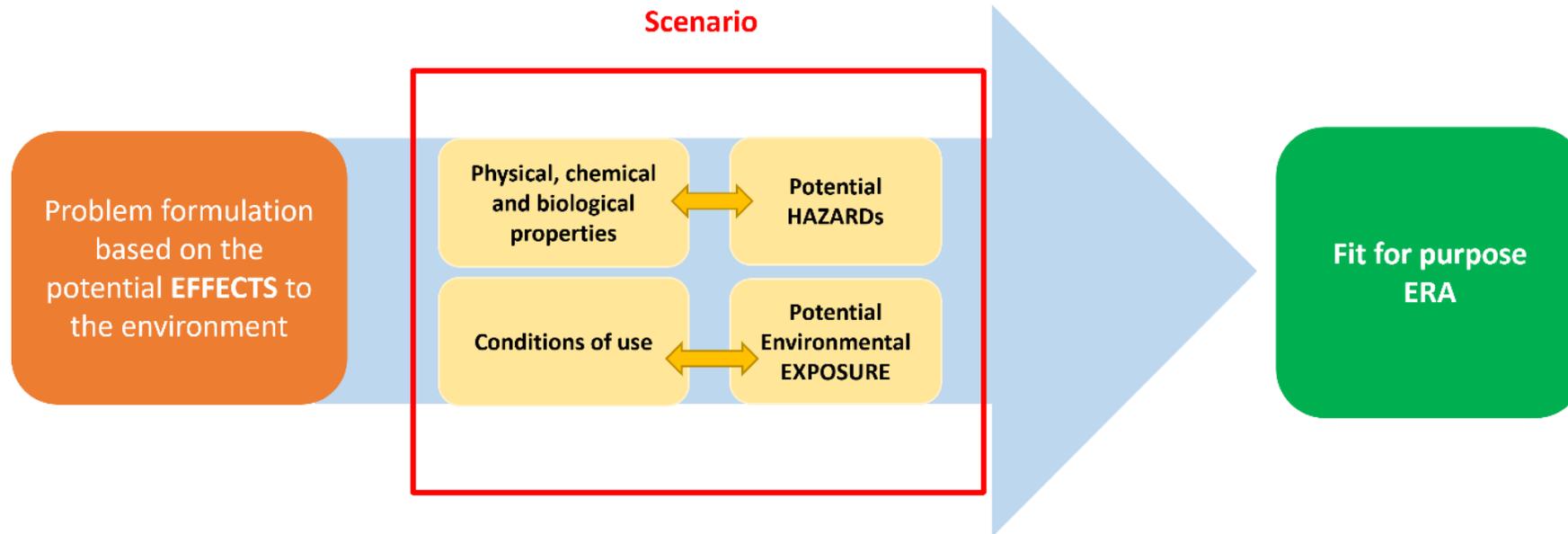
- (a) the plant protection product is unlikely (...) to cause harm (...) e.g. **if the active substance is of biological origin or is functionally identical and structurally similar to it**, such as: (...) a substance originating from or secreted by living organisms, or derived by biological processes (...) or metabolites produced by a micro-organism.

“where a scientific justification” = it needs to be robustly justified

# Facilitating access to market of peptides (II)

- “Problem Formulation” document (Endorsed in Jan 2024)

A fit for purpose risk assessment driven by a problem formulation step!



# Facilitating access to market of peptides (III)

- ❑ Targeted amendments to Regulation (EC) No 1107/2009 (SANTE simplification omnibus):
  - introduce a definition of biocontrol active substances
  - possibility for Member States to grant provisional authorisations for plant protection products containing biocontrol active substances while their evaluation is still ongoing
  - create a fast-track procedure for their approval and authorisation
- ❑ EFSA will be reinforced with additional resources to speed up risk assessment procedures
- ❑ Some targeted stakeholder consultations already held. Views of Member States and stakeholders are being taken into account
- ❑ [Call for Evidence](#) (closed on 14 October 2025)
- ❑ Adoption by end of 2025

# Useful links

- ❑ Reg 1107/2009: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009R1107-20221121>
- ❑ Data requirement active substances: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R0283-20221121#tocId10>
- ❑ Data requirement PPP: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02013R0284-20221121>
- ❑ Uniform principles: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011R0546-20221121>
- ❑ General EC page on Micro-organisms in plant protection: [https://food.ec.europa.eu/plants/pesticides/micro-organisms\\_en](https://food.ec.europa.eu/plants/pesticides/micro-organisms_en)
- ❑ Explanatory notes: [https://food.ec.europa.eu/system/files/2023-10/pesticides\\_ppp\\_app-proc\\_guide\\_imp-data-req\\_micro-organisms-ppp\\_imp-reg-11072009.pdf](https://food.ec.europa.eu/system/files/2023-10/pesticides_ppp_app-proc_guide_imp-data-req_micro-organisms-ppp_imp-reg-11072009.pdf)
- ❑ Guidance document on AMR: [https://food.ec.europa.eu/system/files/2020-11/pesticides\\_ppp\\_app-proc\\_guide\\_180652\\_microorganism-amr\\_202011.pdf](https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180652_microorganism-amr_202011.pdf)
- ❑ Guidance document on secondary metabolites [https://food.ec.europa.eu/document/download/ffdf09b5-77a5-45b5-95f9-b16272f7535a\\_en?filename=pesticides\\_ppp\\_app-proc\\_guide\\_180653\\_microorganism-metabolites-concern.pdf](https://food.ec.europa.eu/document/download/ffdf09b5-77a5-45b5-95f9-b16272f7535a_en?filename=pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern.pdf)
- ❑ Commission communications: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023XC0609%2802%29&qid=1686297487173> AND <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023XC0609%2801%29&qid=1686297476366>
- ❑ Database of guidance documents: <https://webgate.ec.europa.eu/dyna2/pgd/>
- ❑ Problem formulation document: [https://food.ec.europa.eu/document/download/c4d6b7df-b7f9-4b3b-8ce5-b823ccdcf98c\\_en?filename=pesticides\\_ppp\\_app-proc\\_guide\\_horiz\\_problem-formulation-era.pdf](https://food.ec.europa.eu/document/download/c4d6b7df-b7f9-4b3b-8ce5-b823ccdcf98c_en?filename=pesticides_ppp_app-proc_guide_horiz_problem-formulation-era.pdf)

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