



Biological control in the EU under the framework of Reg (EC) 1107/2009

Domenico Deserio
Policy Officer
European Commission, SANTE E4

11th PPPHI- science meets legislation
18-19 Feb 2024

- Overview of the EU framework
- Research needs

Farm to Fork and pesticides

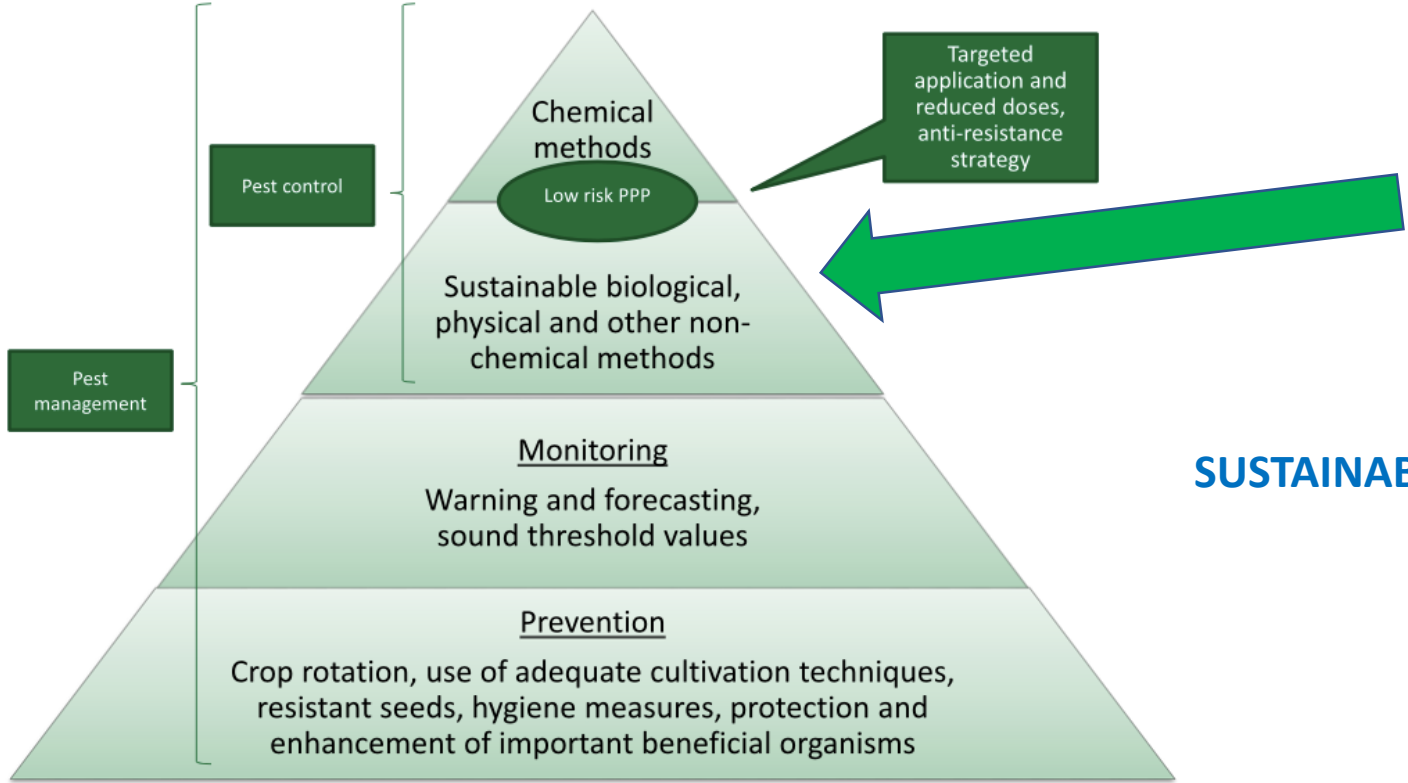


The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

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

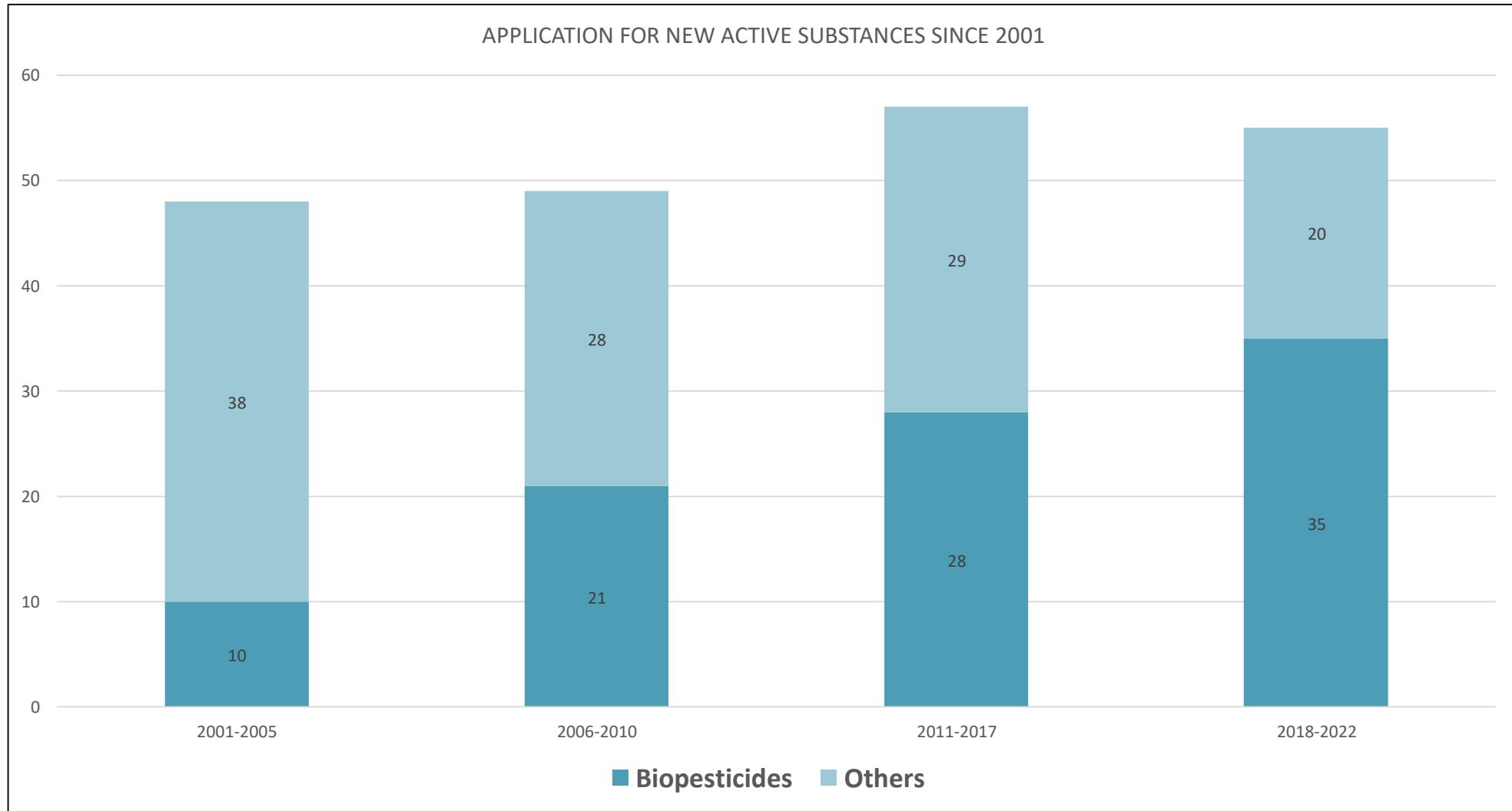


Organic farming is an environmentally-friendly practice that needs to be further developed. The Commission will boost the development of EU organic farming area with the aim to achieve **25% of total farmland under organic farming by 2030.**



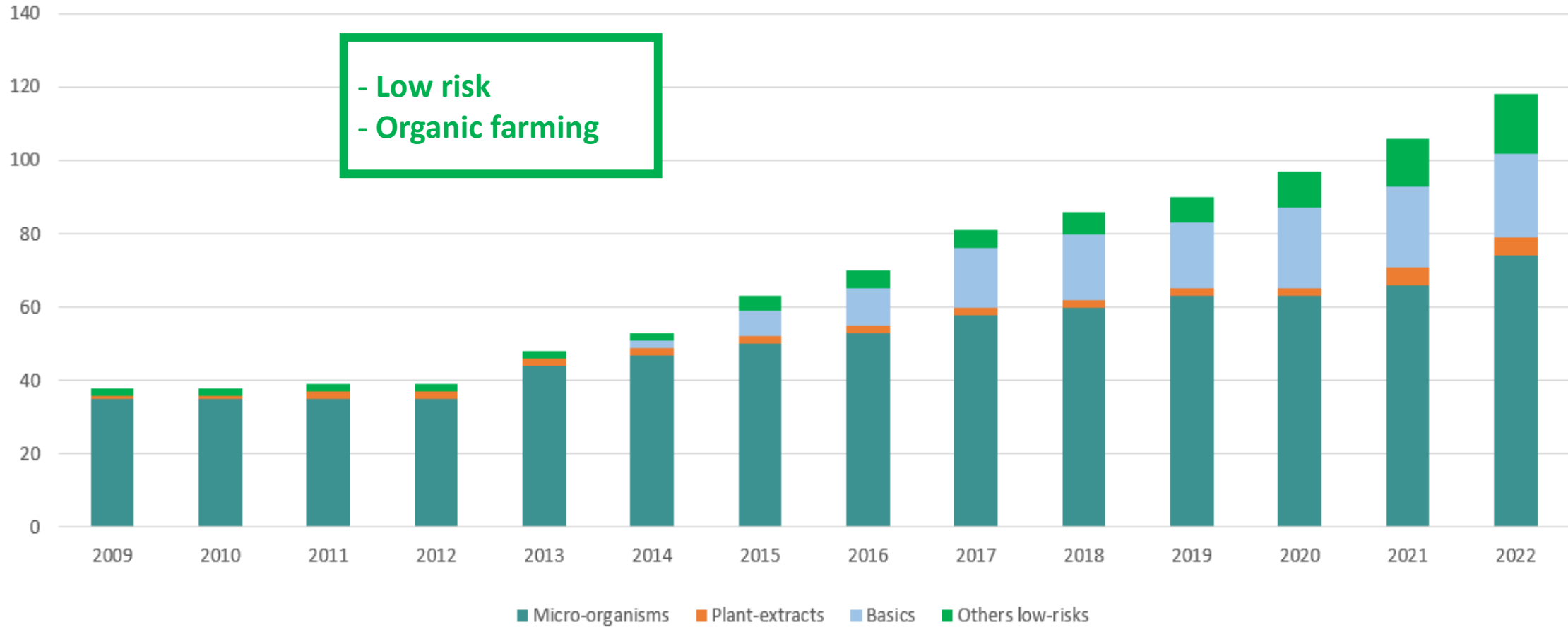
SUSTAINABLE USE OF PESTICIDES – IPM

Trends in applications for new active substances



Availability of low-risk / non-chemical alternatives

Low hazard active substances approved in EU



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
- Endorsed at PAFF October 2023
- Additional database of useful guidance documents

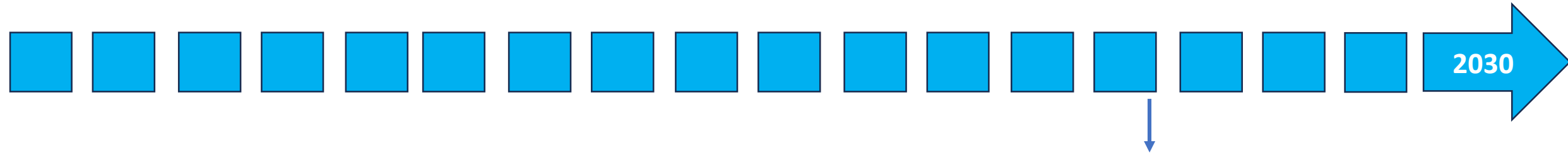
“Need to know” approach

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
- Guidance document on viruses



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Activities on micro-organisms used in PDD

New Regulations and guidance documents on MO

- Guidance document on Metabolites of Concern (Oct 2020)
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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

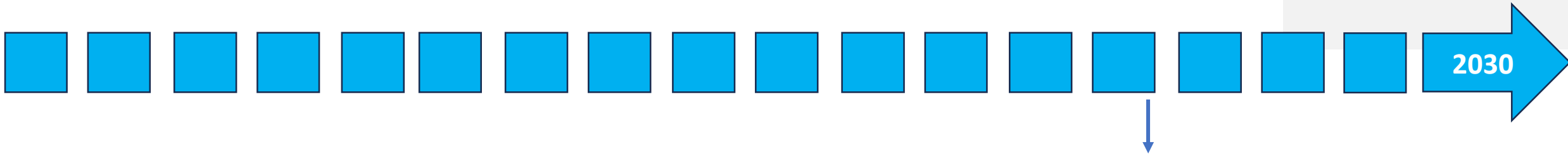
New database

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

Active Substances

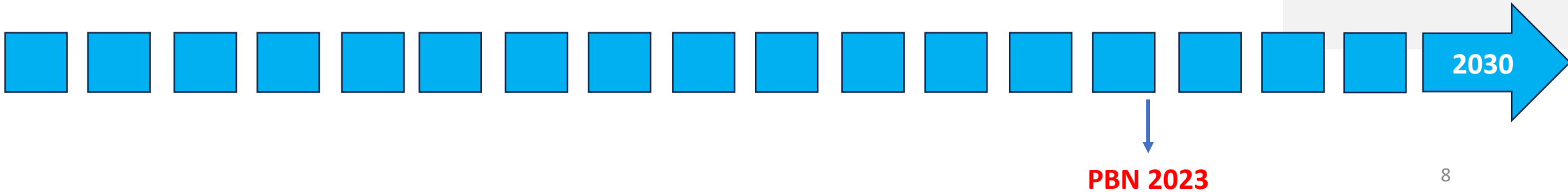
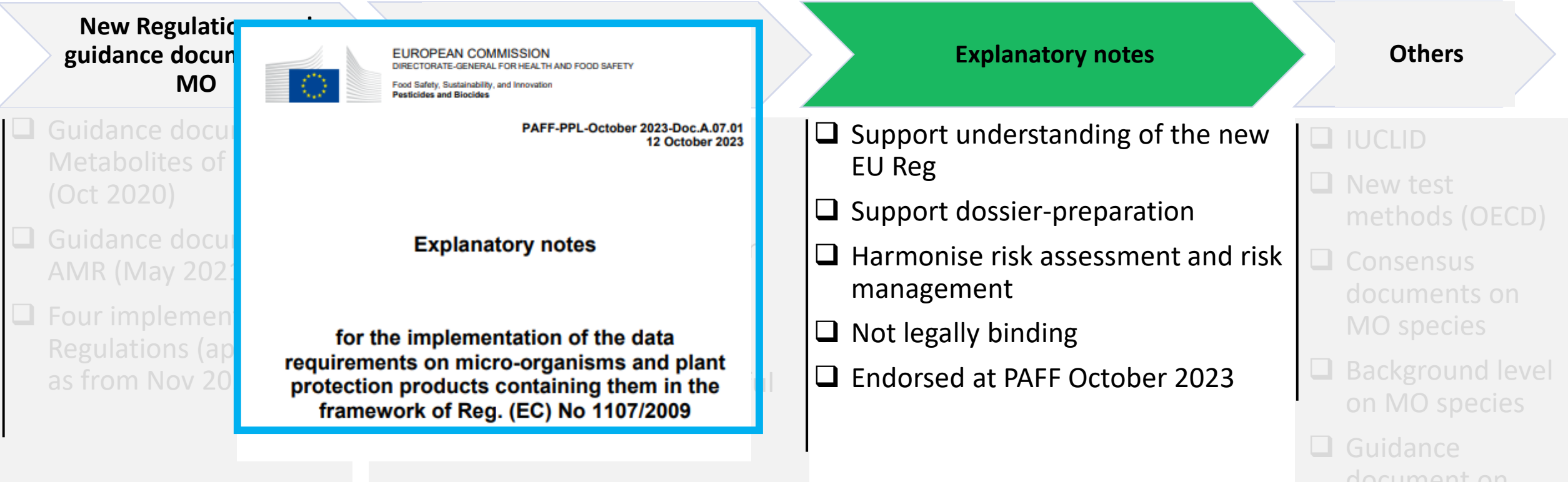
Active Substance Part B (micro-organisms)

+ 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
2.7: Genetic stability and factors affecting it	
<ul style="list-style-type: none"> • EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506) website 	
2.8: Information on metabolites of concern	
<ul style="list-style-type: none"> • EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506) website • EU Guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258) website 	



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Activities on micro-organisms used in PPP



Activities on micro-organisms used in PPP

On-going



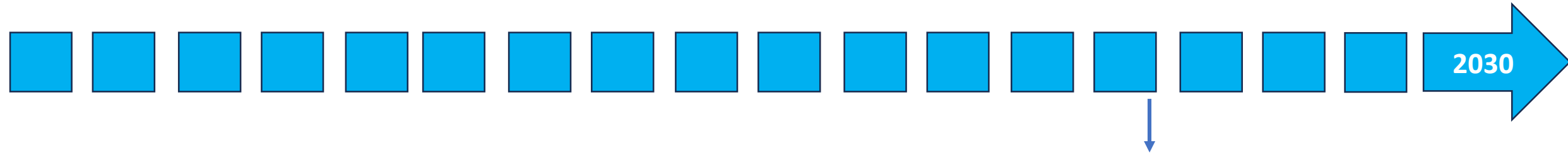
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New test methods (OECD)

- e.g.:
- New Approaches Methodologies (NAMs) to test sensitising potential of MO?
 - overarching Guidance Document on Best Practices for testing,
 - establish a list of non-target arthropods other than bees ,
 - integrate problem formulation in the risk assessment of microbial pesticides
 - Others...

New studies (EC)

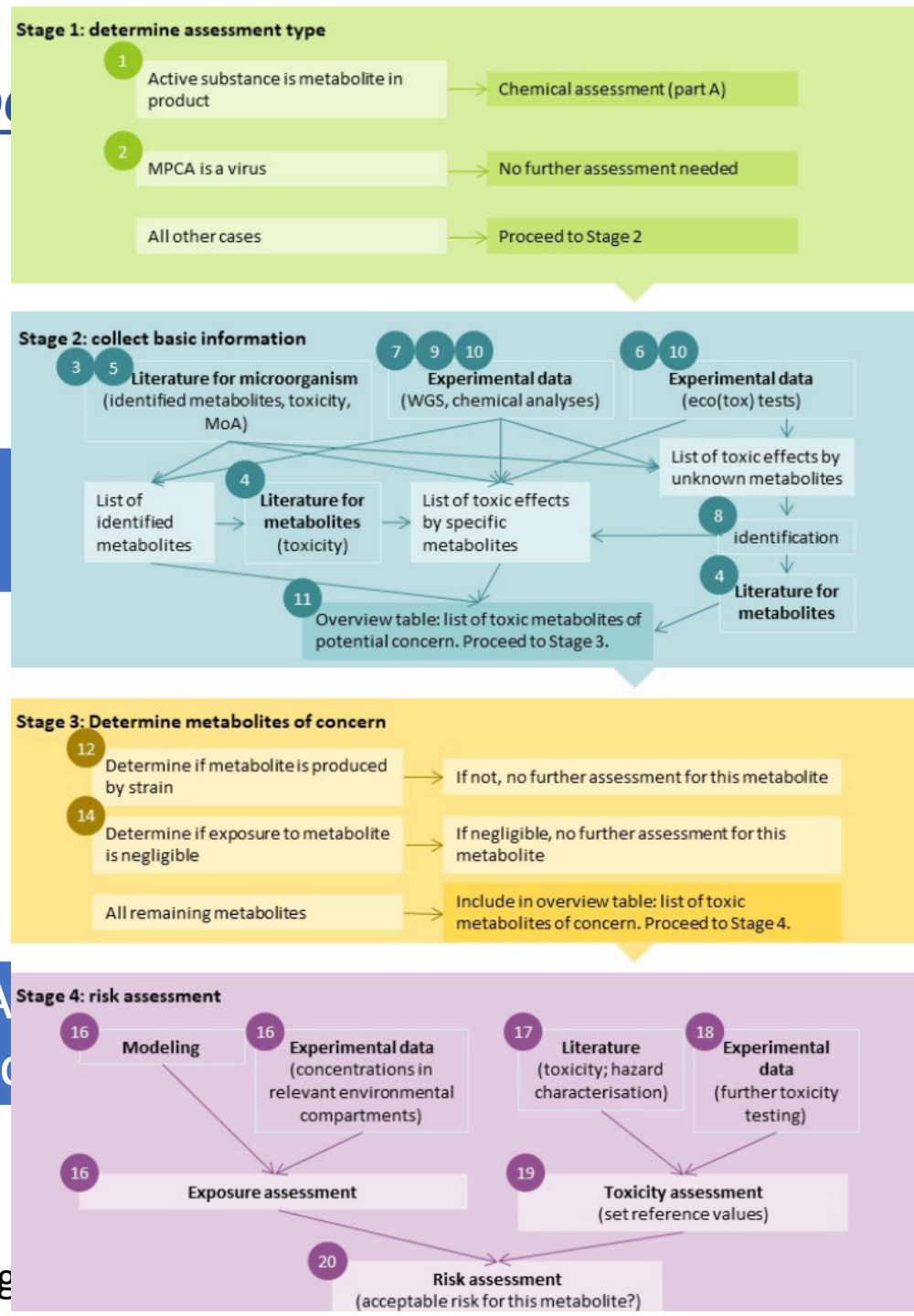
- “Literature review on the occurrence and population levels in soil of micro-organism species used in plant protection”.*
 ✓ Duration: 12 months (Q3 2023 to Q3 2024)
- “Review of biology and ecology of micro-organism species used in plant protection”.*
 ✓ Duration: 18 months (Q4 2023 to Q2 2025)



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Identification of *metabolites*

relevant?



Guidance document

Secondary metabolites

Primary metabolites

In MPCA-AM

In-situ

*MPCA-AM: Microbial Pest Control Agent

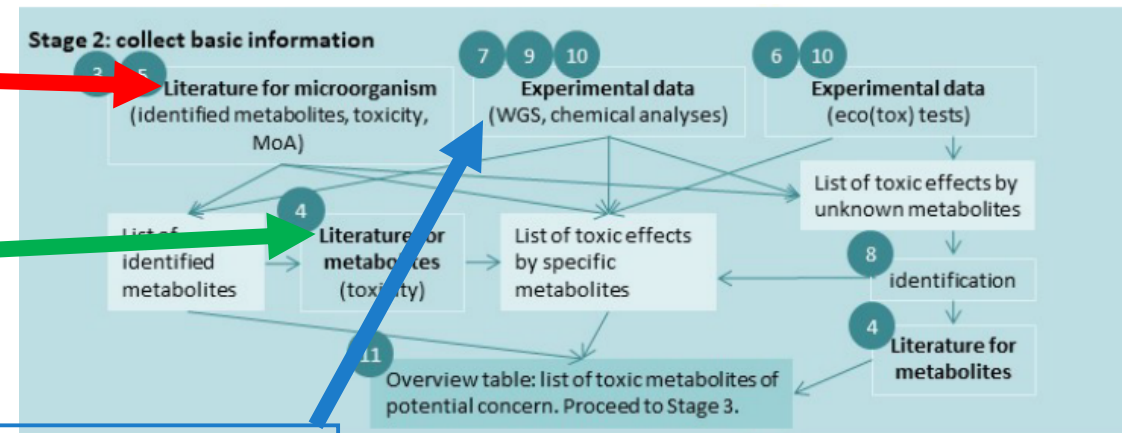
Use of whole genome sequencing

- ❑ Not legally binding, but very useful (e.g., AMR, metabolites of concern, identity)
- ❑ On AMR transfer assessment, ongoing discussion on analysis of mobile genetic elements (see “*EFSA statement on how to interpret the QPS qualification on acquired antimicrobial resistance genes*”)
- ❑ On metabolites of concern...

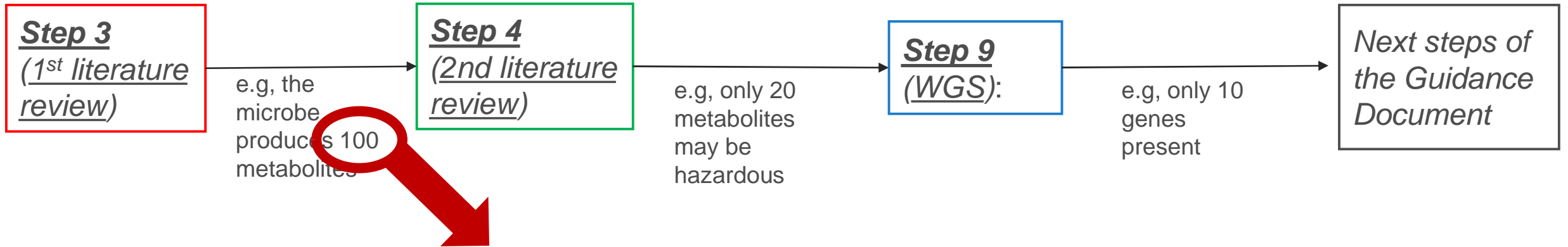
Step 3 (*1st literature review*): which metabolites can the microbe produce?

Step 4 (*2nd literature review*): which metabolites identified in step 3 are hazardous?

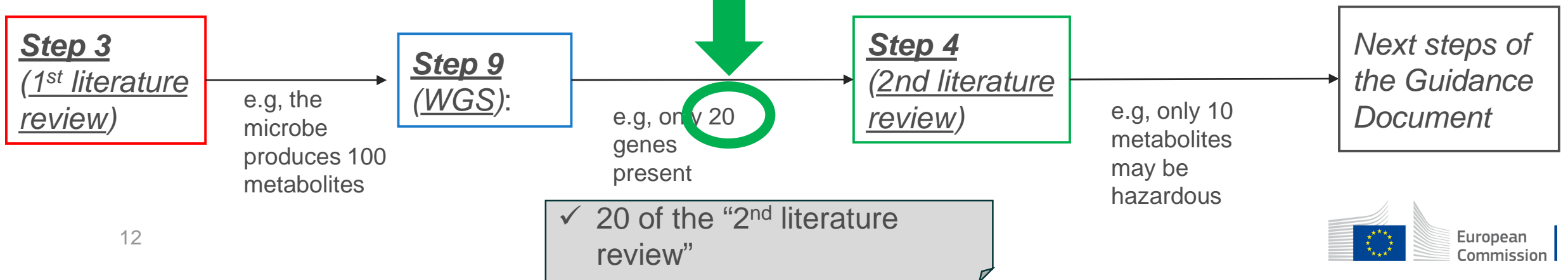
Step 9 (*WGS*): has the microbe genes encoding for hazardous metabolites identified under step 4?



Use of whole genome sequencing – identification of metabolites of concern



✓ Do we need to perform 100 of the “2nd literature review”??? Not necessarily, it is a guidance document, and the order of the steps can be changed if justified...



✓ 20 of the “2nd literature review”

On microorganisms and other biocontrol agents...

- ❑ Ongoing revision of Part A of data requirements and uniform principles.
- ❑ **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)
- ❑ Ongoing study on regulatory aspects relating to biotechnology and biomanufacturing (results planned for end 2025), depending on the results targeted amendments to legislation relevant for biocontrol agents may be considered

- Overview of the EU framework
- Research needs

Risk Assessment/management challenges

some of the on-going EU-funded projects

Ration

Developing a novel risk assessment scheme tailored to the specific characteristics of established and emerging low risk solutions

Vinny

Developing nanoformulated biopesticides in viticulture by investigating microbiome-based metabolites and bioactives from different vineyards in Europe

Tribiome

Deepening the knowledge of soil/plant/animal and human microbiomes and their interconnections to reduce use of conventional chemicals

Excalibur

Developing a comprehensive strategy of soil management improving the effectiveness of biocontrol and bio-fertilisation practices in agriculture

Sagropia

Introducing 13 bio- and low-risk PPP to replace conventional chemicals

NextGenBioPest

Providing novel Biological Control Agents and methods to augment their performance in the field, RNA-based pesticides, Low Risk/Green chemicals

Low concern active substances*

Problem formulation using pathways to breach the protection goal for the environmental risk assessment of substances of low concern

Risk assessment/management challenges

Consortia on micro-organisms

□ New Data Requirement on micro-organisms, scope: “a micro-organism, either as a single strain or as a qualitatively defined combination of strains as they occur naturally or by manufacture”

✓ Efficacy, lower possibility of pest resistance, combination of modes of action...

🤔 Complexity of the assessment

□ Ongoing discussion within the EU Biopesticides Working Group, e.g.,

- ✓ which data requirement should be addressed at strain level, and which one at consortium level?
- ✓ How to adapt assessment approaches based on different types of consortia (natural VS synthetic, mixture of closely related micro-organisms VS “chimeric” consortia)?

Risk assessment/management challenges

New type of biocontrol active substances

- ❑ e.g., Bacteriophages, iRNA, Peptides
- ❑ EU legal framework already covers them, e.g.:
 - ✓ introductory point 1.5 data requirements*: “...information shall not be required, where a justification is provided showing that: (a) it is not necessary owing to the nature of the plant protection product or its proposed uses, or it is not scientifically necessary...”
 - ✓ Part A data requirements: biocontrol substances of chemical nature (e.g., iRNA, peptides)
 - ✓ Part b data requirements: micro-organisms (e.g., bacteriophages)
- ❑ need to develop more experience to eventually engage further regulatory initiatives on these innovations

Where do we need more innovation?

For which crops? e.g.:

Top 5 microbial strains authorised in EU	Total Number of Crops authorised for use	Fruits	Vegetables	Arable crops	Cereals
Bacillus thuringiensis kurstaki	78	7	67	4	0
Pythium oligandrum	22	1	15	3	3
Cydia pomonella granulovirus	6	6	0	0	0
Bacillus amyloliquefaciens	64	15	40	8	1
Beauveria bassiana	59	11	45	3	0

n.b. preliminary analysis based on microbiological-PPP authorised in BE, DE, FR, IT, NL

Against which pests? e.g.:

- Xylella
- herbicides

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#toclid10>
- ❑ 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
- ❑ 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
- ❑ Guidance document on AMR: 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
- ❑ 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

Thank you

For further information:

https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en

https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides_en

https://food.ec.europa.eu/plants/pesticides/micro-organisms_en



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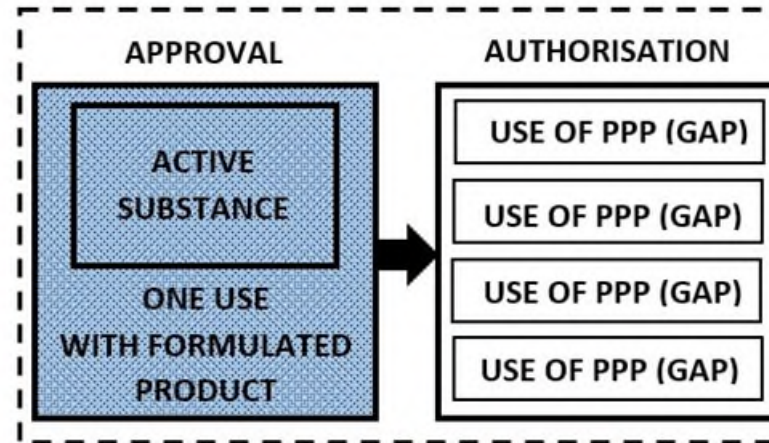
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Regulation 1107/2009 (placing on the market)



Active substances

AS may be used in PPP (1 safe scenario)



PPP PLACING ON THE MARKET
REGULATION (EC) 1107/2009



Plant protection products

PPP may be used under certain conditions
(dose, frequency, conditions and restrictions)



Tiered-based and weight of evidence approach

Example on assessment on human pathogenicity

1- Weight of evidence approach (WoE)

- Biological properties
- Medical data
- Others



2- Pathogenicity and infectivity studies (new data generation)

- Acute oral, and/or
- Acute intratracheal/ intranasal, and/or
- Intravenous/Intraperitoneal or subcutaneous test



3- Specific pathogenicity and infectivity studies (new data generation)

- If WoE and pathogenicity and infectivity studies require further investigation

