Biopesticides specificities in the PPP framework – unlocking novel technologies, and redefining priorities

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IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

What is Biocontrol?

Examples of successful implementation of Biocontrol

Invertebrates

Semiochemicals

Microbials

Natural substances

Biopesticides specificities in the PPP framework

- Increase in biocontrol registration approvals, a shift from chemical
- Biocontrol now represent the majority of AS being applied for and approved at the EU level (35 biocontrol, 20 chemical new AS applications during 2018-2022)
- 37% of all EU-approved active and basic substances are biocontrol
- IBMA survey (March 2023, 26 members) 129 biocontrol substances planned for submission by 2028 (75 new AS, 54 label extension). 28 M ha of potential use, mostly on arable crops

But this is not enough:

- Farmers need more solutions in their toolbox as some chemical solutions progressively disappear and the number of new chemical AS approvals is dropping
- Some other regions progress faster than the EU both in terms of biocontrol uptake and type of solutions approved (Brazil, USA etc.)

Biocontrol is key but there is an elephant in the room

Many biocontrol solutions exist but ...

01 Biocontrol authorisation process is too slow

02 EU Regulation is not designed for biocontrol

03 The arrival of novel technologies need to be further considered at EU level

04 Farmers and Advisers are not sure how to optimise biocontrol performance

Biopesticides specificities in the PPP framework

Risk assessment challenges

- Multiple modes of action
- Modes of action do not necessarily have a clear dose-response relationship
- Usually low hazard/toxicity to mammals (including humans) and other non-target organisms
- Can consist of complex mixtures
- Microorganisms are living organisms which are influenced by numerous biotic and abiotic factors
- Usually not persistent in the environment
- Established environmental fate models are not always adaptable to biopesticides

→ This is why we need to have a biological focused risk assessment

Agronomic benefits

- Low potential for resistance development
- Low to no residues
- Usually target specific, low impact on beneficial organisms and the environment (e.g. breaking down in soil or water)
- Can be readily incorporated into IPM programs

→ Better safety profile, more value for farmers in the food chain

Biopesticides specificities in the PPP framework

A lot has been done by the European Commission and Member States on biocontrol and a considerable number of endorsed documents have been produced, such as :

- Microorganisms Data Requirements, Explanatory Notes, new dRR template
- Revised Guidance Document on Semiochemicals (SANTE/12815/2014 rev. 11)
- Guidance document on problem formulation for ERA

Initiatives to further progress towards a fit for purpose RA for biocontrol

- Biopesticides WG (DG SANTE) – IBMA contribution
- OECD Expert Group on BioPesticides (EGBP) – IBMA contribution
- RATION Project (Risk Assessment Innovation for Low-Risk Pesticides) – IBMA is a member of the consortium
- EFSA GRANT - Develop a stepwise approach for a fit for purpose risk assessment, in particular for low-concern active substances and uses (DRs – PART A)

IBMA approach to novel technologies

- New technologies are being submitted for approval in the EU (bacteriophages, peptides, antibodies, etc.)
- Innovation is often ahead of the regulatory framework; There is no specific risk assessment framework in the EU for some of these technologies
- IBMA is considering novel technologies in the scope of its biocontrol definition (sourced from nature or is nature identical if synthetised)
- IBMA definition is a living document reviewed by a Scoping Committee advised by relevant experts reviewing new technology as necessary

Source: Callaway, E. Do you speak virus? Phages caught sending chemical messages. *Nature* (2017).

Novel technologies are coming!

Bacteriophages

DCM PEA-02® phage mixture has won the Gold Bernard Blum Award 2023 - most innovative biocontrol product at ABIM Annual Biocontrol Industry Meeting

Regulatory challenge: adaptation of the bacteriophage mixture based on continuous monitoring results of the bacterial population

Allelochemicals

Agriodor is developing technologies based on odours for the control of aphids, vectors of sugar beet yellows

Challenge: urgent need for a solution (neonicotinoids not available). Allelochemicals category defined in the semiochemicals GD; technology not yet submitted for approval in the EU.

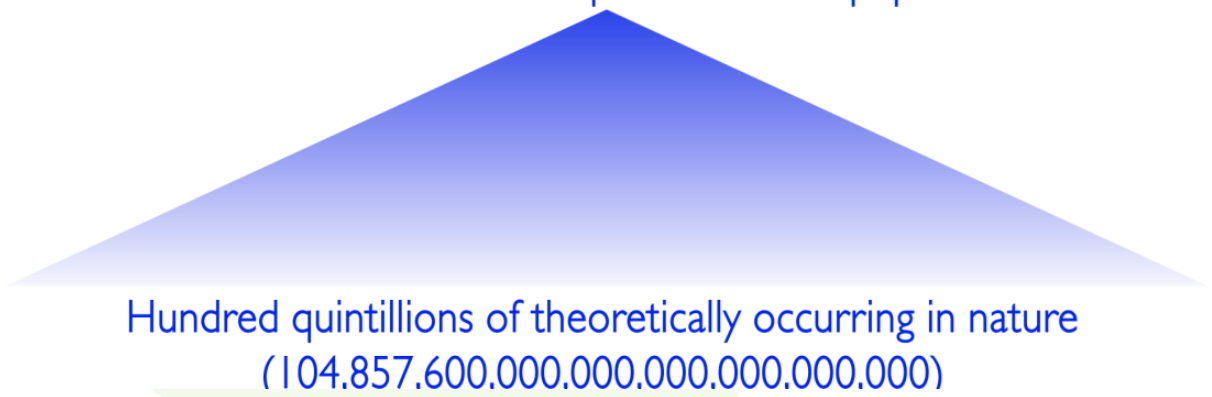
Source: Agriodor

Peptides – an evolving technology

Final remarks

In summary, the classification of natural and natural-like peptides is not an well-defined and universally-accepted concept. Conversely, the definition is still a **multifaceted and evolving notion**

As scientific research advances continue, the regulatory frameworks also evolves, shaping the definition of natural, natural-like and unnatural peptides. Therefore, this notion cannot be represented as fixed image but it should be considered as **an evolving concept**.



- Nature identicality is an evolving concept
- 9 peptides both identical to nature (5) or modified (4) were communicated as ready for submission in the EU between 2023 and 2028 (IBMA survey)

Andrea Chini - National Centre of Biotechnology; Spain

Green sustainable technologies – need prioritization?

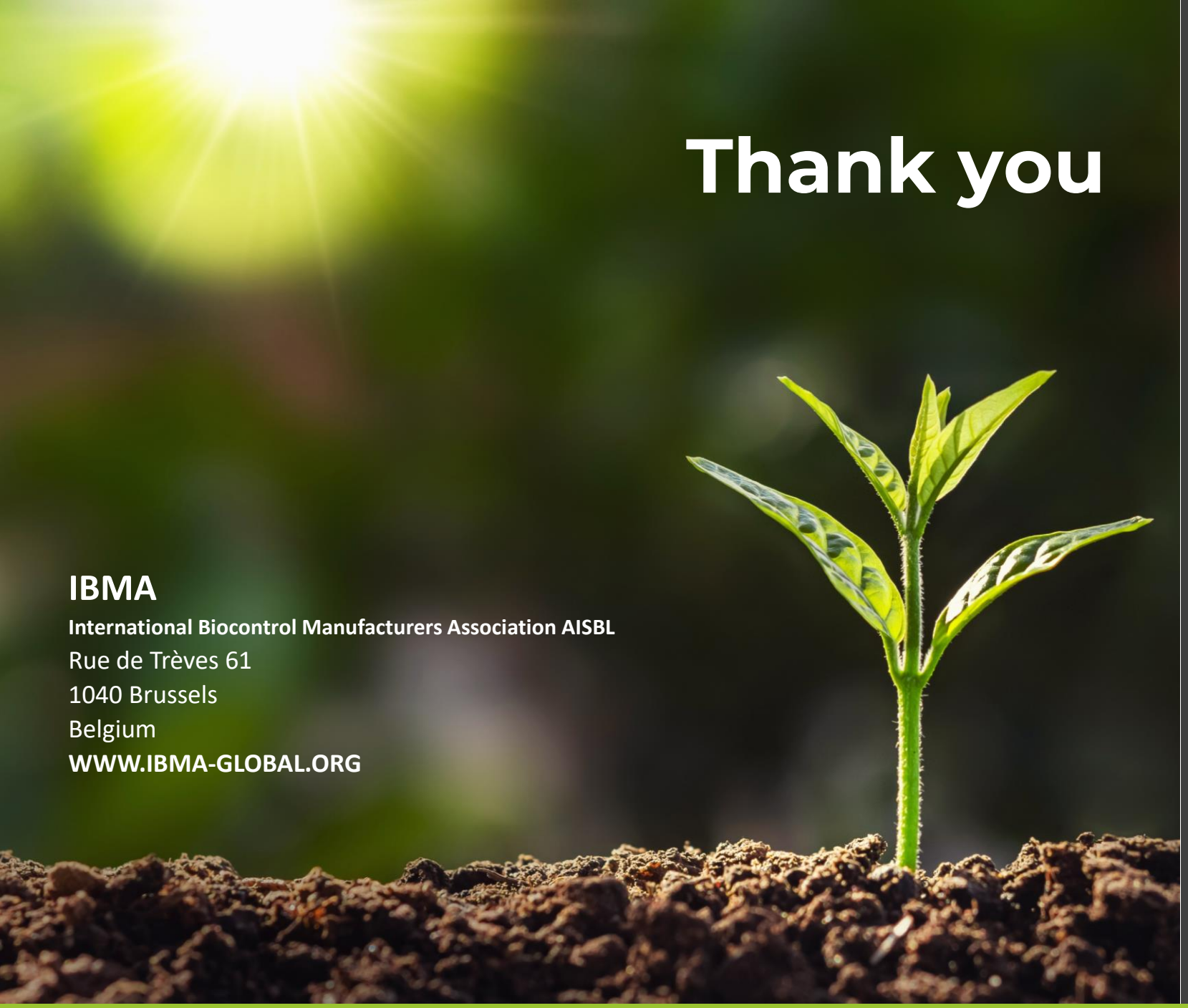
- UN COP biodiversity and climate targets create horizontal policy targets to halt biodiversity decline and mitigate climate change. Biocontrol has a key role to play.
- Ctgb in alignment with the Dutch "*Implementation Programme for the Vision of the Future of Plant Protection 2030*" has implemented a prioritization process through a **Sustainability Desk Plant Protection Products** to ensure that "growers have access to a wider range of products that meet the criteria for sustainability"

Applications need to meet certain criteria to be eligible for this priority procedure. For example, all active substances need to be either (i) low-risk substances, (ii) live microorganisms (including viruses), (iii) non-chemical substances with non-toxic or selective-toxic effects, such as all semiochemicals (including pheromones) and plant extracts with non-toxic or selective-toxic effects; nature-identical compounds with selective-toxic effects.

Conclusion

- Substantial progress has been made at EU level to adapt the risk assessment to the biology of biocontrol products, but more could be done
- Novel technologies with unique modes of action will further expand the biocontrol toolbox. They need an appropriate path to approval based on the need-to-know approach
- We need a prioritization for biocontrol to provide much needed additional solutions in the farmer's toolbox
- Development of digital technologies (monitoring, decision making), advisory and adapted training will assist farmers to ensure the potential of biocontrol product is fully maximized
- IBMA promotes biocontrol and biological innovation to provide farmers with sustainable and efficient technologies, adding value to the agricultural sector in the food chain

Thank you



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