



micropep

# **Regulatory Considerations for Novel Peptide-based Biocontrols**

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**ABIM**

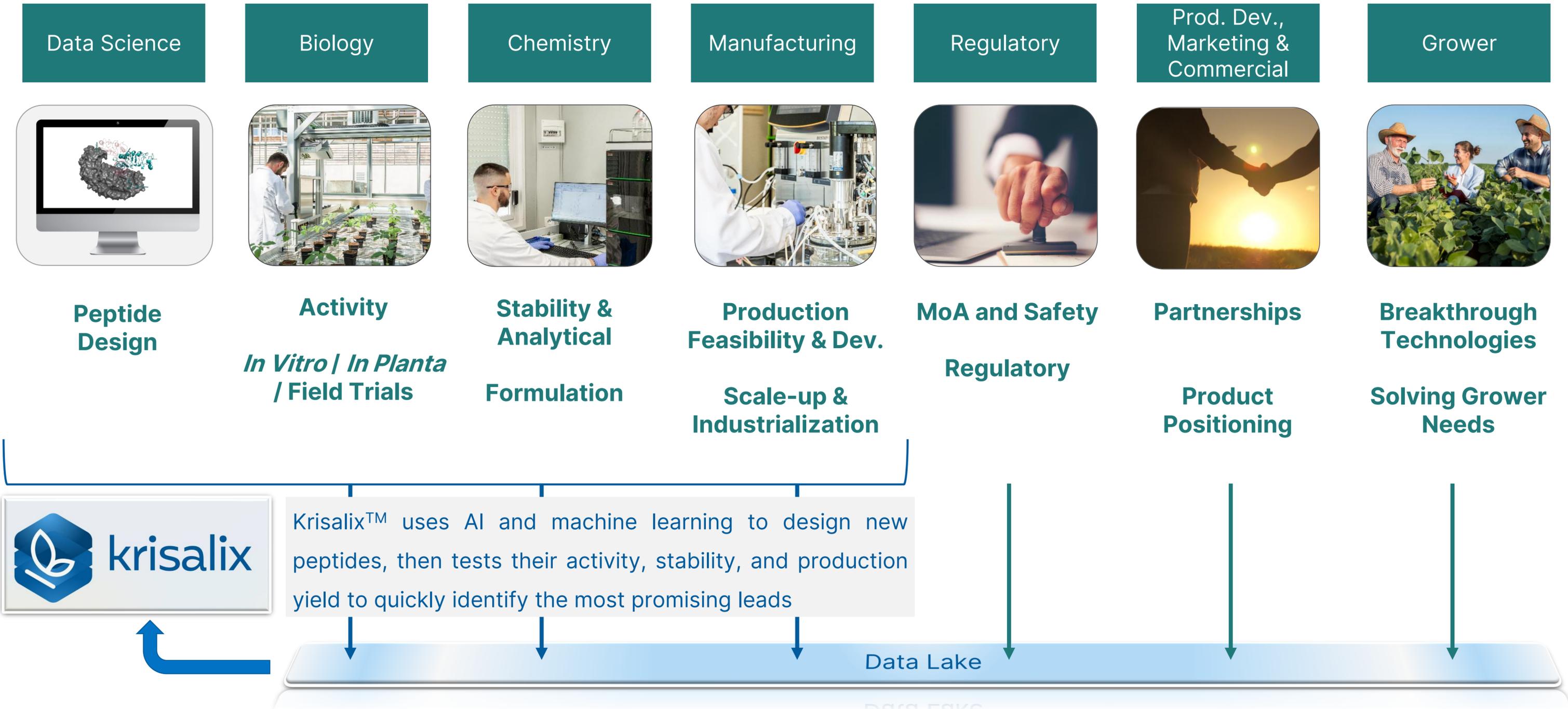
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# The challenges we face... besides the scientific challenges.



- There is a global challenge to increase agricultural productivity to ensure food security and improved nutrition
- We need to farm more efficiently and sustainably to reduce the environmental impact of food production and preserve our limited natural resources
- A lack of harmonized regulatory frameworks, unpredictability, and a regulatory burden that is often disproportionate to the risk posed by peptide-based biocontrols
- Communication of complicated (and quickly evolving) scientific information to society in an era of social media-driven sensationalism and misinformation

# Krisalix™: Micropep's proprietary discovery platform



# MPD-01: The first biofungicide from our design platform



- Mode of Action: **Membrane disruption**  
Antimicrobial peptide (AMP)
- Spectrum: **Broad spectrum**
- Positioning: **Contact fungicide** for preventive control
- Efficacy: **~40%-70% control solo**
- Use rate: **10 to 50 g/ha**
- Application: **Foliar**
- Formulation: **Soluble Liquid (SL)**
- Mixability: **Very good**



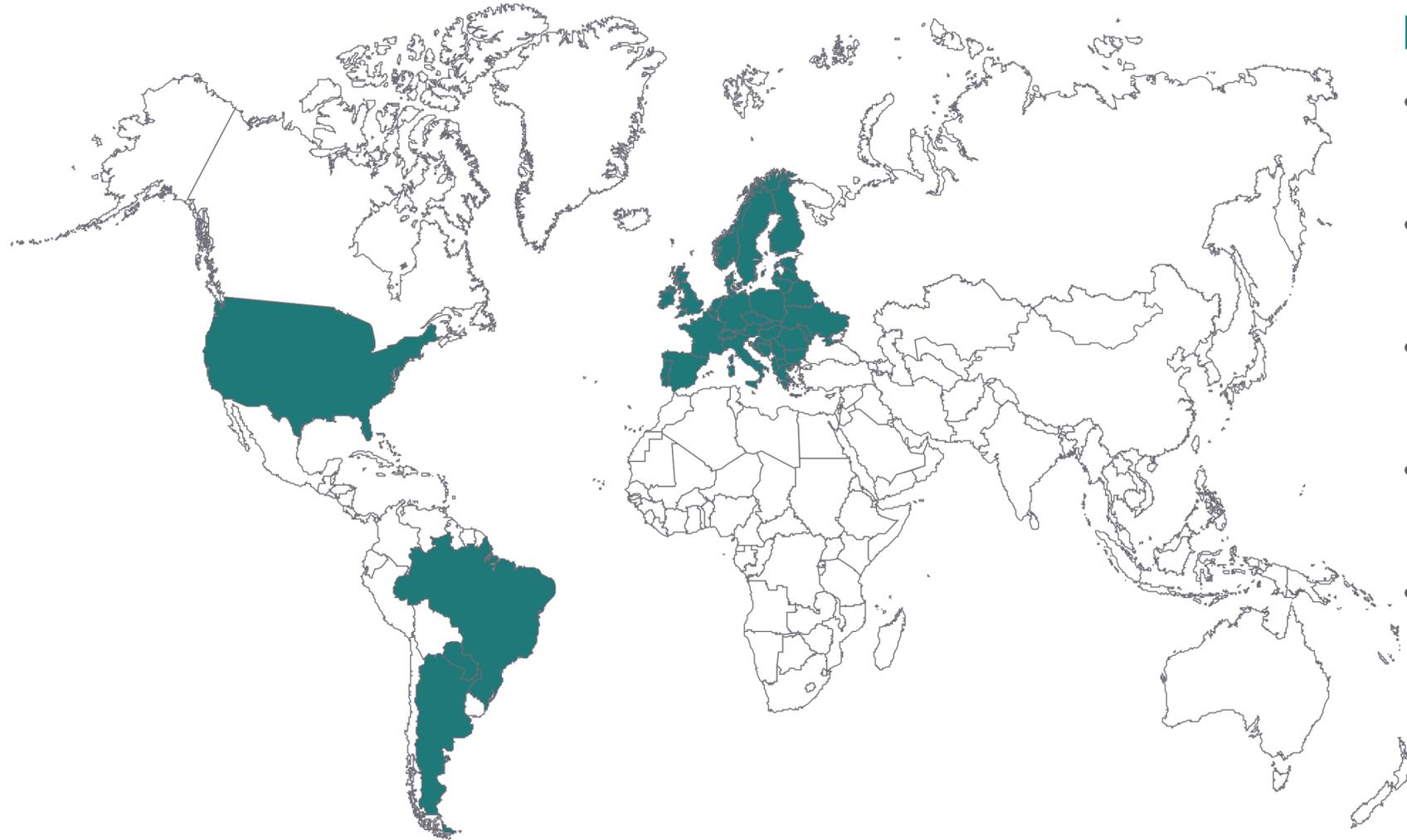
# The performance of MPD-01 has been validated in over 200 field trials to date



Why accept any risk, however low, without demonstrable benefit? Efficacy is critical to registration...

## Key benefits of MPD-01 to the grower include:

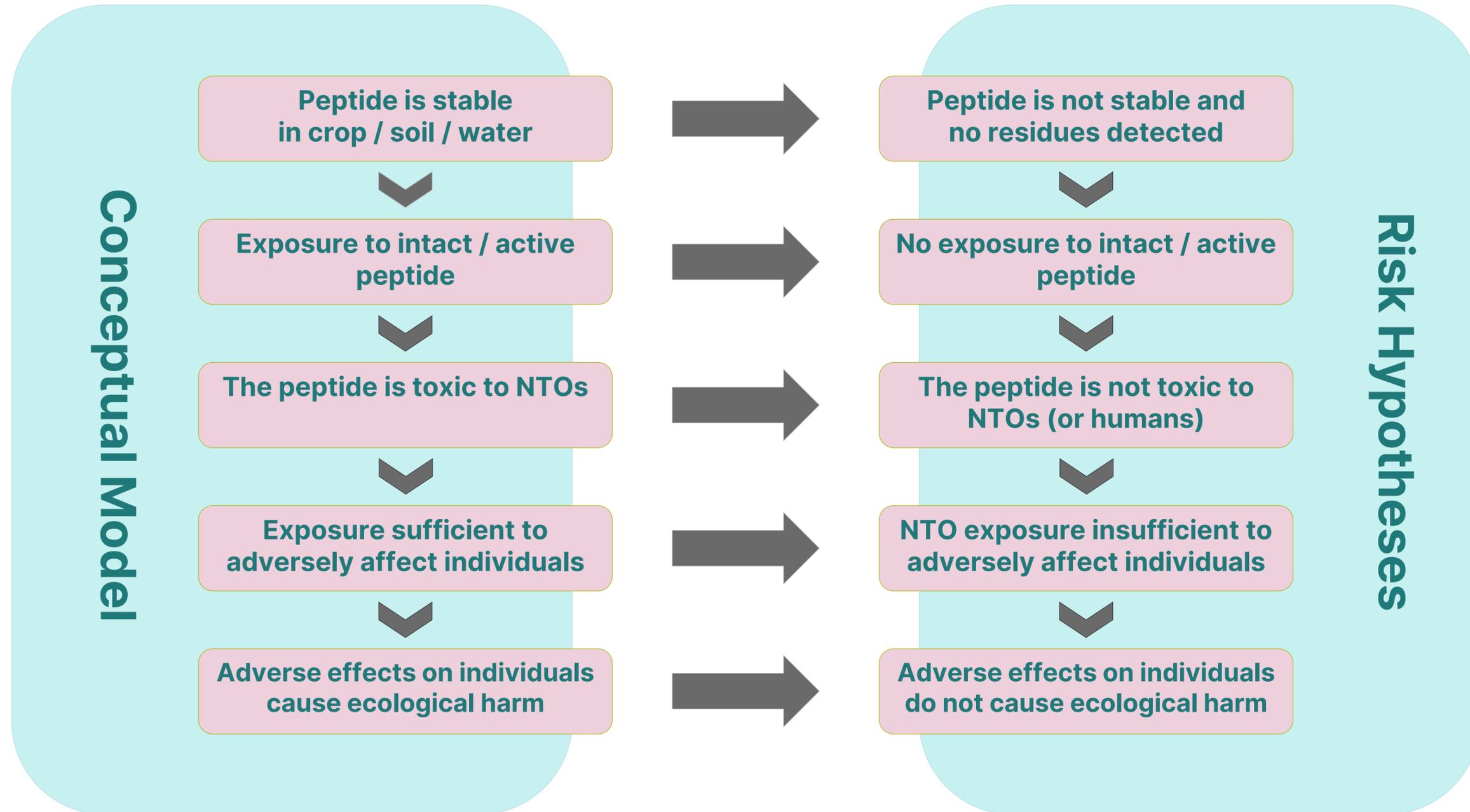
- Efficacy comparable to conventional fungicides, solo and as a mixing partner
- Broad spectrum control of fungal diseases in diverse crops, including field and specialty crops
- Multisite mode of action enables management of resistance to other fungicides when used in programs
- Low application rates and suitability for tank mixing with conventional pesticides
- Highly favorable human and environmental safety profile with no residue concerns or MRLs required



# A simplified problem formulation for risk assessment of a peptide biocontrol



We need to avoid check box approaches! Only those data that inform risk assessment should be required...



# MPD-01: One peptide, three different regulatory pathways!



## USA



- EPA recognizes three classes of Biopesticides and MPD-01 has been classified as a “Biochemical-like” active ingredient
- EPA considers the physical mode of action of MPD-01 to be a “non-toxic MoA”
- Biochemical data requirements apply, as well as some from other Biopesticide classes

## BRAZIL



- Like the US, Brazil recognizes multiple classes of Biopesticides; however, MPD-01 does not meet the regulatory definition of a Biochemical in Brazil
- ANVISA / IBAMA / MAPA do not consider a direct effect on the pathogen to be a non-toxic MoA
- Expected to qualify for a fast-track evaluation with its favorable human and environmental safety profile

## EUROPE



- All plant protection products are registered under Regulation No. 1107/2009; TGAS and PPP data requirements provided in Regulation Nos. 283/1013 and 284/2013, respectively
- Many 283 Part A (chemical) data requirements apply, as well as some from 283 Part B (microorganism)
- Low-risk status (Regulation No. 2017/1432) expected based on its highly favorable safety profile

# How do we move forward to meet these challenges?



- Peptides (comprised of naturally-occurring amino acids) have the potential to bring strong efficacy, new modes of action and selectivity, with low risk to humans and the environment
- Peptide-based biocontrols should have an important place in the future of sustainable agriculture, but barriers to entry must be reduced (proportionate to their risk)
- We need fit-for-purpose legislative and regulatory frameworks to fully realize the benefits of peptide-based biocontrols in agricultural production
- We need to engage all stakeholders with reliable, consistent messages about the many benefits (to farmers, to the environment) to gain regulatory alignment and societal acceptance



**Sustainable biochemical crop protection solutions  
powered by breakthrough micropeptide active ingredients**

**ABIM  
October 2025**

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