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# Shifting Regulations and Opportunities in the European Biopesticides Market

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Presented by Oluwatobi Oni, Ph.D.



# General Introduction

- Increasing interest in innovative biopesticide technologies (e.g., microbial consortia, RNA interference [RNAi] molecules, peptides, and bacteriophages) in Europe
- Shift partly driven by biotechnological advancements and policy shifts towards “greener” agriculture
- 30% share of a \$6 billion global biopesticide market, projected to maintain this market share for the next seven years (Markets & Markets 2023, Cognitive Market Research 2023)
- Stringent European regulations and lagging regulatory frameworks present a significant challenge to market entry for innovative solutions
- Overcoming challenges necessitates adopting the right strategies



# Biopesticide Technologies Overview

- Biopesticides in Europe:
  - microbials (bacteria, fungi, protozoa, viruses), plant extracts (botanicals), semiochemicals (pheromones), and novel alternative modalities (e.g., RNAi and peptides)
- RNAi and peptide-based solutions are still lacking. Moreover, no bacteriophage or microbial consortia-based active substances are currently approved in the EU or UK
- Novel technologies offer specificity, rapid breakdown, deterrence of resistance development by pathogens, and efficacy



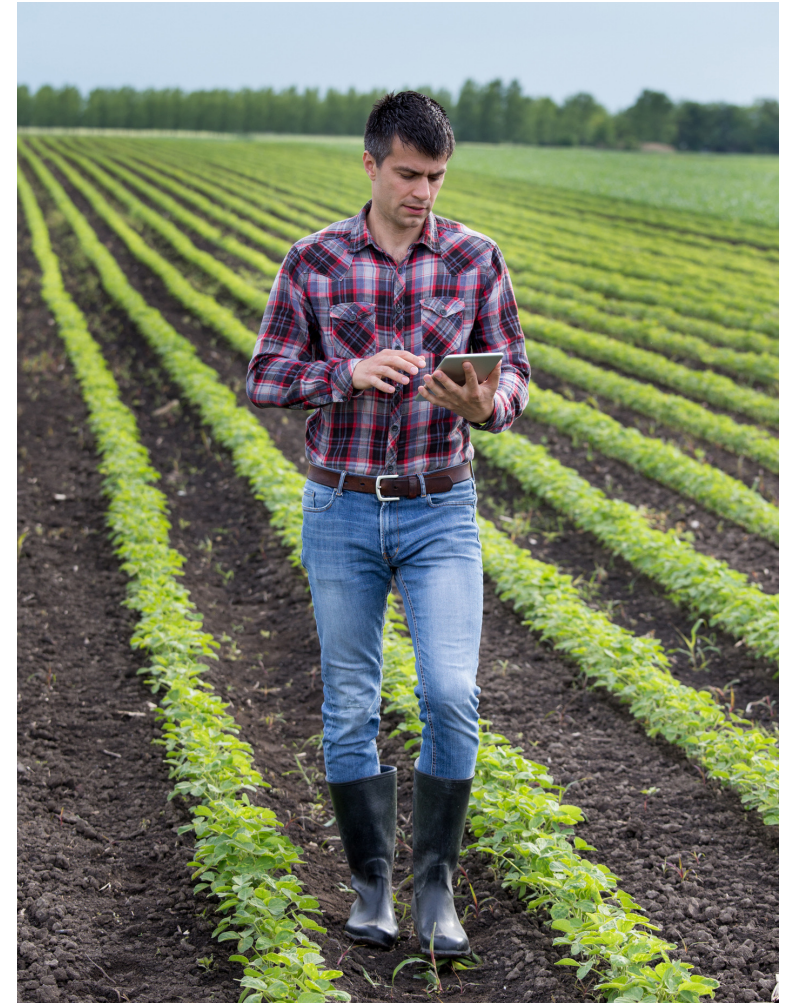
# Regulatory Challenges – Lagging Regulatory Frameworks

- Existing frameworks mostly suitable for chemical pesticides
- Lack of adaptation for innovative technologies such as RNAi, peptides
- Until 2022, a strain-centric approval system for microorganisms limited the possibility of registering bacteriophage cocktails or microbial consortia as microbial active ingredients
- Recent modifications to EU microbial data requirements (Part B of Regulations (EC) No. 283/2013 and 284/2013) allow for the possibility to register bacteriophages and microbial consortia
- European regulators appear to be embracing advancements in formulations containing microorganisms



# Regulatory Challenges – Unclear Data Generation and Risk Assessment Strategies

- Limited European guidelines and standardized protocols to generate data necessary to demonstrate the safety and efficacy of innovative technologies
- Adaptation of existing protocols and risk assessment methodologies will be necessary
- Expert knowledge of innovative technologies and a sound understanding of their unique challenges in relation to conventional chemicals is required to adapt protocols and risk assessment methodologies



# Navigating Forward: Collaborative Approaches

- Align with the right technical and regulatory experts
  - Seek experts with deep understanding of modern and often sophisticated concepts and techniques in molecular biology, genetics, and bioinformatics.
  - Collaborating with experts who combine both technical and regulatory expertise in these areas will be crucial
- Early engagement with regulatory authorities
  - Recent modifications to the EU microbial pesticide registration requirements and experiences dealing with European regulators indicate a growing openness to streamline procedures for novel plant protection technologies
  - Regulatory authorities (e.g., Ctgb in their latest biopesticides evaluation manual) have stressed the importance of leveraging insights from other regulatory frameworks for novel technologies and initiating discussions early in the application process
  - Proactive dialogue will help ensure methodological coherence, reduce delays, facilitate smoother evaluations, and potentially pioneer innovative biopesticide solutions in Europe



# Conclusion

- Increasing interest in novel biopesticide technologies in Europe driven by biotechnological advancements and more favorable policies
- Shifting European regulations indicate potential new market opportunities for novel biopesticide technologies in Europe, although some challenges still exist
- Overcoming existing regulatory challenges will require collaboration with experts, early engagement with regulators, adapting methodologies, and leveraging insights from other regulatory jurisdictions
- Proposed approaches will expedite the launch of innovative solutions, benefiting all stakeholders



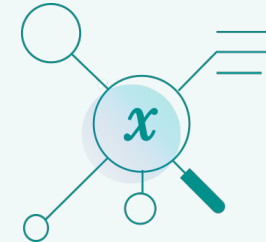
# The Exponent Approach



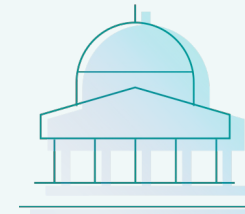
Experts merge technical proficiency in microbiology, molecular biology, genetics, and bioinformatics with regulatory insight essential for successful novel biopesticide registrations



Tailored data generation strategies, preparation of high-quality application dossiers



Rigorous scientific approach to meeting regulatory requirements at active substance approval and product registration phases



Proactive engagement with regulatory authorities throughout the registration process, facilitating introduction of innovative biopesticide technologies into markets



# Contacts



**Robert Sunley, Ph.D.**

Senior Managing Scientist  
(Harrogate, UK )

[rsunley@exponent.com](mailto:rsunley@exponent.com)



**Oluwatobi Oni, Ph.D.**

Managing Scientist  
(London, UK)

[ooni@exponent.com](mailto:ooni@exponent.com)



**Michael Watson, Ph.D.**

Managing Scientist  
(Harrogate, UK )

[mwatson@exponent.com](mailto:mwatson@exponent.com)