

# Nanotechnology-Enabled Biocontrol: Formulation Breakthroughs and Regulatory Complexities

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# About us



Independent consultancy company with private owners  
Founding year 2001



Extensive EU, UK & CH regulatory expertise and scientific knowledge



Strong performance in first registration and registration amendment of chemicals



Agrochemicals, biopesticides, fertilizer and biostimulants, biocides, veterinary medicines and industrial chemicals



Specialists in development of proven successful regulatory strategies



Successful long-term working partnerships with global clients



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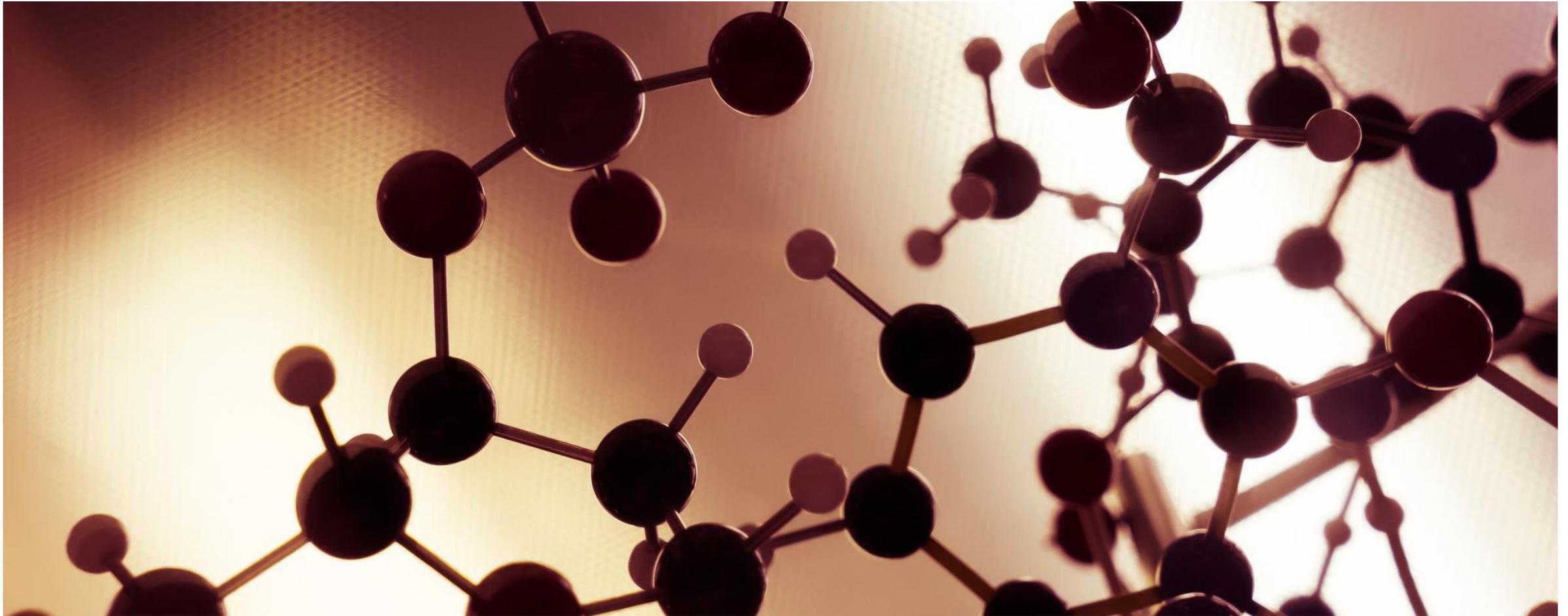


# Introduction & context

- Agriculture faces increasing pressure for sustainability and reduced chemical inputs.
- Biocontrol: uses natural enemies or biological compounds for pest management.
- Nanotechnology enhances performance, stability, and delivery of these agents.
- Regulatory frameworks are evolving to keep pace with innovation.



# What is a nanomaterial?



# EU Commission recommendation 2022 definition of nanomaterial

*A natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, where 50% or more of these particles in the number-based size distribution fulfil at least one of the following conditions:*

- 1. have one or more external dimensions in the 1–100 nm range,*
- 2. are elongated with two dimensions <1 nm and the other >100 nm*
- 3. or are plate-like with one dimension <1 nm and the others >100 nm.*

*In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100  $\mu\text{m}$  need not be considered.*

*However, a material with a specific surface area by volume of < 6  $\text{m}^2/\text{cm}^3$  shall not be considered a nanomaterial.*

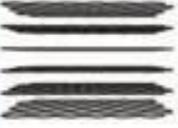
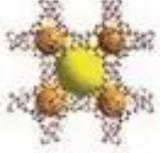
# EU regulatory context: nanomaterial definition and impact on biocontrol

- Recommendation, not legally binding .
- Horizontal scope and applies across all sectors.
- The origin of the material is not relevant
- External dimensions are relevant but not nanostructures on surfaces or internal nanostructures
- Includes: solid particles (silica, chitosan, clay).
- Excludes: soft systems (nanoemulsions, micelles) and particles with  $\geq 2$  dimensions  $> 100 \mu\text{m}$ .
- If a product contains a nanomaterial, it will not automatically become a nanomaterial

# Types of nanomaterials in biocontrol

- Organic nanomaterials:
  - Polymeric nanoparticles (e.g., PLGA, chitosan).
  - Lipid-based systems (liposomes, nanoemulsions).
- Inorganic nanomaterials:
  - Silica, titanium dioxide, silver, zinc oxide.
  - Clay-based or carbon nanotubes (as carriers).
- Hybrid/Composite systems:
  - Combining organic–inorganic properties for enhanced stability and targeted release.

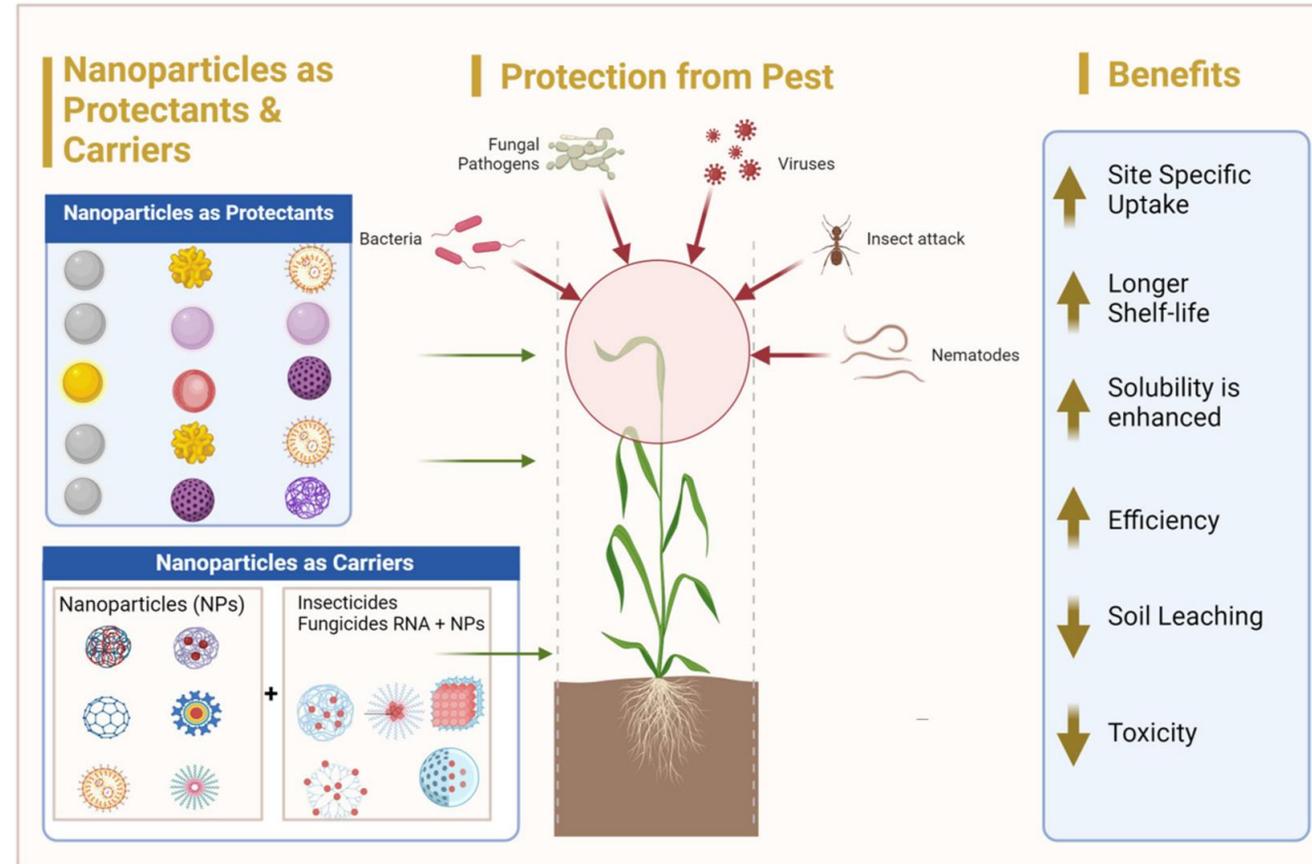
Classification based on composition

	Carbonaceous	Inorganic	Organic	Nanocomposites
0D	 Fullerene	 Au NP	 Liposome	 Core-shell
1D	 CNT	 ZnO Nanorod	 CNC	 Nanofiber
2D	 Graphene	 MXene	 COF	 Van der Waals
3D	 Graphite	 3D MOF	 Dendrimer	 Polymer Matrix

Shuaibu et al. 2021

# Nanoformulation strategies

- Nanoencapsulation: protects microbial or enzymatic agents from UV and desiccation.
- Nanoemulsions: stabilize essential oils and natural extracts.
- Nanogels/nanoclays: improve adhesion and rainfastness.
- Smart nanosystems: release triggered by pH, humidity, or enzymes.



# Advantages in plant protection

- Improved efficacy and stability of biological control agents (BCAs).
- Protects BCAs from environmental stressors.
- Lower dosage and reduced application frequency.
- Enhanced leaf adhesion and rainfastness.
- Reduced off-target impacts and chemical inputs.
- Ensures sustained release and precise delivery of BCAs.



# Environmental and health concerns

- Small size = high reactivity and mobility in soil and water.
- Potential bioaccumulation in non-target organisms.
- Unclear long-term toxicity for humans and ecosystems.
- Nanoparticles may affect soil microbiome and beneficial insects.
- Need for life cycle analysis and exposure modelling.



# Toxicological & environmental testing

- Testing challenges:
  - Particle aggregation and transformation complicate results.
  - Lack of standardized OECD protocols for biological formulations.
  - Many in vitro assays not adapted for nanoscale systems.
- Parameters to characterize:
  - Size, zeta potential, solubility, surface coating, dissolution rate.



# Regulatory challenges and path forward

- Challenges: lack of harmonized testing and data interpretation.
- Overlapping jurisdiction and unclear approval pathways.
- Need science-based, proportional risk assessment.
- Encourage collaboration between academia, industry, regulators.



# Conclusion & takeaways

1. Nanotechnology boosts efficacy and sustainability of biocontrol.
2. Risk assessment remains complex but essential.
3. EU regulation must evolve to support responsible innovation.

