



Microorganismi in biopesticidi: la valutazione del rischio e il ruolo di EFSA

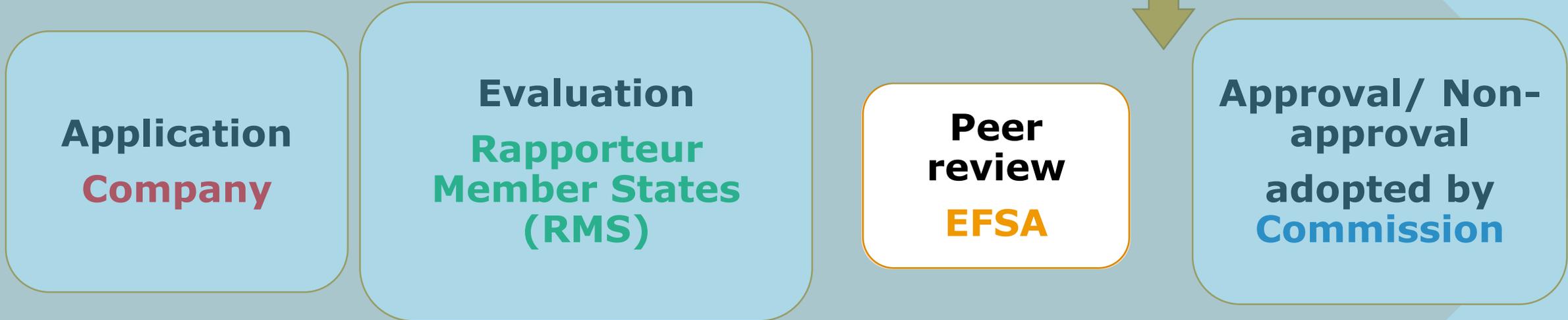
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Unità Pesticides Peer Review

Trusted science for safe food

Active substance evaluation process

- Standing Committee for Plants Animals Food and Feed (PAFF, 27 MS)
- Restrictions of use and/or risk mitigations could be set



Risk Assessment

Risk Management

Dual system in evaluation of pesticides (EU and MS level)
EFSA's role:

Conducting the EU **Peer review** of active substances for use in PPPs



Delivery of **Conclusions** for the individual active substances to support the EU decision-makers

- Conducted by EFSA scientific staff and risk assessment experts from the Member States
- Main workflows:
 - New a.s.(NAS): Regulation (EC) No 1107/2009
 - Renewal (AIR): Commission Implementing Regulation (EU) No 844/2012 and No 2020/1740

CONCLUSION ON PESTICIDES PEER REVIEW



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Peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AT10

European Food Safety Authority (EFSA),
Fernando Alvarez, Maria Arena, Domenica Auteri, Anna Federica Castoldi, Arianna Chiusolo, Angelo Colagiorigi, Mathilde Colas, Federica Crivellente, Chloe De Lentdecker, Mark Egsmose, Gabriella Fait, Varvara Gouliarmou, Franco Ferilli, Alessio Ippolito, Frederique Istace, Samira Jarrah, Dimitra Kardassi, Aude Kienzler, Roberto Lava, Renata Leuschner, Alberto Linguadoca, Christopher Lythgo, Oriol Magrans, Iris Mangas, Ileana Miron, Tunde Molnar, Laura Padovani, Juan Manuel Parra Morte, Rositsa Serafimova, Rachel Sharp, Csaba Szentés, Andrea Terron, Anne Theobald, Manuela Tiramani and Laura Villamar-Bouza

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, France, for the pesticide active substance *Trichoderma atroviride* strain AT10 and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative use of *Trichoderma atroviride* strain AT10 as a fungicide on lettuce (field use). The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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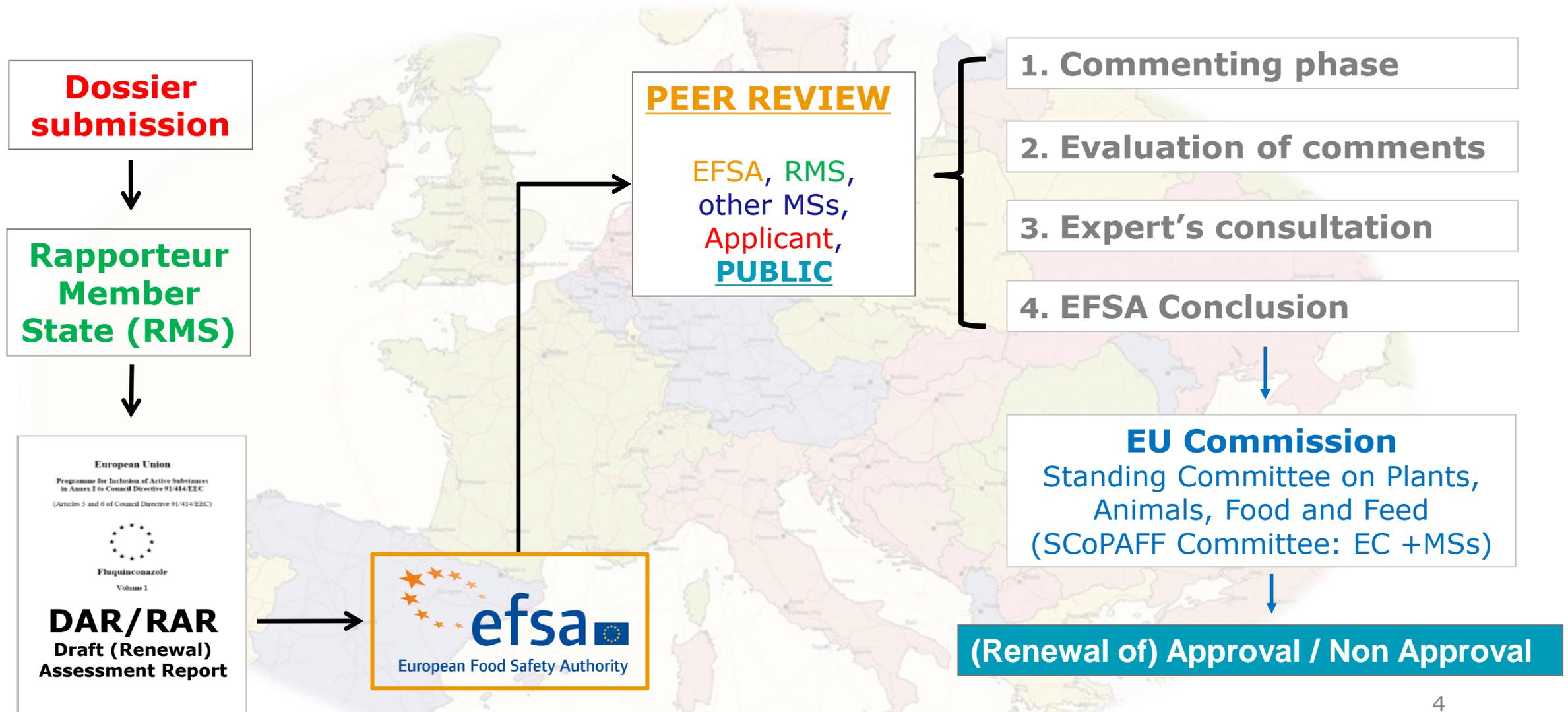
Keywords: *Trichoderma atroviride* strain AT10, peer review, risk assessment, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2019-00113

Correspondence: pesticides.peerreview@efsa.europa.eu

Active substance evaluation process



Hazard

vs.

Risk

A Hazard is something that has the potential to harm you

Risk is the likelihood of a hazard causing harm

SHARK



A shark in the sea is a hazard



Swimming with a shark is a risk

LIGHTNING



Lightning is a hazard



Standing under a tree during a thunderstorm is a risk

Risk assessment of microorganisms

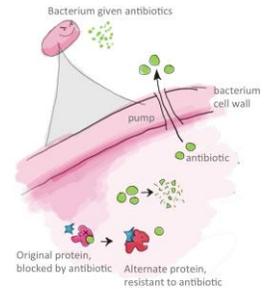
Hazard identification



Pathogenicity and infectivity



Toxicity



Antimicrobial resistance

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$$\text{Risk} = \text{hazard} + \text{exposure}$$

the microorganism
hazardous metabolites

Qualitative assessment:

Needed to determine exposure route, based on peer-review literature data. If concerns identified:

Quantitative assessment:

required for the relevant environmental compartments of exposure.

Environmental fate and behavior:

Related to origin and the properties of the mo
→ will the mo and metabolites survive?

Persistence and multiplication of the mo in:
soil, water and air → will persist at levels higher than background?

Ecotoxicology:

Toxicity, infectiveness and pathogenicity on:

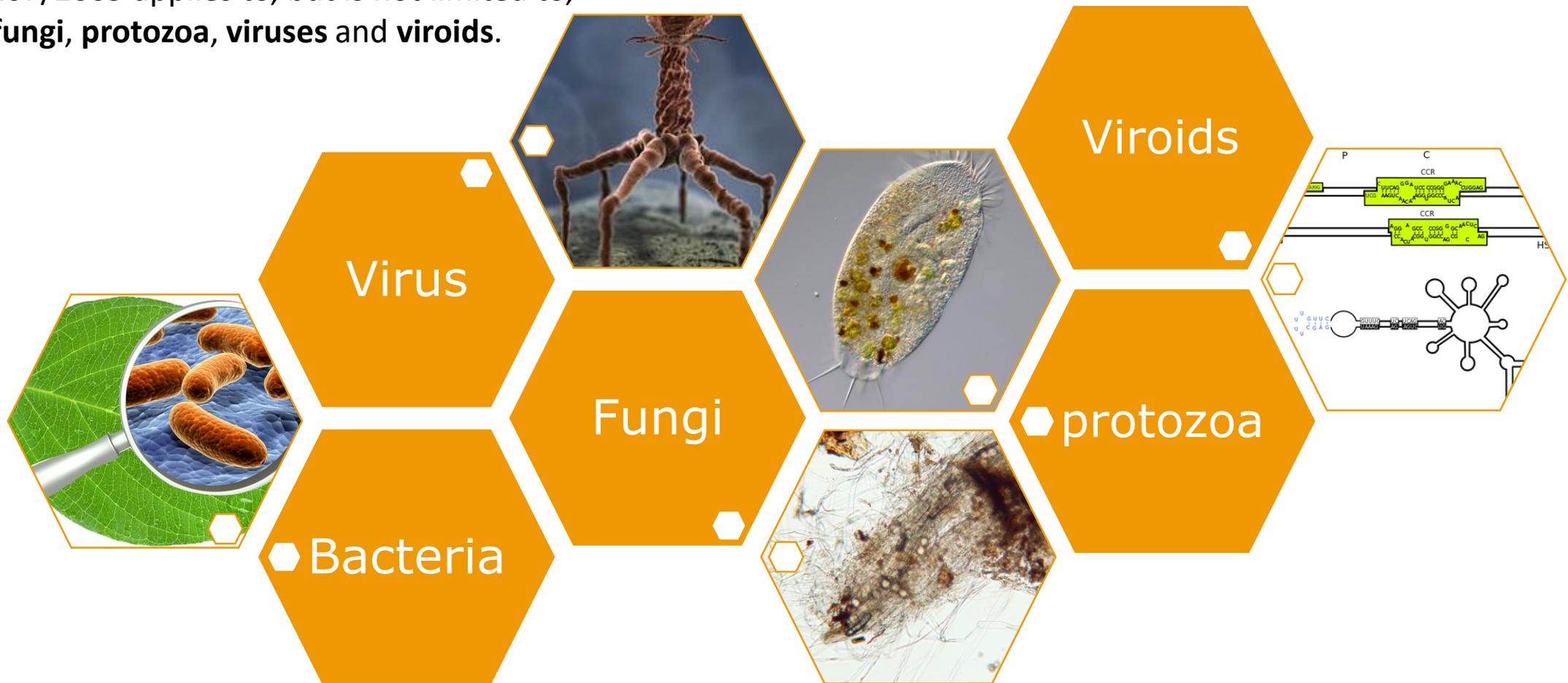
Birds | Aquatic organisms | Bees and other arthropods | Earthworms | Soil microorganisms

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Types of microorganisms in Reg 1107/2009

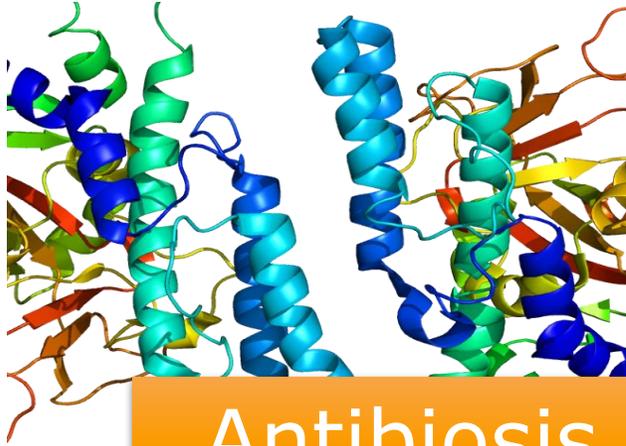
The term 'micro-organism' as defined in Article 3 of Regulation (EC) No 1107/2009 applies to, but is not limited to, **bacteria, fungi, protozoa, viruses and viroids**.



Used as **bactericide, fungicide, insecticide, herbicide, plant defence induction**

Mode of Action of microorganisms against pests

DIRECT

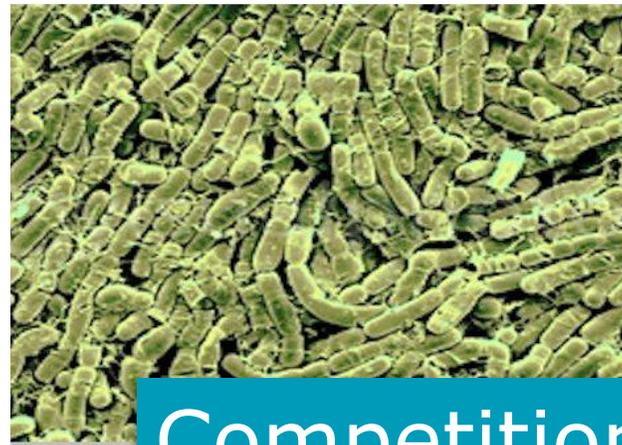


Antibiosis



Parasitism

INDIRECT



Competition



Elicitors

Parasitism

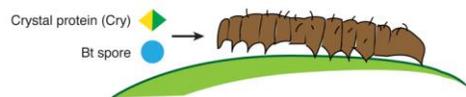


Beauveria bassiana spp.

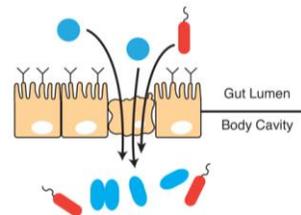
Fungal spores attach to the insect cuticle, then germinate and spread within the host

Antibiosis

(A) Larvae ingest Bt spores and Cry proteins



(C) Toxin binding causes cell lysis destroying barrier to body cavity



(B) In larval midgut, proteolytic digestion of proteins release Cry toxins, which bind to epithelial receptors



Bacillus thuringiensis spp.

Bacteria produce toxins (e.g. insecticidal Crystal proteins vs Lepidoptera, Coleoptera and Diptera)

Elicitors (Induced defense response of plants)



Mild Pepino mosaic Virus isolates

Mild isolates are able to induce the biosynthesis of metabolites involved in the defense response of plants

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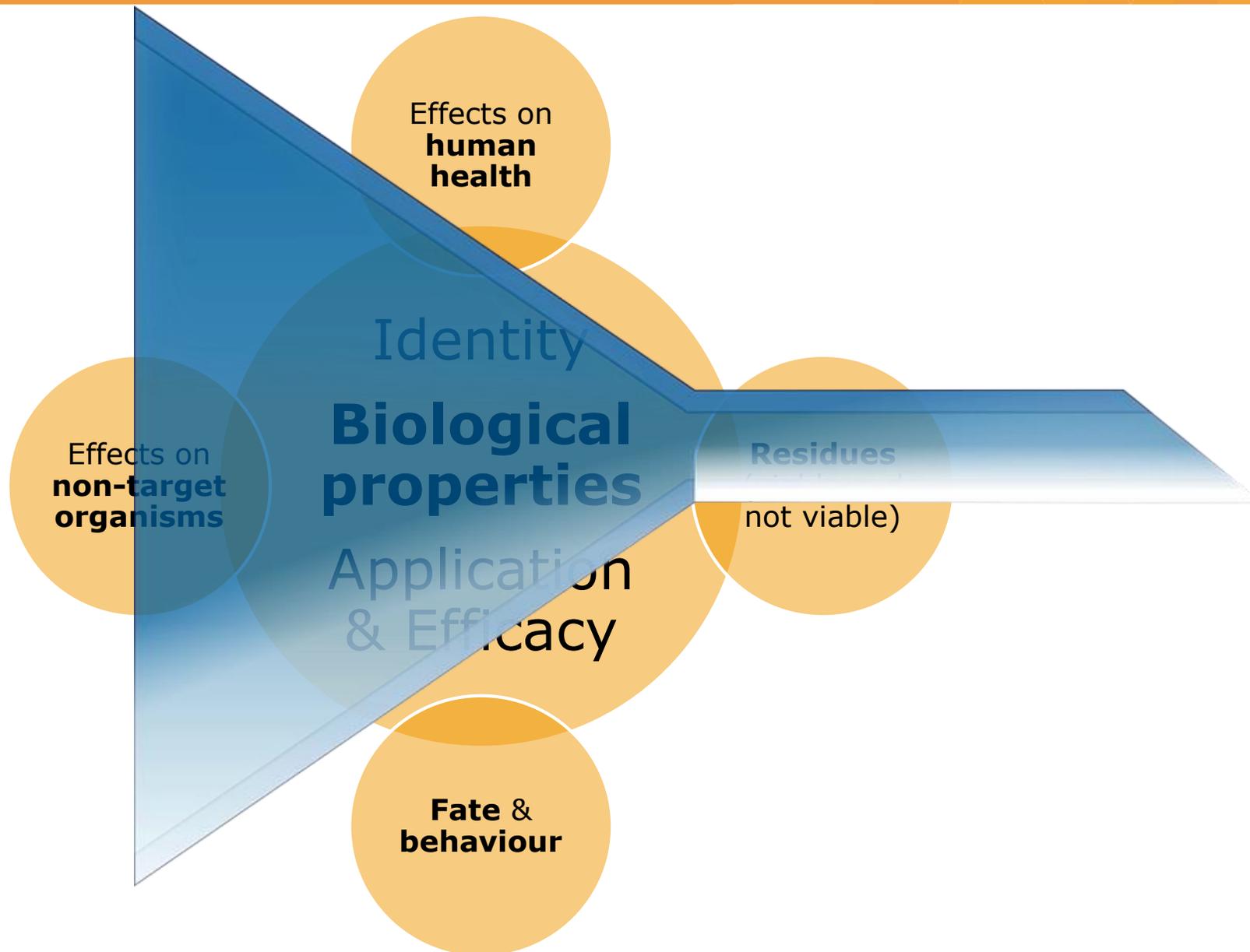
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