Innovation in Crop Protection – Biologicals

CLI Technical Monograph on Microbial Crop Protection Products

JMPS Open Meeting, Galway / Ireland, 18 June 2025

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on behalf of CropLife International - Specification Expert Group (CLI-SEG)

PURPOSE

Advancing innovation in agriculture for a sustainable future.

VISION

CropLife International plays a leading role in enabling a sustainable food system.

Agenda

Innovation in Crop Protection
-
Biologicals

Technical Monograph no. X (DRAFT)
-
Guidance for Viable Microbial Products

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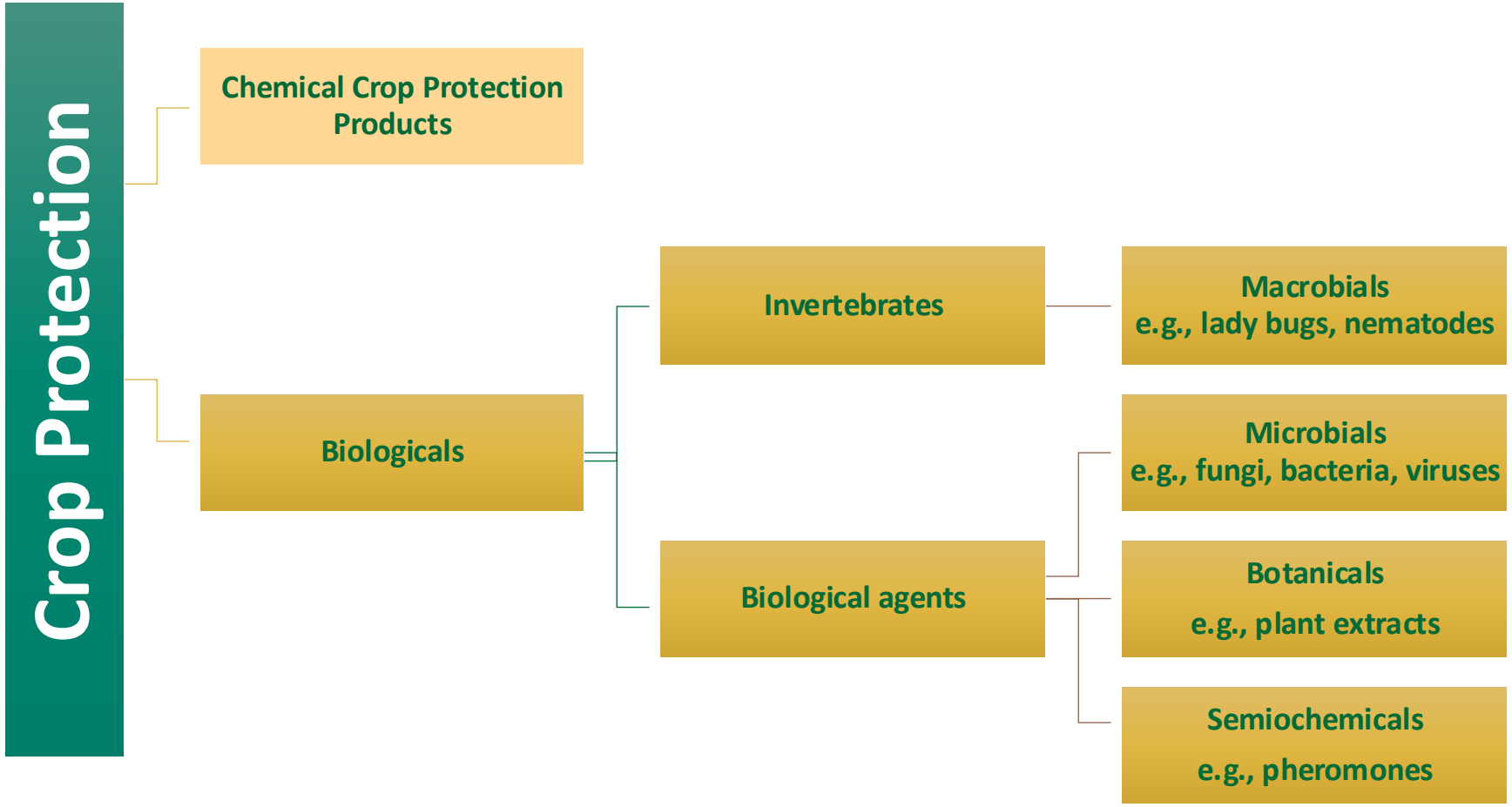
Innovation in Crop Protection
-
Microbial Products

Innovation in Crop Protection

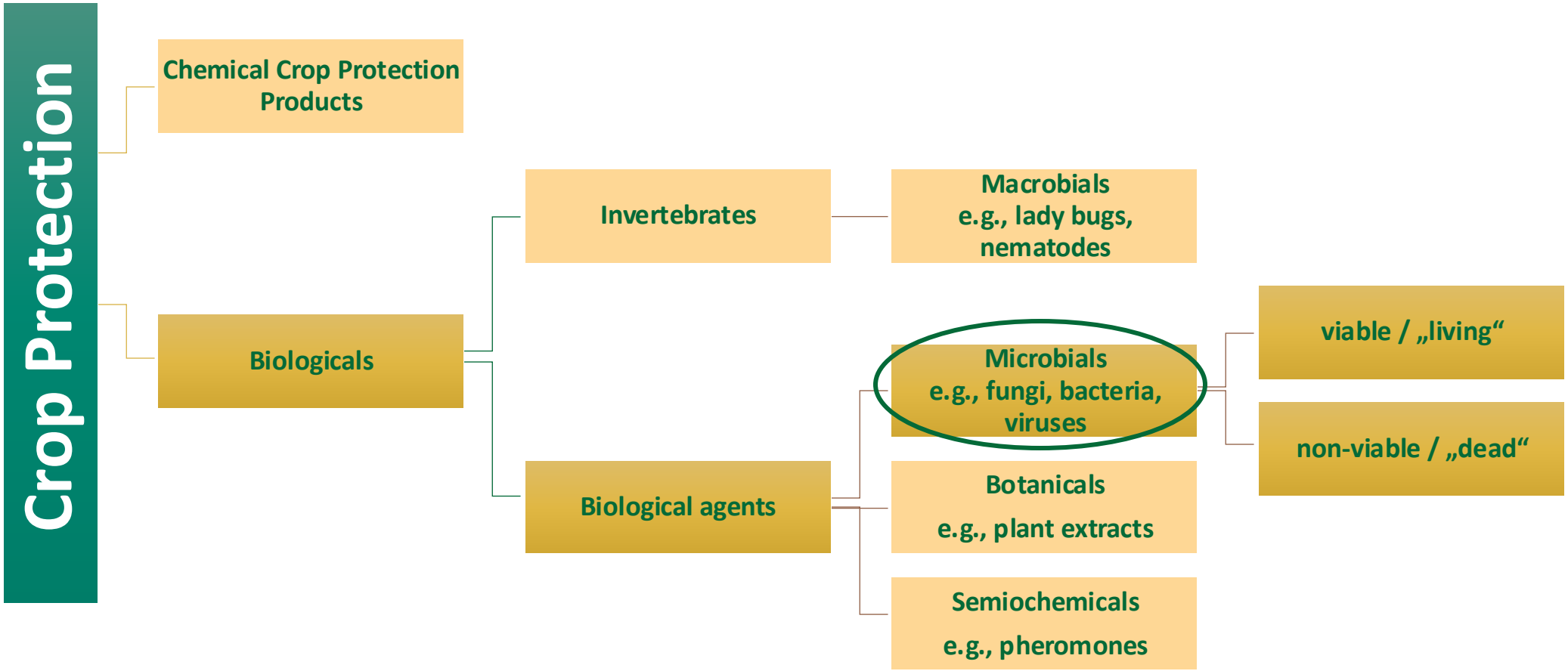
Biologicals: Enriching Farmer‘s Toolbox



Farmer‘s Toolbox: **chemical** & **microbial** solutions complement and enrich each other.

Innovation in Crop Protection

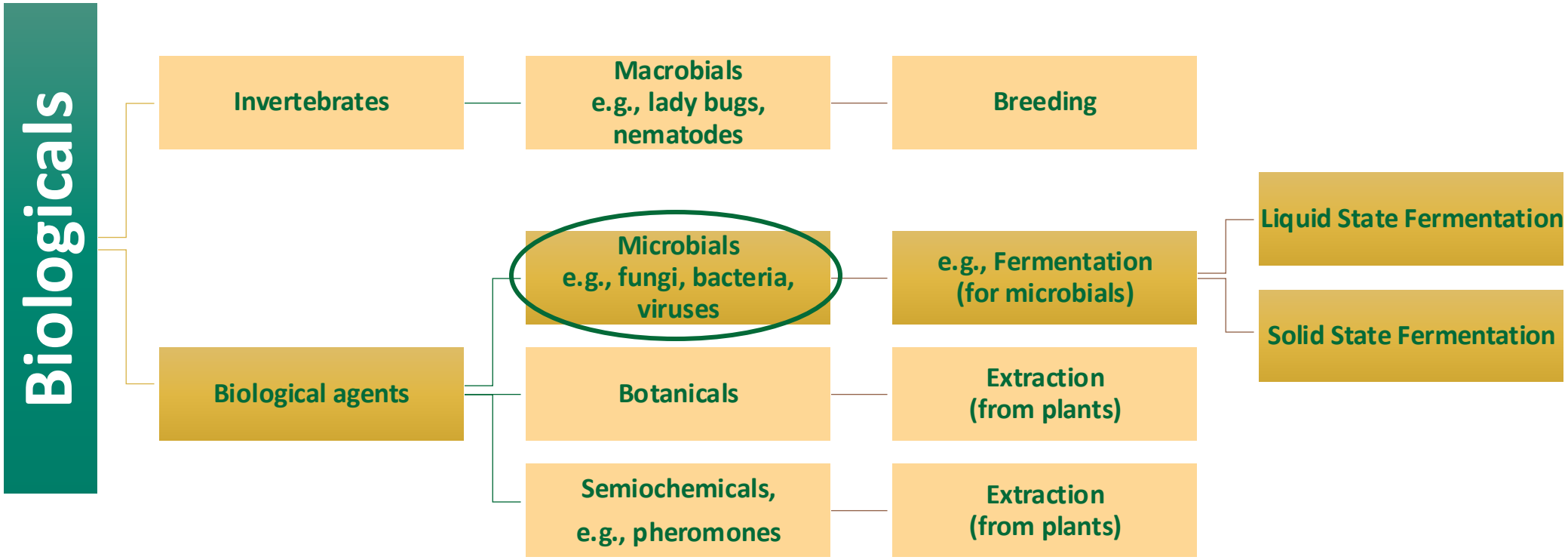
Biologicals: Enriching Farmer‘s Toolbox



Farmer‘s Toolbox: **chemical** & **microbial** solutions complement and enrich each other.

Innovation in Crop Protection

Sources of Biologicals



Sources of **biological** solutions vary broadly.

Microbial Products

Manufacturing by Liquid State Fermentation

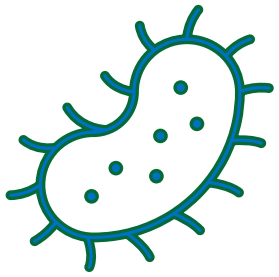
- Separation of **Spores / Cells** from other fermentation components may not be technically feasible or desirable for liquid fermentation products.
- Integrated Process:
  - No isolation of Active Ingredient (Microbial Pest Control Agent)
  - Formulated Product (Microbial Pest Control Product) obtained by further processing of fermentation broth

Microbial Products

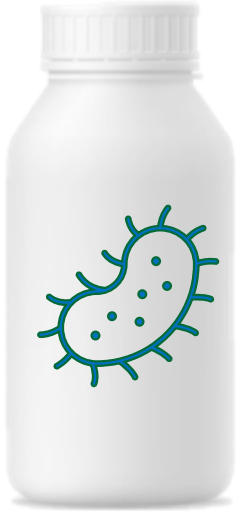
MPCA *versus* MPCP

- **Microbial Pest Control Agent (MPCA)**
  - Isolation of Active Ingredient (A.I.) often not feasible / desirable
  - Material Accountability Study for Registration typically not performed on A.I.-level

- **Microbial Pest Control Product (MPCP)**
  - Consequently, Material Accountability Study for Registration usually performed on product-level



Integrated process



Microbial Products

Drivers of Innovation in Agriculture

Source: Fotolia

Complement and diversify farmer‘s toolbox:

- Resistence Management (FRAC Code BM 02: living microorganisms)
- Iteration of chemical and biological spray applications
- Lower residues of chemical spraying partner(s)
- Typically, 0 Day Pre-Harvest Interval
- Depending on the legislation, microbials may be exempt from MRLs

Potential for Certification as Input for Organic Agriculture

Source: Bayer

Contribute to regional targets by providing and implementing sustainable solutions, e.g., in context of EU Green Deal.

Microbial Products

Crop Protection Market

- Microbial Products make growing contribution
- Better availability on large scale
  - Application of large-scale fermentation to crop protection
  - Decreasing Cost of Goods (CoGs) by up-scaling
  - Increasing product quality
    - Higher physical stability of formulation
    - Growing experience, how to formulate living microorganisms
  - Depending on strain, shelf-life may even be comparable to chemical products

Microbial Products

Limited Options of Applicable Formulation Types

Microbial Formulations

- **Liquid Formulation Types**
  - SC / FS
  - OD
  - DC
- **Solid Formulation Types**
  - WG / WP
  - GR

possible:

not possible:

CropLife International Technical Monograph no. 2 (8th edition, 2022)

Microbial Products

Regulatory Landscape

- Microorganisms can be part of many different product types and depending on the claims, they are regulated as crop protection products, (bio)pesticides, bio-stimulants, fertilizers, etc.
- Regulations for Crop Protecting Products based on chemical Active Substances are well established and harmonized across most countries.
- Unfortunately, this is not the case for regulatory frameworks and guidance applied to biological crop protection products.

Microbial Products

Regulatory Landscape

- Regulatory frameworks and guidance applied to biological crop protection products…
  - are far more diverse and not harmonized,
  - may not consider microbial nature and often remain derived from those of chemical products,
  - Leading to differences in classification, c.f., organic certification (what goes in – what comes out),
  - issues in evaluation.
- With limited experience and knowledge, more guidance would be helpful!

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Guidance for Viable Microbial Product

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Microbial Products

- In scope: Microbial Products for
  - crop protection
  - environmental protection
  - animal or public health such as vector control products.
- Applicable to products based on viable MPCAs (microorganisms or viruses).
- Products no longer containing viable microorganisms due to further processing, may not be considered MPCPs/MPCAs in some countries.
- Bio-fertilizers are not in scope of this Technical Monograph.

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Active Ingredient Definition (MPCA)

- Global harmonization is not established.
- Typically, viability of microbial agent is considered a prerequisite for a MPCA / MPCP.
- However, Active Ingredients originating from non-replicating microbial agents are considered as MPCAs in some countries.
- Biological activity of MPCAs can be based, e.g., on one or a combination of:
  - proliferation and competition for resources
  - pathogenicity to the target organism (e.g., endomopathogenicity, saprophytic activity)
  - activation of a plant defense mechanism
  - production of one or more metabolite(s) or precursors that have a beneficial effect in terms of pest control.

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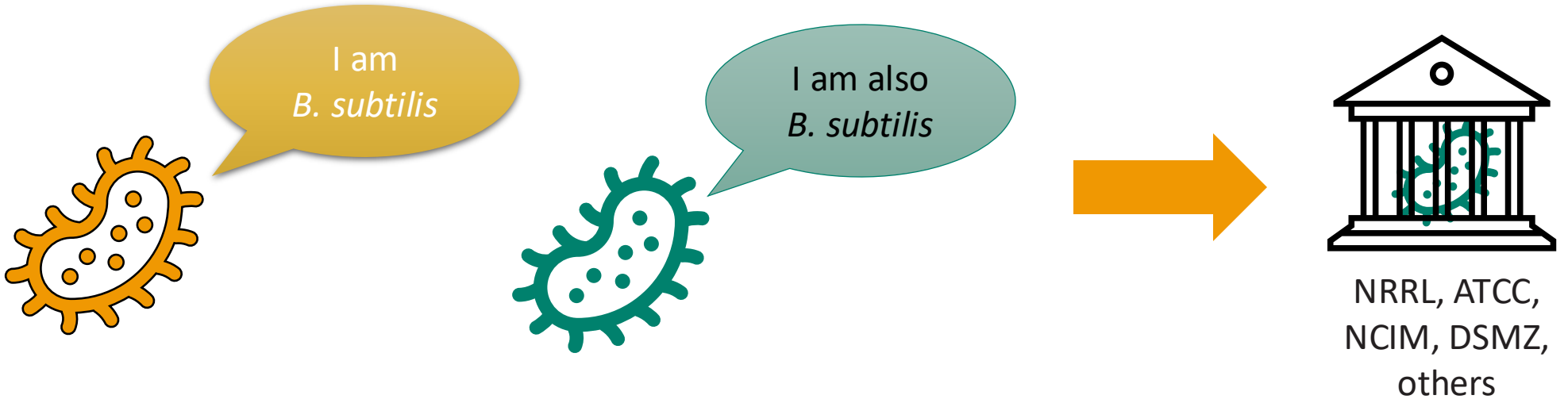
Analytical Methods for Identity of MPCA / MPCP

- Identity of MPCA is typically proven at strain-level.



- Reference strain is stored in strain banks or internal culture collections.
- Cultures are deposited under the Budapest Treaty for patented strains.
- Use of e.g., biochemical markers, qPCR, colony morphology or combination thereof to determine identity.

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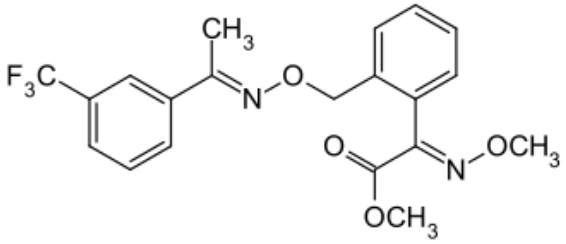
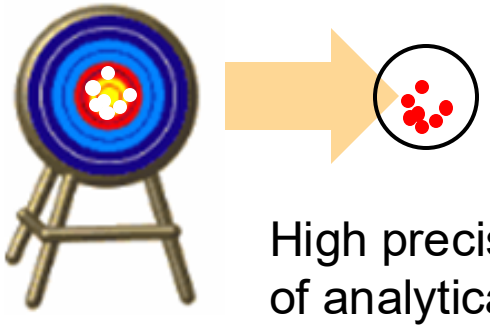
Analytical Methods for MPCA / MPCP Quantification

- Chemical Active Substance



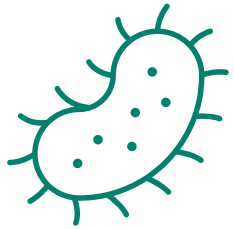
Analytical Method: e.g., LC-UV

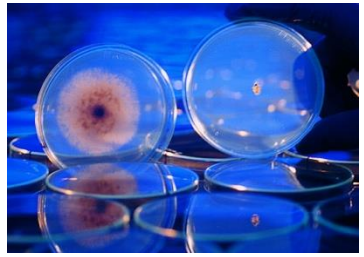


High precision / accuracy of analytical methods

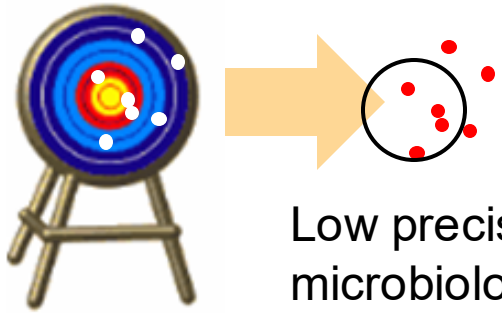
- Validation, e.g., acc. to SANCO3030rev.5

- Microbial Active Substance





Analytical Method: cfu counting



Low precision / high RSD of microbiological methods typically low resolution

- No official guidance for validation of microbial methods. Acceptance criteria to be defined.

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Microbial Contaminants in MPCA / MPCP

- Generating of MPCA / MPCP is a biological process and presence of pathogenic contamination should be prevented.
- Microbial Contaminants are controlled in MPCPs.
- Absence of general and uniform regulations for critical microbial contaminants, methods of identification, and acceptance criteria in key regions.
- Therefore, OECD no. 65 ("… in food") is typically referred to, listing
  - Analytical Methods
  - Acceptance criteria
- Note: Acceptance criteria should not be more stringent than those applied to food!
- Guidance: Best practice document on Microbial Contamination Prevention and Quality Management in the Manufacture of Agricultural Biologicals (CLI 2024).

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Storage Stability & Shelf Life of MPCP‘s

Accelerated Storage acc. to CIPAC MT 46.4

- No requirement
- Option to use, where applicable

Low Temperature Storage

case by case only
(note: no crystal growth in MPCPs)

Shelf Life

real-time, conditions depending on MPCP

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Applicability of Physical Tests using CIPAC MT to MPCP‘s

- In general, standard methodologies & requirements for chemical Crop Protection Products are applied to MPCPs, cf. „Manual on the development and use of FAO and WHO specifications for microbial pesticides” (1st edition, FAO / WHO, Rome and Geneva 2024)

- Experience in labs shows differences (non-comprehensive examples):
  - Suspensibility: not easy to pass limit of 60 % which was developed for chemical products
  - Adhesion-to-Seeds & Distribution-to-Seeds
    - High RSD of microbiological method
    - Challenges in separating biological matrices (microbial spores / cells from seeds)
    - Non-sterile biological matrix could lead to contamination of microbiological assay, and lead to false positive results

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Applicability of Physical Tests using CIPAC MT to MPCP‘s

- Differences to chemical products should be acknowledged in guidelines.
- Where requirements are technically not applicable or results not meaningful, allowance of waivers could be an option.
- Methodologies should be flexible to adapt to the needs of the individual product.
- Quantification methods are key in many CIPAC MT methods, e.g., suspensibility, adhesion to seeds.
- Create flexibility to allow for non-conventional or indirect techniques for quantification, e.g., use of color determination could be an alternative solution for adhesion test.

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Fitness for Use of MPCPs

In General

All products used in Crop Protection are expected to be fit for use

… this applies to chemicals, microbials same as to macrobials (e.g., lady bugs)


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Questions &
Comments
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THANK YOU