



FAO innovative developments in regulating biocontrol products.

Pests, weeds
& diseases
cause up to

30-40%

Crop losses

Society requires regulation

Consumer safety

Operator and worker safety

Environmental safety

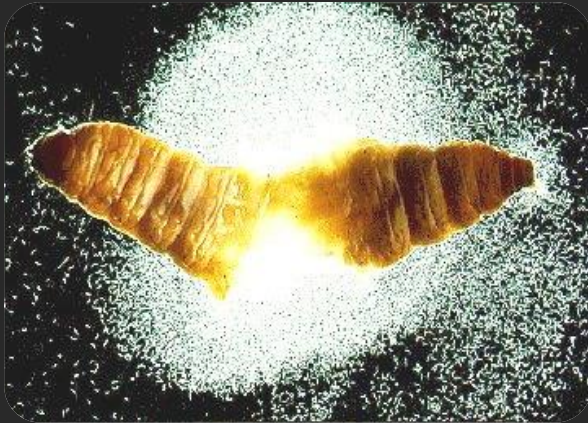
Crop safety

Assure product quality

Regulatory question:

Are biocontrol agents
different from
conventional chemical
pesticides ?

Macroorganisms



Botanicals



Semio-chemicals



Microorganisms



Micro-organism biopesticides

Cydia pomonella granulosis virus

Pasteuria penetrans

Trichoderma harzianum **FUSARIUM OXYSPORUM**

Isaria fumosoroseus

Bacillus firmus

Clonostachys rosea **Coniothyrium minitans**

BACILLUS THURINGIENSIS

Bacillus subtilis

Gliocladium catenulatum

Lecanicillium lecanii

Metarhizium anisopliae

Ampelomyces quisqualis

Trichoderma asperellum

Beauveria bassiana

Multiple modes of action

Kill host

Competition

Stimulate plant defenses

Confer plant resistance



Technology innovation areas

Active substances

Production

Formulations

Delivery

Biological control agents

Biology

Ecology

Population management

Adapted guidance & global harmonisation



FAO

OECD - BPSG

EU

EPPO

Food and Agriculture Organisation of the United Nations

FAO is an intergovernmental organization, FAO has 194 Member Nations, two associate members and one member organization, the European Union.

Food and Agriculture Organisation of the United Nations

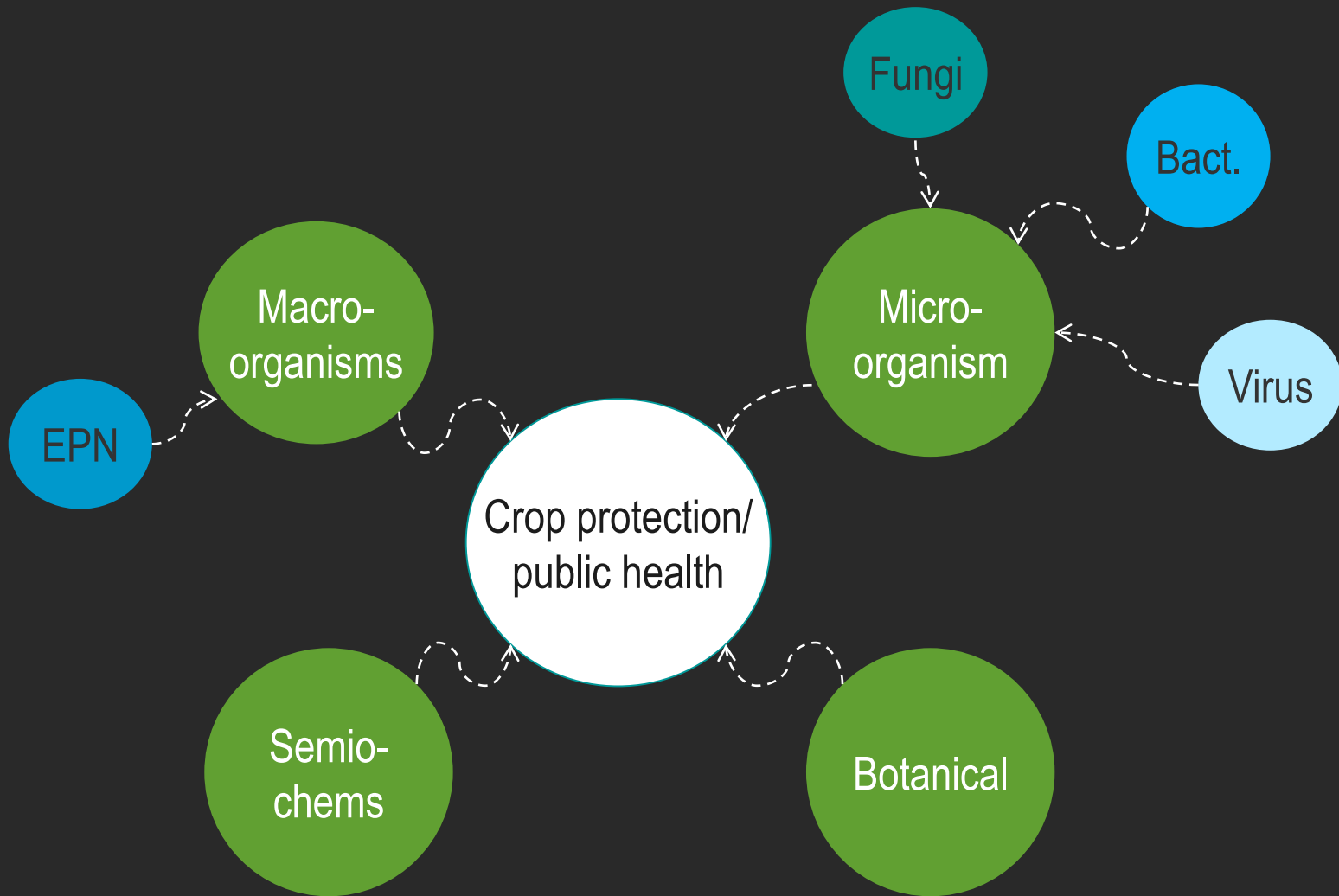
FAO promotes biological pest control agents and
IPM/IVM

“Pro-actively favouring registration of less hazardous products where such alternatives are viable and available”

FAO/WHO Panel of experts on pesticide management (JMPPM)

Guidelines for the
registration of
micro-organisms,
Botanicals
&
semio-chemicals
for
Plant protection
&
Public health

Knowledge intensive



Regulatory capacity

About 80% of regulatory departments globally have <2 people working on PPP registration

- Traditional remedies
- Small scale (local) production
- Innovation – for new technology
- Business development – biocontrol industry
- Imported products – registered elsewhere
- In-country testing capacity – limited?
- In some countries health and safety in production is part of registration

Proportional regulatory requirements but still ensure safety and quality

- Tiered testing requirements
- Data requirements and evaluation specific for technologies
- Pre-registration meetings between authorities and applicants
- Support reasoned case or waivers of some tests or data
- Fast-tracking of technologies
- Shorter review times
- Exchangeability of data
- Provisional or limited-use registration (allows temporary or localized use, while awaiting further data from tests or field use monitoring)

- Traditional remedies – home use only
- Clear definitions
- Comprehensive guidance to describe technology
- Harmonise with microbial guidance
- Harmonised with botanical guidance
- Harmonised with semio-chemical guidance
- Rationalised efficacy requirements
- Data does not have to be GEP – accredited facilities
- Minimising data requirements for some (microbial) substances ?

The benefits of this approach are to:

- Reduce registration as a barrier
- Quicker registration
- Need less specialist expertise
- Increase the availability of microbial products
- Reduce the number of 'illegal' products sold that try to avoid the cost and time of registration

But no compromise of quality standards

Regulatory innovation

Proportional

Relevant

Quicker

Cost effective

Thank you for your attention



RATIONALE
BIOPESTICIDE STRATEGISTS