



Can regulation keep pace with biofungicide technology?



# Bioprotectants – biological technologies – biocontrol solutions

Macroorganisms



Microorganisms



Botanicals/Natural substances



Semio-chemicals

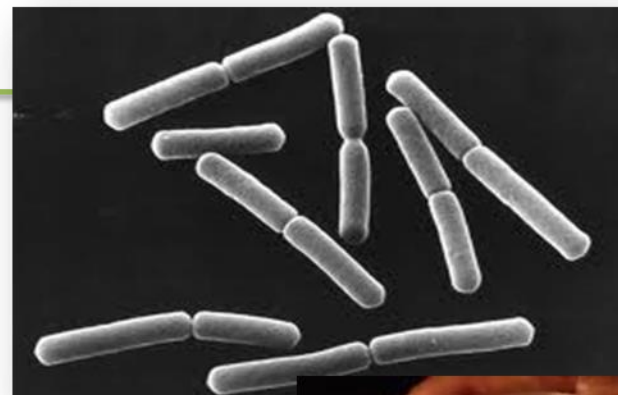
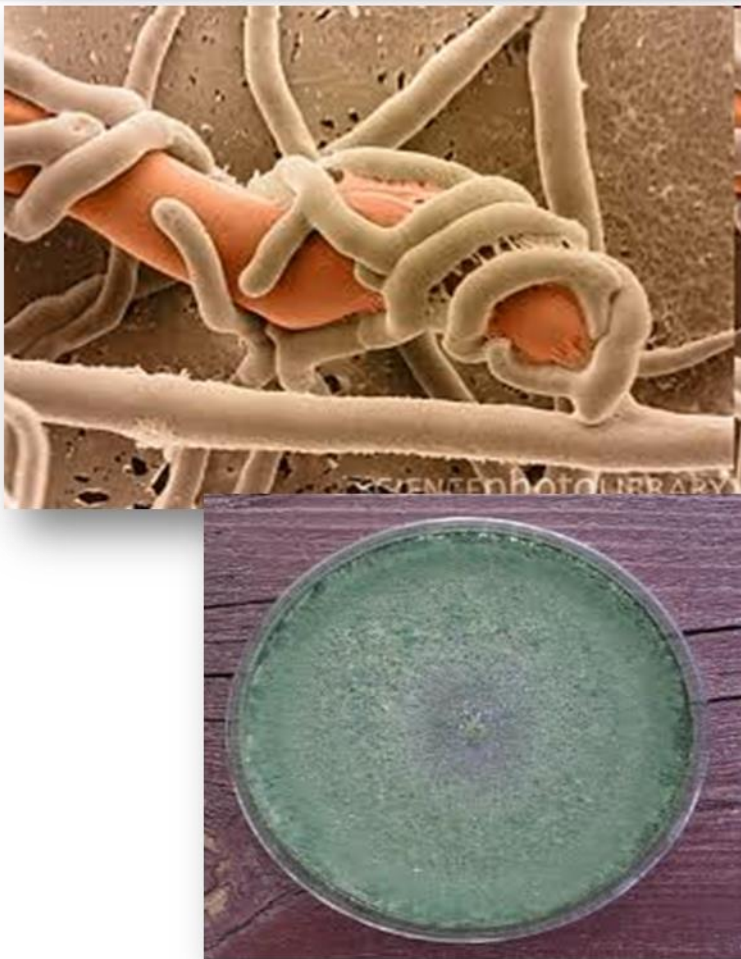


Biocontrol,  
Natural enemies,  
Beneficials

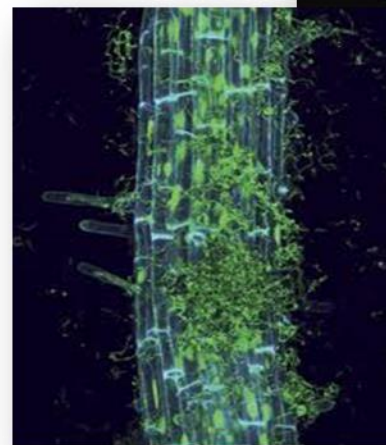
Biopesticides – biorationals - biologics

Bioprotectants have multiple modes of action on target pests and multi-interactions with plants

# Microbial biofungicides – MoA



*Bacillus subtilis*





# Microorganism biofungicides examples

Active Substance	Product Name	Target(s)
<i>Ampelomyces quisqualis</i> strain M10	AQ10	Powdery mildew
<i>Bacillus subtilis</i> strain QST713	Serenade ASO	<i>Botrytis</i> spp.
<i>Candida oleophila</i> strain O	Nexy1	Post harvest diseases
<i>Coniothyrium minitans</i> strain CON/M/91-08	Contans WG	<i>Sclerotinia</i> spp.
<i>Gliocladium catenulatum</i> strain J1446 (new species name <i>Clonostachys rosea</i> )	Prestop	Botrytis, soft rots
<i>Lecanicillium muscarium</i> strain V-6*	Mycotal	Whitefly, thrips, scale
<i>Peniophora gigantea</i>	PG Suspension	PGR
<i>Streptomyces griseoviridis</i> strain K61	Mycostop*	Soft rots
<i>Trichoderma atroviridae</i> strain T34	T34	<i>Fusarium</i> sp. on dianthus
<i>Trichoderma harzianum</i> strain T22	Triatum P	Root diseases

# Botanicals or plant extracts

Garlic



Thyme



Cymbopogon sp.



Clove



Orange oil



Spearmint



# Botanical examples

Active Substance	Product Name	Type of product	Target(s)
Maltodextrin	Eradicoat	Biorational	Mites, aphids, whitefly
Maltodextrin	Majestik	Biorational	Mites, aphids, whitefly
Fatty Acids	Savona	Fatty Acids	Whitefly, thrips, mite, aphids
Laminarin	Vacciplant	Botanical	Cereal diseases
Citronella oil	Barrier H	Botanical	Herbicide
Garlic concentrate	Eagle Green Care	Botanical	Free living nematodes
Cold pressed orange oil	Prev-AM	Botanical	Insects & fungi

# Biocontrol technology - multiple modes of action

Production of alarm compounds – phytohormone stimulation

Stimulation of new biosynthesis of phytochemicals

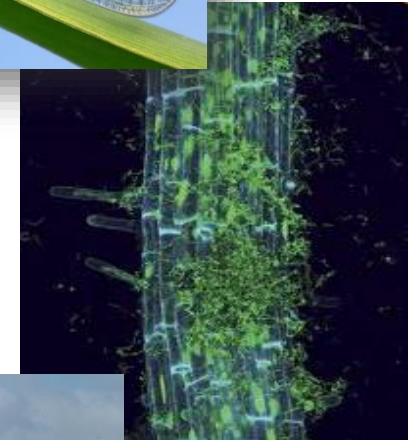
Stimulation of plant defense mechanisms

Induction in roots, shoots and leaves

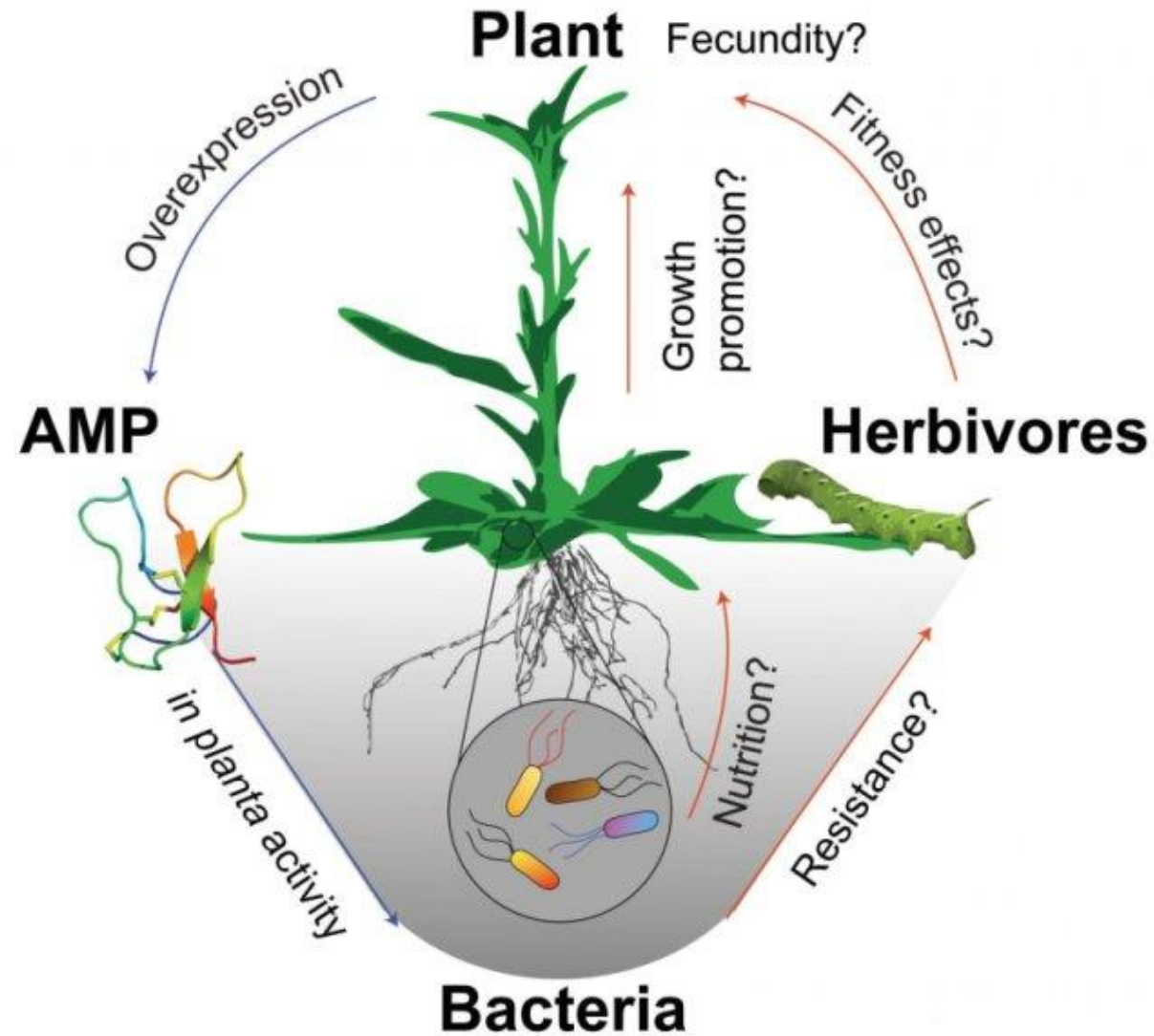
Physical kill of target

Toxicity to target

Change the behaviour



# Plants in the agro-ecosystem





# Ways biocontrol technologies are used

Use strategy	Biocontrol technology			
	Macroorganism	Microorganism	Natural substance	Semiochemical
Introduction (classical biocontrol)	✓	✓		
Conservation	✓	✓		
Augmentation	✓	✓		✓
Inundation	✓	✓	✓	✓

# Strategy for microbial biocontrol use – predominantly inundative



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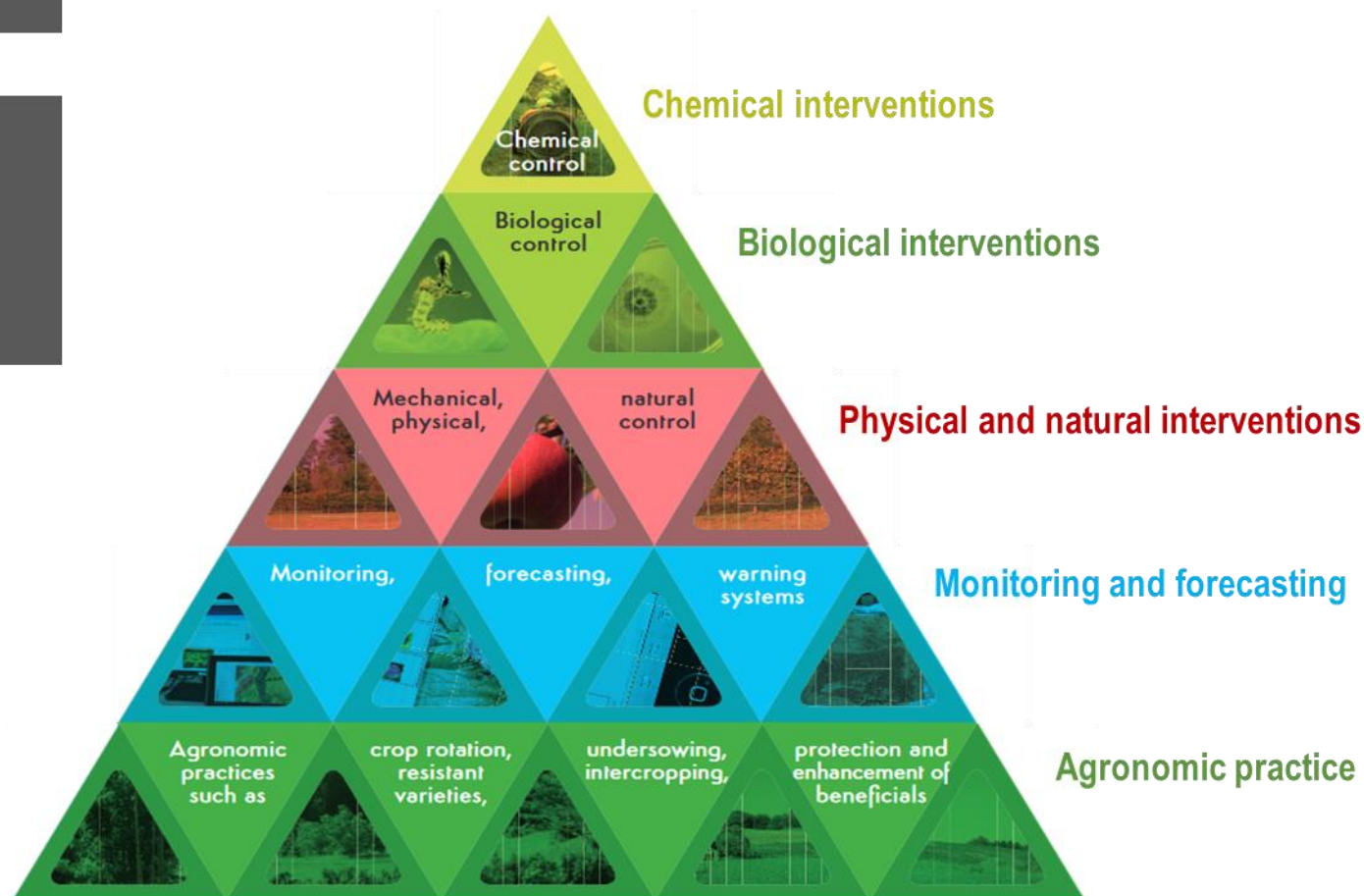
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# Integrated Pest Management (IPM)

IPM promoted for decades

EU Sustainable Use Directive 2009/128/EC : IPM compulsory since 2014



# Bioprotection - global markets

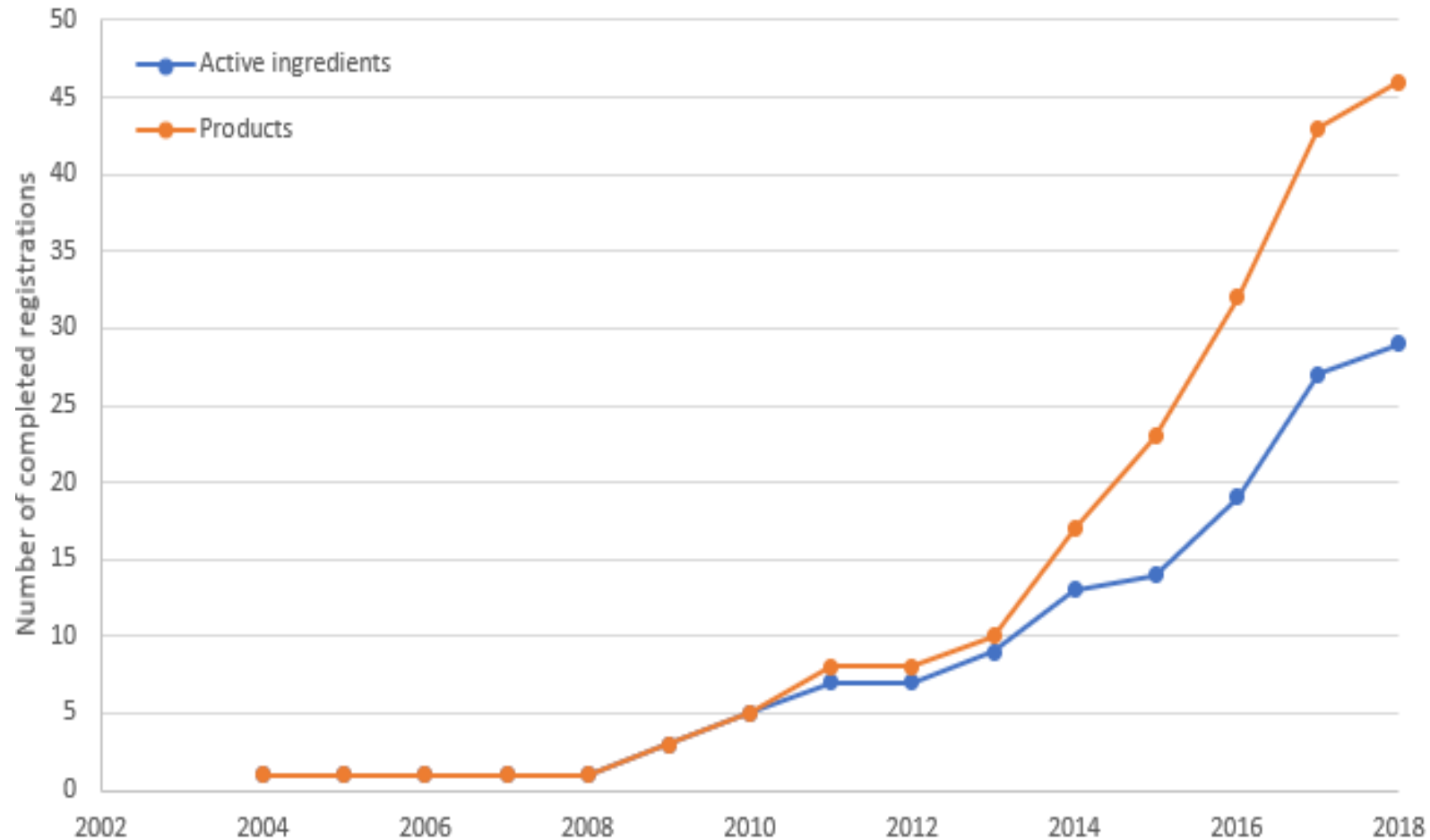


CAGR estimated at > 20%

\* DunhamTrimmer, 2018, 2021

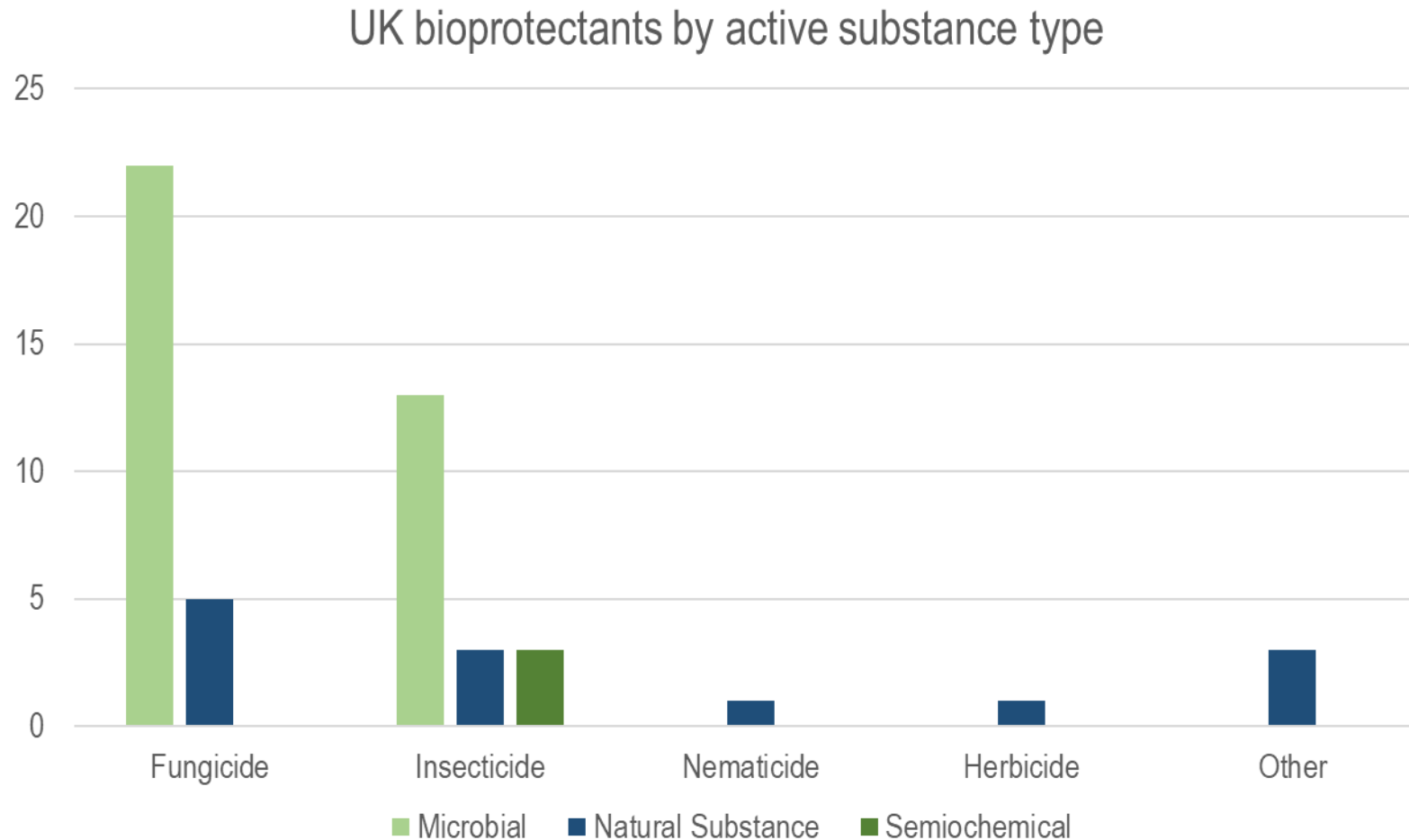


# Market development of bioprotectants - UK



First UK commercial  
authorisation in 2004

# Number of bioprotectants – UK 7<sup>th</sup> February 2021



## Bioprotectant totals

Active substances = 51 (out of 259) ~20%

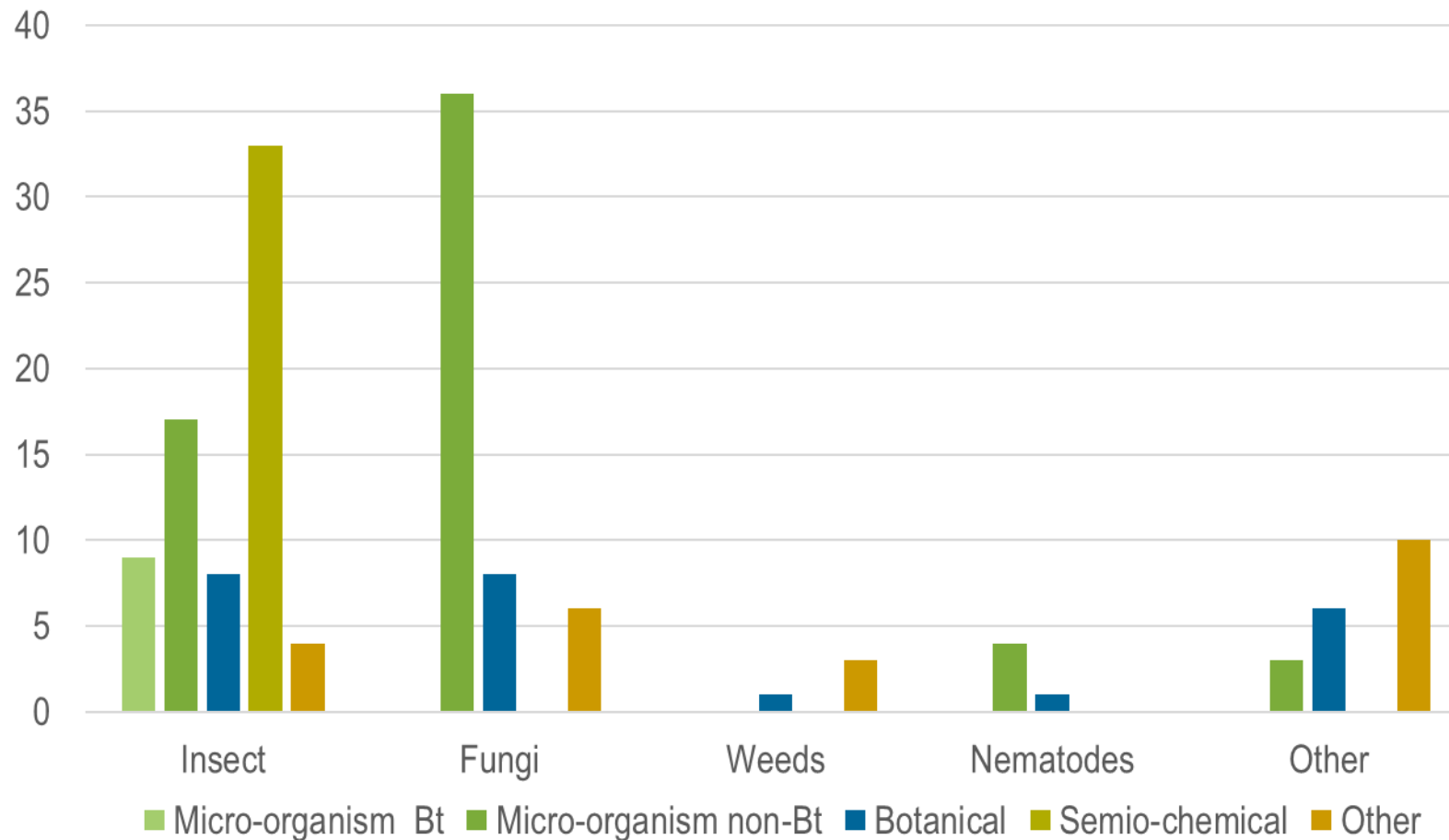
Products = 103 (out of 3137) ~3%

Few Low Risk products yet

32 active substances for use in open field

70 products for use in open field

# EU bioprotectant\* PPP - active substances



Approved PPP

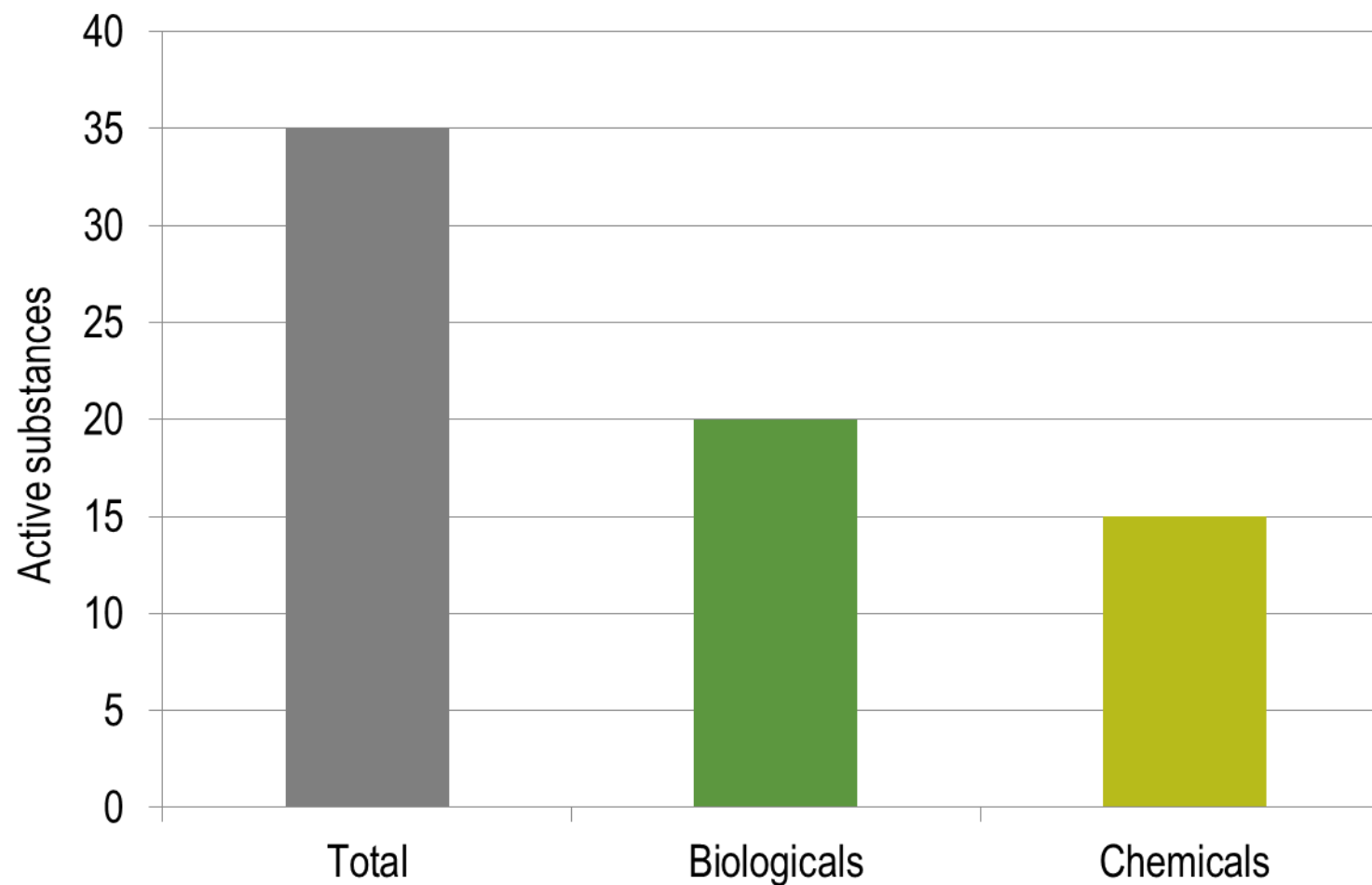
> 40% approved PPP  
= biological technologies

Total all PPP = 493

EU active substances (updated February 2021)\*

\* Definition of bioprotectant PPP not fixed so approximate numbers only

# EU plant protection substances – pending registration\*



\* February 2016



# Regulatory groupings for biocontrol plant protection technology

## Regulations

ABS for all biopesticides

Import/export rules for macrobials (and  
microbials)

Plant protection/pesticide registration  
needed

## Registered

Conventional chemicals

Microorganism

Semiochemicals

Natural substances

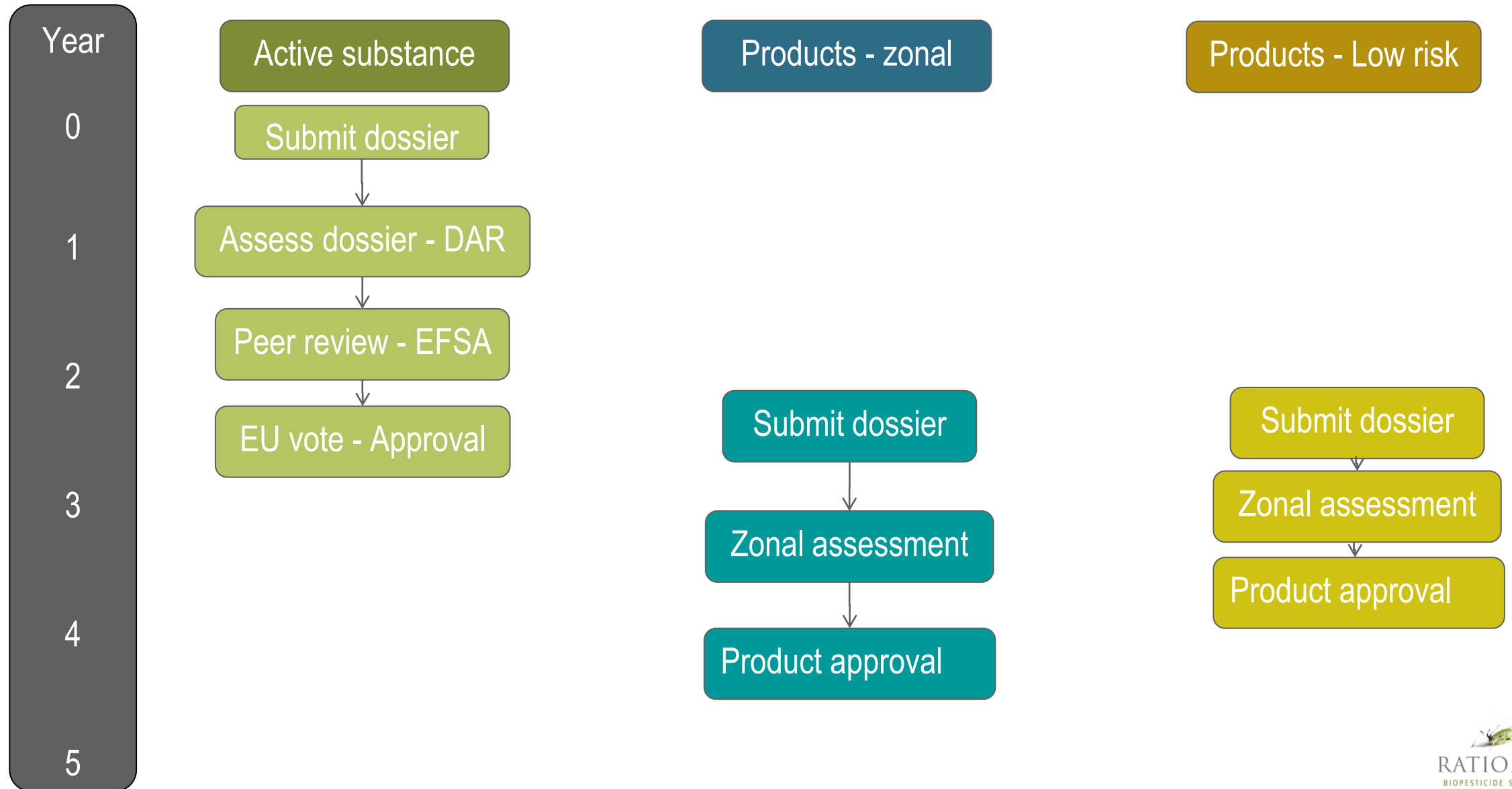
Botanicals

## Registered/Out of scope

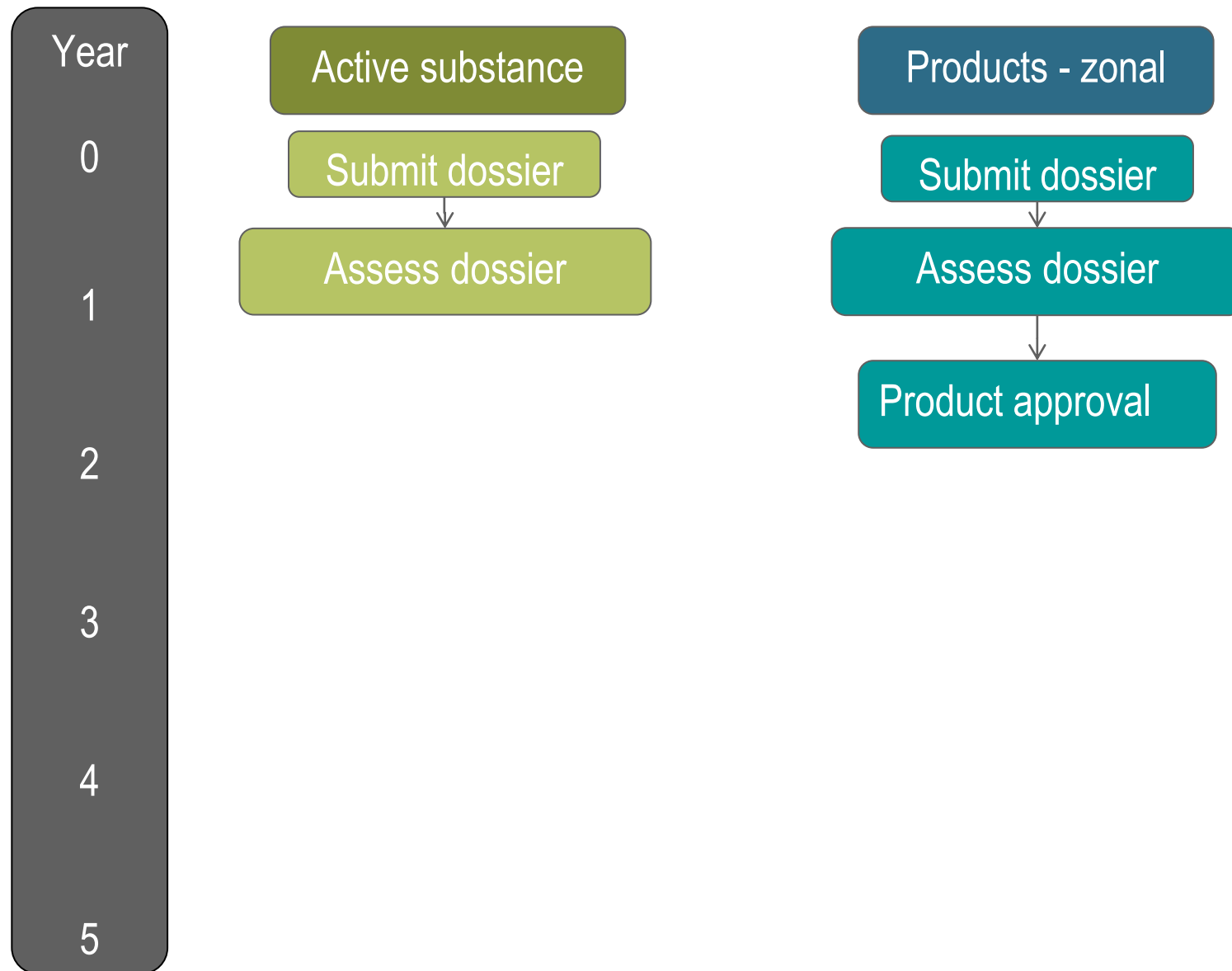
Macroorganisms

Entomopathogenic nematodes

# Registration timeline - EU



# Registration timeline – USA, Brazil, Kenya etc.



# Registration timeline – why are they different

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## Risk consideration

EU

Precautionary  
principle

USA

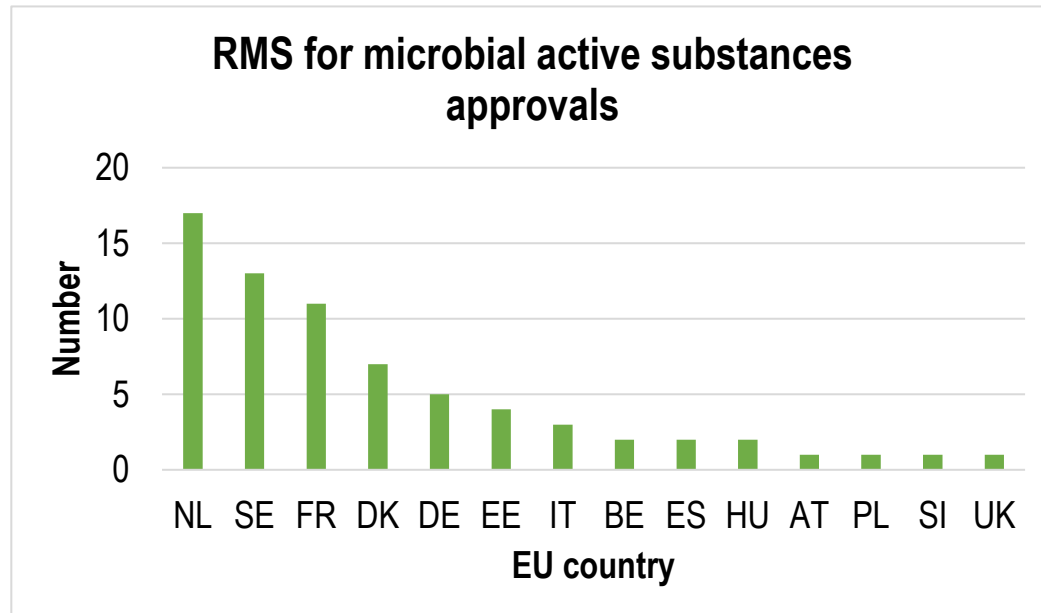
Generally Regarded  
As Safe (GRAS)\*



# Biological technology specific regulation

## Improving regulatory approval processes for biopesticides and other new biological technologies in agriculture

Wyn Grant, University of Warwick, UK; and Roma Gwynn, Biorationale, UK



## Good regulatory practice:

1. Dedicated biological technology regulators
2. Clear pre-submission and submission process
3. Provide a high-level framework for the principle that data are excluded 'except when ...'
4. Trusted partnerships
5. Harmonisation of evaluations
6. Reciprocity of evaluations between regulatory agencies
7. Reciprocity/extrapolation for efficacy data

<http://dx.doi.org/10.19103/AS.2020.0073.04>

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# What makes the difference for biofungicide regulation?

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Government policy for agriculture  
– promoting IPM, sustainable  
agriculture

Growers demand for products so  
they can meet MRL and other  
standards

Aim for reduction of harm for  
humans and environment

# Global harmonisation ?



FAO  
OECD – EGBP  
EPPO

EU  
USA & Canada  
CILSS West Africa  
East Africa Community  
ASEAN

# A change in understanding contexts

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## Biological based crop protection

soil ecology, plant ecology, landscape ecology, biology, microbiology, genetics, microbial ecology, population biology, plant physiology, population modelling, landscape modelling, population ecology, etc.....

and maybe, sometimes, even chemistry

Thank you for your attention

