

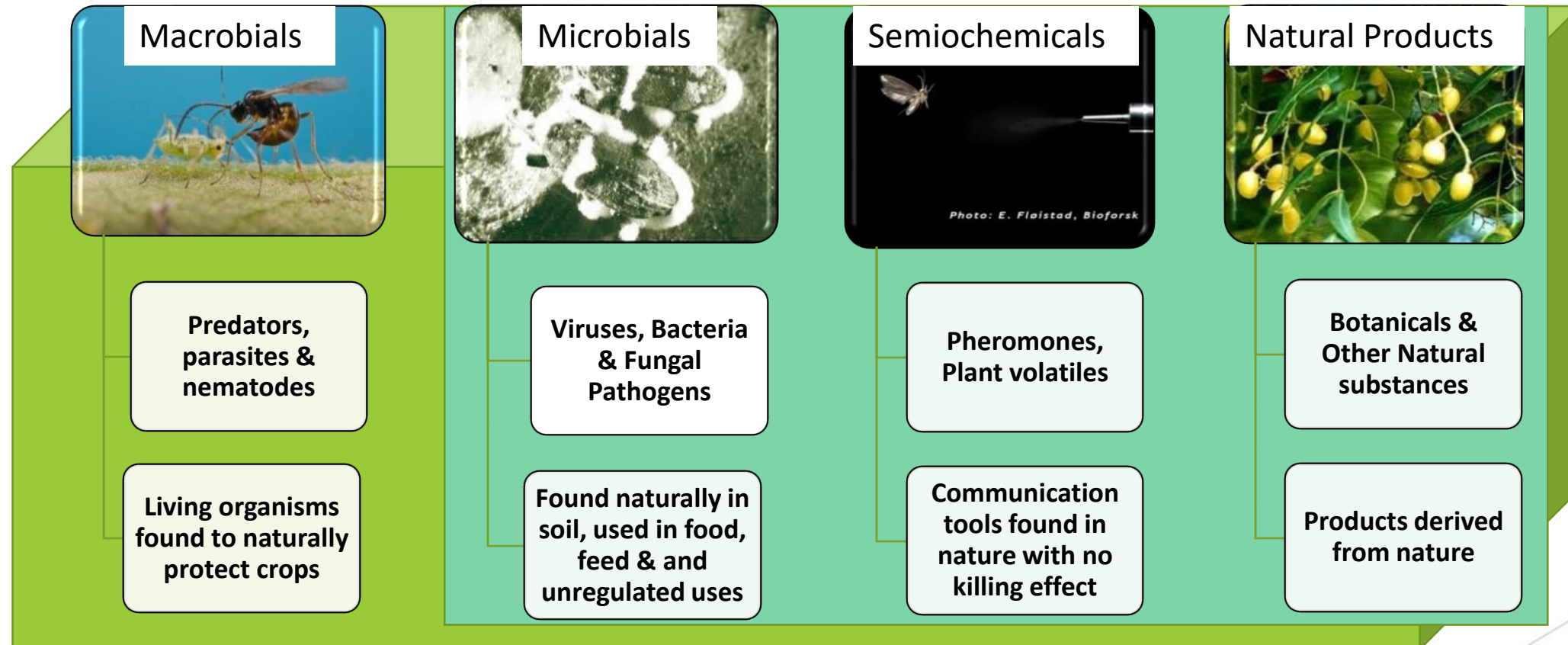
# IBMA contribution to the EU Sustainable Agriculture Expert Group

David Cary, Executive Director of IBMA

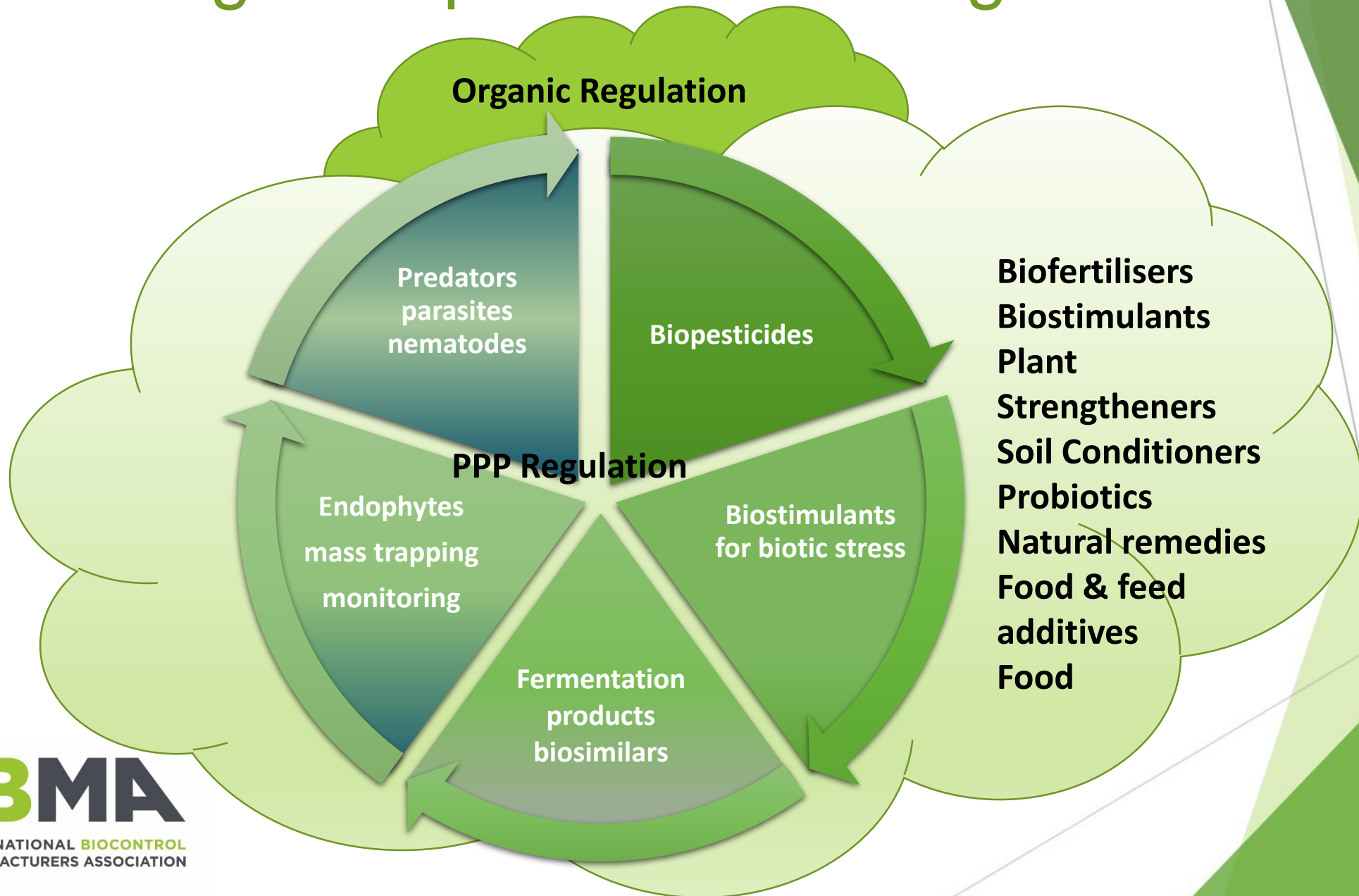
Willem Ravensberg, President of IBMA



# What “tools” are available from the Biocontrol industry?



# Where do biological inputs fit within regulation?





# Low-risk Procedures



Category \ Procedure	Candidate for substitution	Standard Case	Low-risk active substance
Evaluation Timeline for initial a.s. approval	3 years+	3 years+	3 years+
Duration of initial a.s. approval	7 years	10 years	15 years
Evaluation Timeline for initial product authorisation (registration)	1 year+	1 year+	120 days
Duration of a.s. approval at renewal	7 years	15 years	15 years

The benefit of being granted the status of low-risk is only inferred at the end of the procedure.

The benefit achieved for being a low-risk active substance is a 5 year longer initial approval period. This is not given for subsequent renewals.

The benefit achieved for a low-risk PPP (plant protection product) is the shortened 120day procedure which Member States often ignore and wish to lengthen.

Realistically little benefit is currently seen from having low-risk status

Category Procedure	Candidate for substitution	Standard Case	Low-risk active substance
Evaluation Timeline for initial a.s. approval	3 years+	3 years+	0.5 years to Completeness + LR Check Provisional Approval 2.5 years after Completeness Check
Duration of initial a.s. approval	7 years	10 years	Unlimited apart from data call-ins
Evaluation Timeline for initial product authorisation (registration)	1 year+	1 year+	120 days
Duration of a.s. approval at renewal	7 years	15 years	Not applicable

The benefit of being granted the status of low-risk would be provisionally inferred when the revised Completeness Check is done and then confirmed at the end of the procedure. PPP submissions can be submitted after Completeness Check.

The benefit for being a low-risk active substance would then be for an unlimited initial approval period granted when full approval and status is noted. There is no requirement for subsequent renewals.

The benefit achieved for a low-risk PPP (plant protection product) is retained at a 120day procedure. PPPs can then be brought to market.

Provision for data call-in exists within the legislation and should be used if scientific evidence points to a risk that could affect the status of the active-substance and PPPs containing it.



+ includes stop the clock time

Category Procedure	Candidate for substitution	Standard Case	Low-risk active substance
Evaluation Timeline for initial a.s. approval	3 years+	3 years+	1.5 years to DAR
			Provisional Approval
			1.5 years after DAR
Duration of initial a.s. approval	7 years	10 years	Unlimited apart from data call-ins
Evaluation Timeline for initial product authorisation (registration)	1 year+	1 year+	120 days
Duration of a.s. approval at renewal	7 years	15 years	Not applicable

The benefit of being granted the status of low-risk would be provisionally inferred when the DAR is published at then confirmed at the end of the procedure. PPP applications can be submitted after provisional approval.

The benefit for being a low-risk active substance would then be for an unlimited initial approval period granted when full approval and status is noted. There is no requirement for subsequent renewals.

The benefit achieved for a low-risk PPP (plant protection product) is retained at a 120day procedure. PPPs can then be brought to market.

Provision for data call-in exists within the legislation and should be used if scientific evidence points to a risk that could affect the status of the active-substance and PPPs containing it.

# Summary of low-risk changes sought

- Revert to a Provisional approval system for low-risk a.s.
- Unlimited approval status given for low-risk a.s.
- Retain 120day evaluation timeline for low-risk PPPs
- Unlimited approval status given for low-risk PPPs
- Reduced efficacy data requirements for low-risk PPPs
- Label advertisement for low-risk PPPs
- Introduce a biopesticide stream for evaluations
- Establish a group of expert biopesticide evaluators





IPM



# Vital to sustainable Agriculture:

## Integrated Pest Management

*working with and not  
against nature*



# IPM must not forget inputs that are not regulated

- Microbials
- Plant breeding
- Build up of natural enemy bank
- Crop rotations
- Physical and mechanical control
- Ecosystem services
- Etc.

# Hurdles to use of Biocontrol & IPM

- Transfer of information
  - General principles
  - Local tailoring to be fit for purpose
- Lack of Harmonisation of regulations
  - Global and Regional harmonisation required
  - Cross sector harmonisation
  - Agricultural input harmonisation
  - Smart integration of regulations eg 1107/2009 & 834/2007; 1107/2009 & 2003/2003

# Merging of Agricultural Systems

## Organic

- Holistic Systems based
- Use of IPM principles
- In harmony
- Trust
- Certification

## Conventional

- Production focus
- Redefining IPM
- Constantly requiring correction
- Silver bullets
- Resistance

Movement forced

Policy changes

External  
influences

Unsustainable in  
current form

# Future Sustainable Crop Protection Agriculture

- **Founded on prevention and monitoring**
- **Intervention only when needed**
- **New tools all nature-based solutions**
- **Biopesticides, biostimulants, biofertilisers**
- **Resilient soils and resilient plants (microorganisms, seed treatments)**
- **Automation, ICT tools and intelligent equipment minimise use of products and exposure**
- **Holistic approach**
- **Interventions upon a licensed PCA written recommendation**



# Factors affecting adoption: Macro factors

- Political and societal needs favour the use of bioprotection (environment, biodiversity, food safety)
- Increased legislation of chemicals will stimulate development of low-risk solutions
- A driving force is the requirement of retailers and consumers for residue-free food
- The biocontrol industry has reached a sufficient level of maturity enabling realistic participation and continued solid growth in the future



# Many thanks!

David Cary & Willem Ravensberg

