IBMA presentation to the Southern Zone Steering Committee Meeting, Athens 1st July 2016

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Low-risk active substance and PPP Procedures

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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

+ includes stop the clock time

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

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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

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+ includes stop the clock time

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.

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.

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+ includes stop the clock time

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

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Species specific biocontrol active substances and products: a special case!

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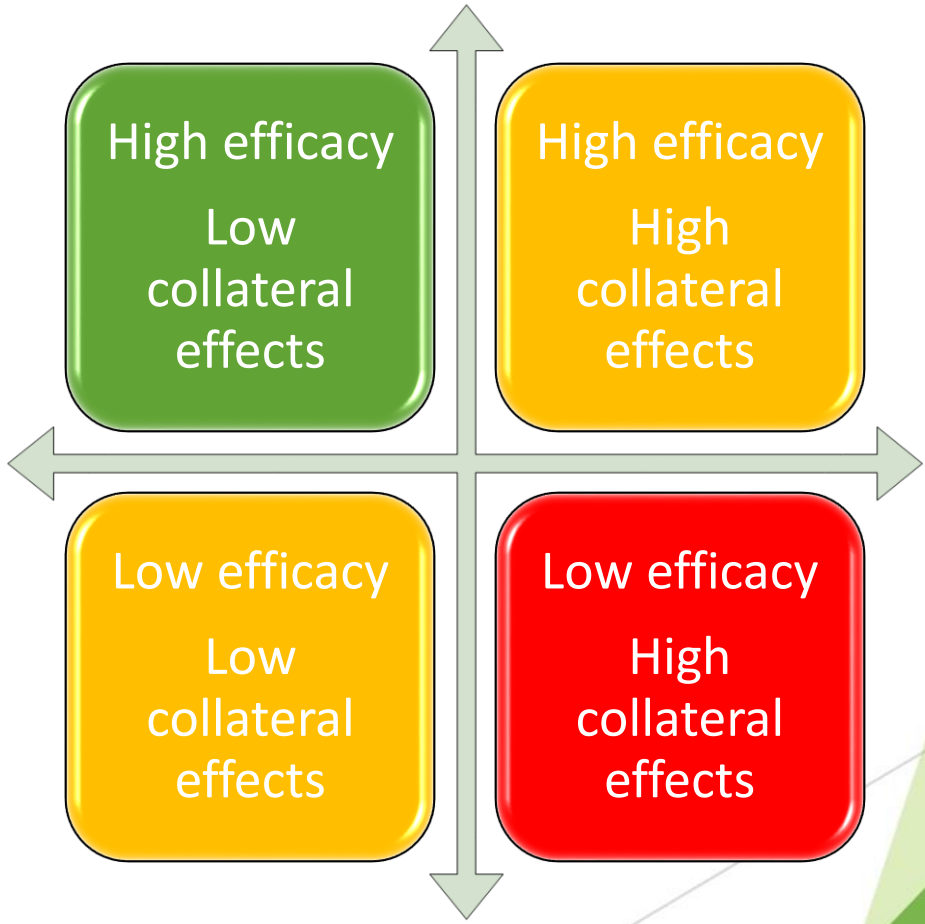
SUPD Annex iii
General principles of integrated pest management

- Point 4. Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.



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Pinpointed control = advantages & disadvantages

- Types of species specific biocontrol solutions
  - Pheromone attractants
  - Baculoviruses
- Low-risk criteria
  - Both a.s. groups separately identified & characterised
- Markets
  - Some large markets eg. *Cydia pomonella*
  - Many very small markets eg. *Spodoptera littoralis & Adoxophyes orana*

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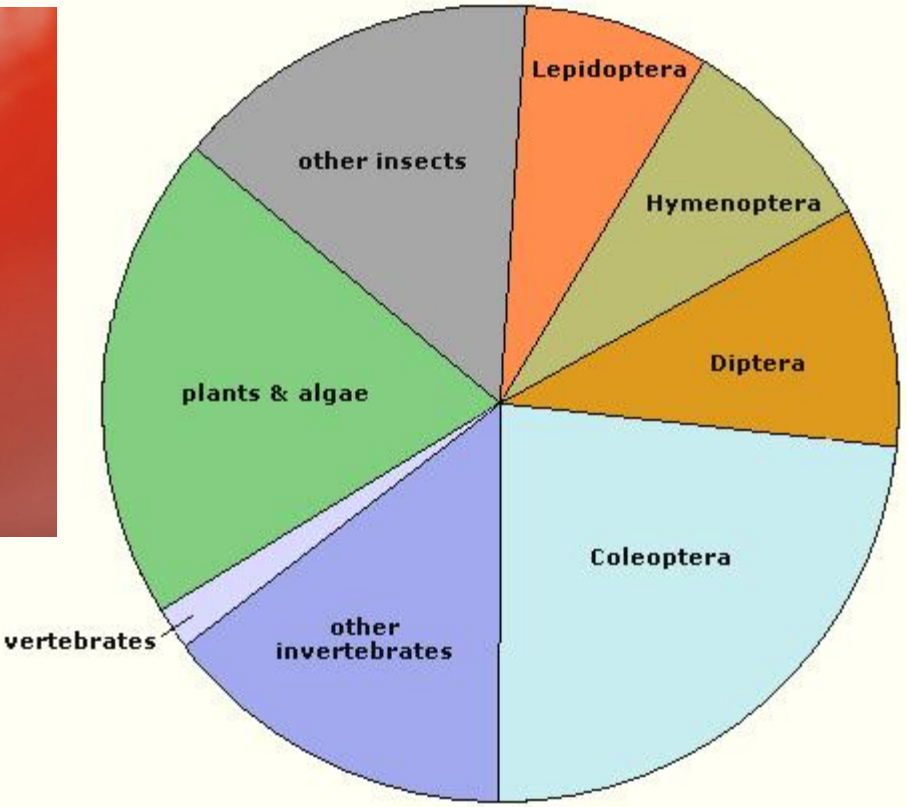
Species specific control



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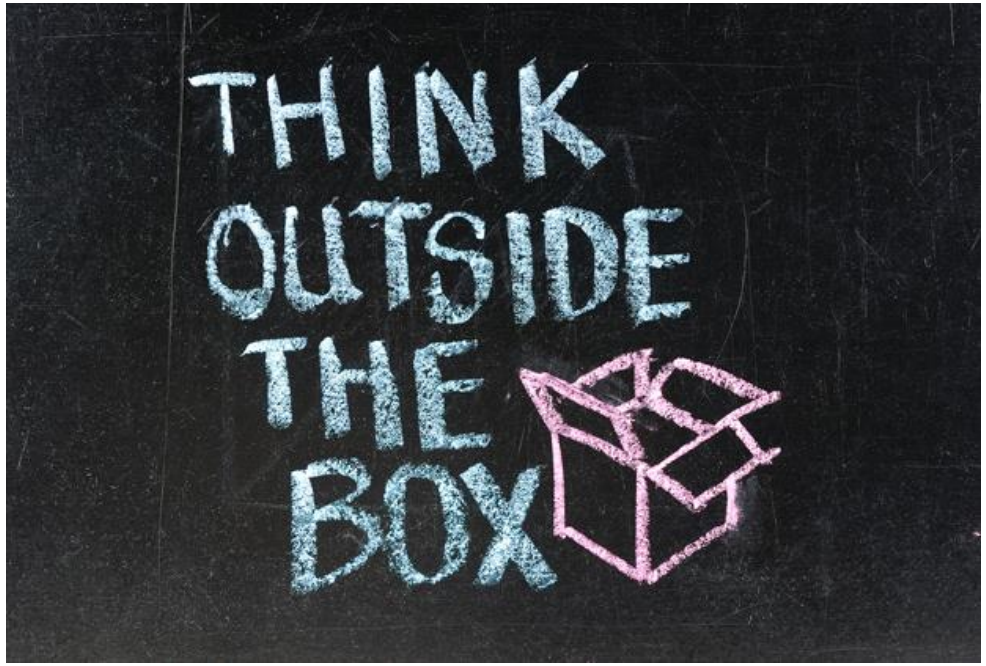
Possible regulatory solutions

- Grouped a.s. approvals
- Single EU regulatory zone for low-risk PPPs
- Exemption for species specific control measures
- Indefinite approval & authorisations
- REACH style tonnage limits for notification



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Biological inputs into agriculture and regulation

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Future Sustainable Agriculture

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

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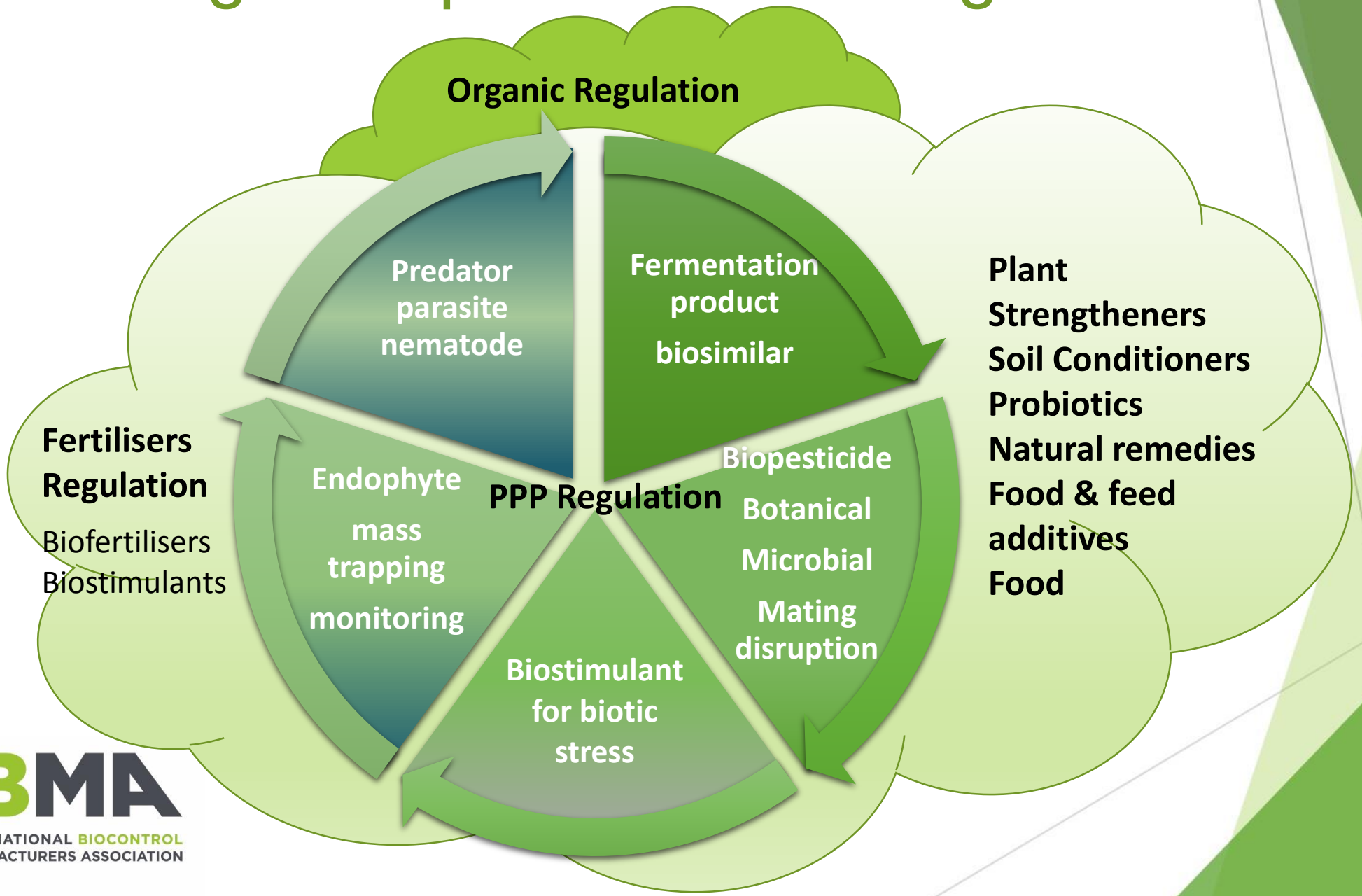
Where do biological inputs fit within regulation?



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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 diverse biological solutions
- We need to check or monitor that these are the low-risk ones
- Many driving forces: influence of retailers and consumers for residue-free food, environmental responsibility & farmers wanting a diversity of tools
- The biocontrol, biostimulant and related industry has reached a sufficient level of maturity enabling realistic participation and continued solid growth in future agriculture

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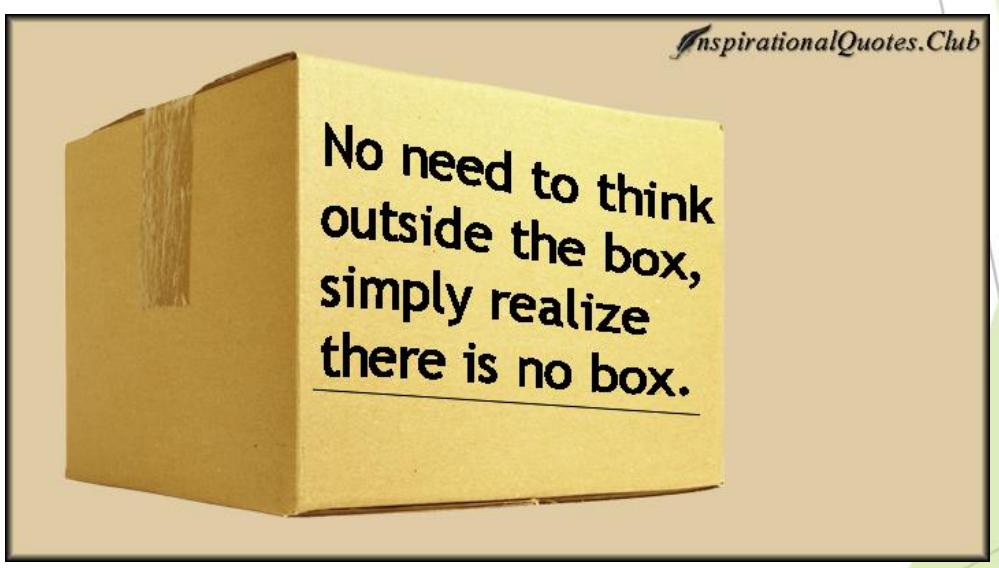
Possible regulatory solutions

- Single EU Agency
- REACH style notification system
- Biological inputs into agriculture
- Biological inputs into the environment
- Specialised evaluation of any true risks posed!



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Many thanks!

David Cary

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