

IBMA presentation to the
South Zone Steering
Committee Meeting,
Oeiras 7th July 2016

“Issues for co-operation
between regulators and
the biocontrol industry”

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Low-risk active substance and PPP Procedures & Criteria



low-risk changes sought

- Fast track or provisional approval system for low-risk a.s.
- Time unlimited approval status given for low-risk a.s.
- Retain 120day evaluation timeline for low-risk PPPs
- Time unlimited approval status given for low-risk PPPs
- Reduced efficacy data requirements for low-risk PPPs
- Label claims for low-risk PPPs

Category Procedure	Candidate for substitution	Standard Case	Low-risk active substance
Active substance renewal	7 year approval	15 year approval	15 year approval

Priority given for renewal evaluations for active substances anticipated to be low-risk as was priority given for active substances designated as candidates for substitution

Category Procedure	Candidate for substitution	Standard Cases Zeta cypermethrin Tau fluvalinate	Low-risk active substance SCLPs
Active substance expiry dates assuming an evaluation of 3 years	2029	30/11/2036 21/5/2039	31/8/2035

Inconsistencies between Criteria main text and annex or implementation

- Microbials
- AMR
- Guidance to be prepared by EU Biopesticides EG
- Semiochemicals
- Issue of inconsistency



Other issues

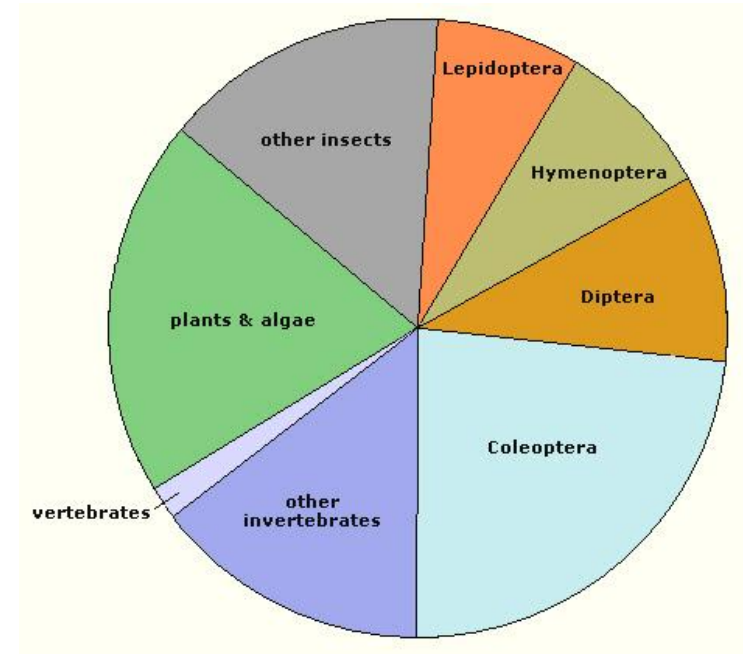


Niche uses of highly specific biocontrol solutions

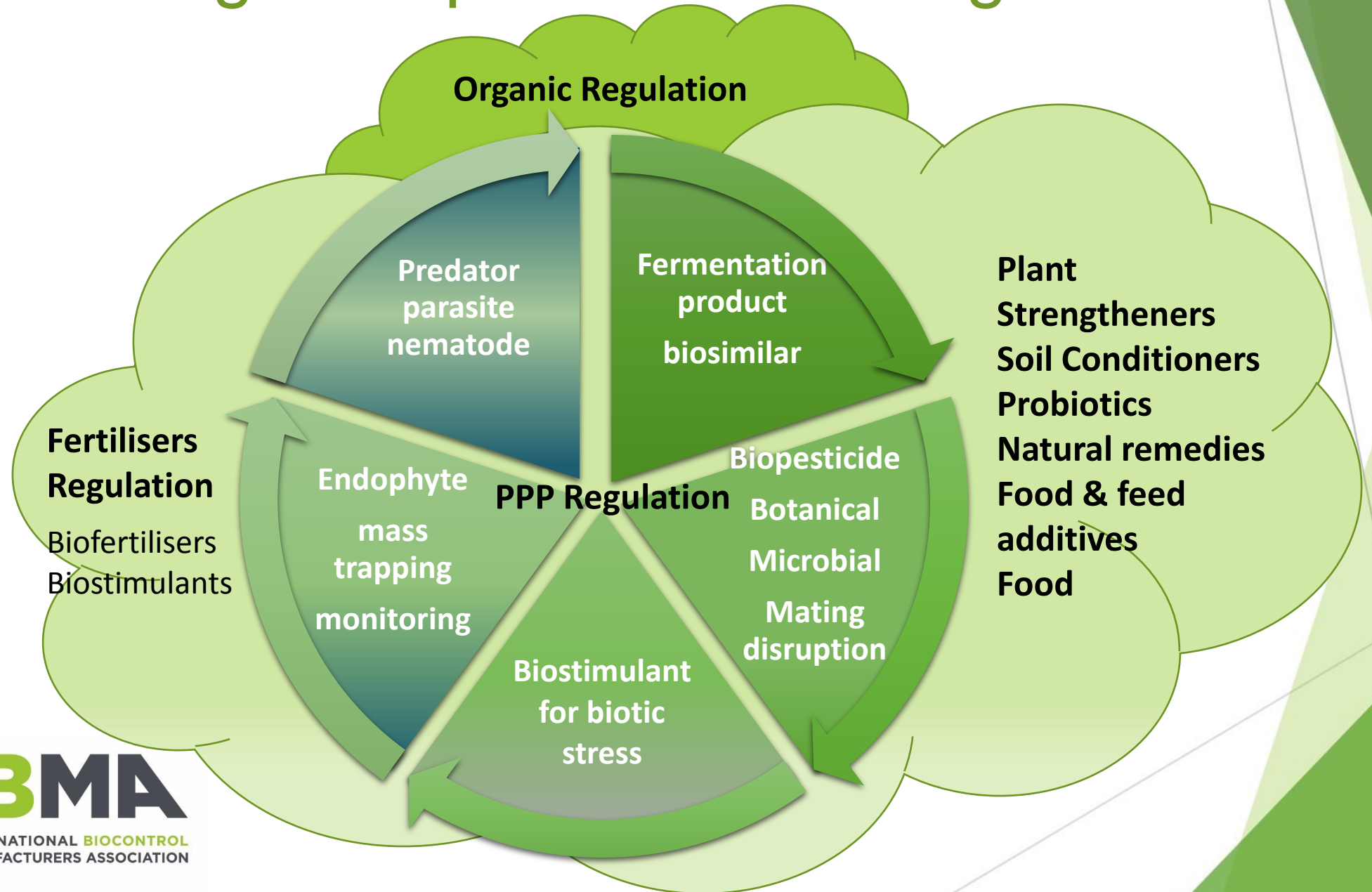
- Types of species specific biocontrol solutions
 - Pheromone attractants
 - Baculoviruses
- Low-risk criteria
 - Both a.s. groups separately identified & characterised
- Markets
 - Some large markets eg. *Cydia pomonella*
 - Many very small markets eg. *Spodoptera littoralis* & *Adoxophyes orana*

Possible regulatory solutions

- OECD Seminar discussions:
- Grouped a.s. approvals
- Single EU regulatory zone for low-risk PPPs
- Linkage with minor uses
- Indefinite approval & authorisations
- REACH style tonnage limits for notification



Where do biological inputs fit within regulation?



Engagement with EU Sustainable Agriculture EG and MUCF

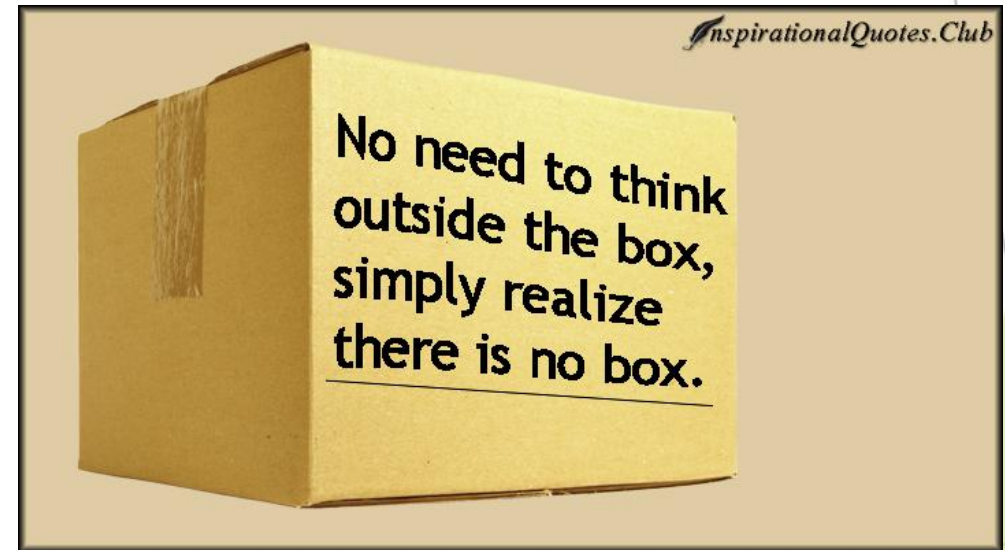
- Support of Implementation plan
- Support of specified issues low-risk and IPM
- Support of MS prioritised issues in DK, NL, SE and IT
- Participate in MUCF meetings and issues
- Promote minor uses with IBMA members
- Global minor uses meeting and outcomes
- Single zone

Issues under REFIT

- Zonal authorisations
- Mutual recognition
- Timelines
- Biological active substance and product specific issues
- Invasive pests and diseases
- Efficacy
- Terminology
- Emergency authorisations

Possible additional regulatory solutions sought under REFIT

- Single EU Agency eg EMA
- Minor uses & niche solutions
- REACH style notification system
- Data call in system
- Expert group of biopesticide evaluators
- Biopesticide stream for evaluations
- Biological inputs into agriculture
- Data relevance / waiver system
- Specialised evaluation of any true risks posed!





Many thanks!

David Cary

