



**a Biocontrol Industry Perspective
on Regulation of EPN's**

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Outline of talk

- **Introduction**
- **EPN based pest control products**
- **The biopesticide market and industry**
- **Regulations of EPN's**
- **Recommendations for regulation**
- **Conclusions**



Introduction

- **Biological control of pests successful**
- **More than 150 natural enemies available**
- **EPN's succesful use >> 15 years**
- **Microbial pest disease control: early days**
- **The biopesticide industry: small and young**



The biopesticide market

■ World pesticide market		\$ 25 billion
- Biopesticides ~ 1%		\$ 300 million
■ Europe pesticide market		\$ 5 billion
- Biopesticides ~ 2%		\$ 97 million
	EPN's	\$ 6- 7 million
- Microbials	26%	\$ 25 million
- Non Bt-sales	20%	\$ 5 million

source: Frost & Sullivan, 2001. The European Biopesticide Market .

The Biopesticide Industry

- Europe : 20 – 25 companies
- North America : 10 – 15 companies
- History : > 175 companies
- Small and young companies (SME's)
- Products and companies come and go:
withdrawals and bankruptcies
- **EPN producers Europe and N. America: each ca 5**

EPN producers

Europe

- **Andermatt Biocontrol, CH**
- **Becker Underwood, USA**
- **Enema, G**
- **Koppert, NL**
- **Owiplant, P**

N. America

- **Biologic Company USA**
- **Certis, USA**
- **Int. Biocontrol Systems,
USA**

EPN species / products

■ *Heterorhabditis*

- *megidis*

- *bacteriophora*

- *indica*

■ *Phasmarhabditis*

hermaphrodita

■ *Steinernema*

- *carpocapsae*

- *feltiae*

- *glaseri*

- *riobrave*

- *scapterisci*

Why are EPN's used?

- soil pests
- chemicals not available
- chemicals not compatible with IPM
- chemicals not efficient
- pests resistant to chemicals
- food crops (herbs)

Where are EPN's used?

man-made environments:

- glasshouses
- mushroom houses
- golf courses, lawns
- field crops, orchards
- (forestry)

→ where are real risks?

Regulation of EPN's (IBCA's)

- **Registration** : A, CH, CR, HU, NOR, SE, PO, SLW, S-K, Jp, NZ,
C+S America
- **Import permit** : UK, IRL, USA, CND, MEX for non-native spp
- **New Regulation:** NL, B, G
- **Procedures** : many national requirements/procedures
OECD guideline, EPPO guidelines,
FAO code of conduct
- **Other laws** : Biodiversity, Invasive Alien Species, Phyto
Sanitary Acts

Regulation of EPN's (IBCA's)

Need for harmonization

- **Clear procedures**
 - simple
 - fast
 - cheap (dossier, fee)
 - doable
- **Focus on**
 - potential risks
 - non-native species

Regulation of EPN's (IBCA's)

Potential risks

- **Applicator and worker**
- **Consumer health (human, animal)**
- **Environment**
 - **non-target effects**
 - **natural ecosystems**

Regulations

Regulations and reality

Regulation starts with simple ideas.

Once written down they become more rigid.

Additional requirements easily implied. Simplification almost impossible.

Studies more detailed over time. Certified studies requested

→ at the end: big barriers for further development of BCA's

Recommendations for regulation (1)

- Include all stakeholders (regulators, scientists, industry)
- Keep requirements simple, quick, cheap and doable by everyone
- Procedures should be clear (no open end-points):
 - Decision periods known and short
 - Fee's low
 - Focus on non-native spp.
 - Keep native spp procedure very simple

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Recommendations for regulation (2)

- Regulate species, not product
- Where needed mitigate certain applications
- Leave out efficacy
- Leave out benefits comparison
- Each producer applies for approval
- Create a harmonised procedure

Recommendations for regulation (3)

- **Develop a new guideline, appropriate for EPN's**
- **Use expert judgement and literature for risk assessment**
- **Develop appropriate studies (where needed)**
- **Accept mutual recognition (Zonal registration)**

Recommendations for regulation (4)

Focus on Main Issues

- Establishment
 - Dispersal
 - Non-target effects
 - Real risks
- After > 15 years of use no problems

Conclusions

- **Harmonised procedure**
- **Appropriate guideline**
- **Regulate only in case of risks**
- **Include all stakeholders**
- **No barrier for new products and industry**