



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

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Outline of talk

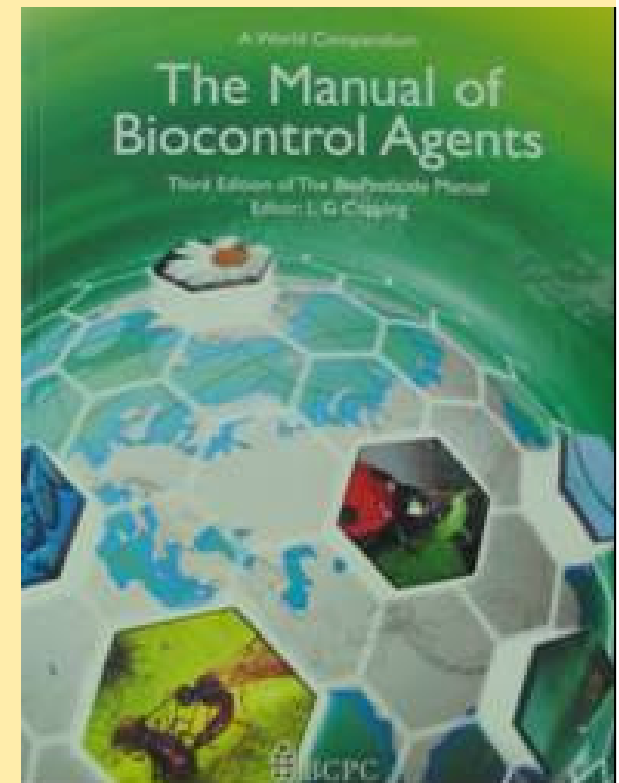
- **EPN producers and products**
- **Safety of EPN's**
- **Regulations of EPN's**
- **Recommendations for regulation**
- **Conclusions**

Biopesticides

**World-wide overview: micro- and macro-organisms:
The Manual of Biocontrol Agents 2004:**

▪ micro's	112
▪ nematodes	8
▪ macro's	127

Source: The Manual of Biocontrol Agents
(L. Copping – BCPC)



The biopesticide market

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

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

EPN producers

Europe

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

N. America

- **Biologic Company USA**
- **Becker Underwood USA**
- **Int. Biocontrol Systems,
USA**

EPN species / products

■ *Heterorhabditis*

- *megidis*

- *bacteriophora*

- *indica*

■ *Phasmarhabditis*

hermaphrodita

■ *Steinernema*

- *carpocapsae*

- *feltiae*

- *glaseri*

- *riobrave*

- *scapterisci*

Green = used in Europe

Why are EPN's used?

- **soil pests**
- **chemicals not available**
- **chemicals not compatible with IPM**
- **chemicals not effective**
- **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)**

EPN's and safety

COST Action 850 - Microsoft Internet Explorer provided by Koppert Biological Systems

Bestand Beveiligen Beeld Eenvoeren Extra Help

Vorige

Adres <http://www.cost850.ch/index.html> Go naar Koppelingen

Crops, Pests & Agents Companies & Products Legal & Safety Experts

COST Action 850: Publications

Cost 850 "Biocontrol Symbiosis", WG 3 and 5 Meeting: Evaluation of Risks Related with the Use of EPN and Discussion on Requirements for Registration of Invertebrate Biocontrol Agents, Kiel, Germany, 06-07 November 2004

Download [Programme \(PDF, 17 KB\)](#)

Presentations:

- Ralf-Udo Ehlers: Aims of the Workshop ([Download PDF, 221 KB](#))
- Joop van Lenteren: OECD Guideline - and the ERBIC project ([Download PDF, 1334 KB](#))
- Franz Bigler: Overview on the Engelberg workshop and attempts to harmonize ([Download PDF, 180 KB](#))
- Uli Kuhlmann: Selection of non-target species for host specificity testing ([Download PDF, 198 KB](#))
- Jeffrey Bale: How to test establishment? ([Download PDF, 578 KB](#))
- Dirk Babandier: Environmental risks related with dispersal and establishment ([Download PDF, 549 KB](#))
- Anton Loomans: Regulation of IBCAs in the NL ([Download PDF, 898 KB](#))
- Willem Ravensberg: Industry view on Regulation of IBCAs ([Download PDF, 192 KB](#))
- Bernard Blum and Richard Greatrex: IBMA's achievements and failures to influence the discussion ([Download PDF, 138 KB](#))
- Ralf-Udo Ehlers: Safety of EPN ([Download PDF, 241 KB](#))

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Internet

EPN's and their bacteria

The intestinal microorganisms associated with entomopathogenic nematodes are:

- *Xenorhabdus* spp. from *Steinernema* spp.
- *Photorhabdus* spp. from *Heterorhabditis* spp.

Each dauer juvenile carries 100-200 bacteria cells

Do the bacteria pose a risk?

for the producer?

for the applicator?

for the environment?

EPN's and safety

SAFETY TESTS (around the eighties)

Pathogenic effects

- *Xenorhabdus bovienii* (Obendorf *et al.* 1983) 0
(guinea pig, rat, mouse, rabbit)

- *Xenorhabdus nematophila* (Poinar *et al.* 1982) 0
(mouse, chicken)

- *Photorhabdus luminescens* (Poinar *et al.* 1982) 0
(mouse, chicken)

(After Boemare, 2004. Cost 850, Kiel Workshop)

Source: www.cost850.ch

COST Action 850: Publications

Cost 850 "Biocontrol Symbiosis", WG 3 and 5 Meeting: Evaluation of Risks Related with the Use of EPN and Discussion on Requirements for Registration of Invertebrate Biocontrol Agents, Kiel, Germany, 05-07 November 2004



EPN's and safety

POTENTIAL RISKS

1. To the producer

Allergenicity, sensitisation (as with all biological material)

Safety precautions need to be taken in frame of Labour Acts, not in framework of regulations for release of BCA's

2. To the applicator

exposure is very limited, is there a risk?

3. General

Some human infections reported of *Photorhabdus luminescens*

EPN's and their bacteria

EPN's and bacteria in the environment

Non target effects: many studies report that the risk is very limited

ERBIC:

Case study: risk index for *Steinernema feltiae* in field crops in Finland

SUM = risk index 53

(between 35 and 70 more info needed; max is 125)

(after Hokkanen, 2004. Cost 850, Kiel Workshop)

Source: www.cost850.ch

COST Action 850: Publications Cost 850 "Biocontrol Symbiosis", WG 3 and 5 Meeting: Evaluation of Risks Related with the Use of EPN and Discussion on Requirements for Registration of Invertebrate Biocontrol Agents, Kiel, Germany, 05-07 November 2004



EPN's and their bacteria

Bacteria in the environment

Application of EPN's: 0.5 million/m²
Bacteria: 100 million/m²

Per m² of soil: 1 m² x 10 cm depth = 10E5 cm³
Applied per m²: 10E7 bacteria → 100 bacteria per cm³

General: 10E7 bacteria per gram of soil

If 1 cm³ = 1 gram:

→ 100 bacteria extra = 0.001 %

→ Is this a risk for the soil (micro)flora and fauna?

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

■EPPO guideline:

**EPPO Standards on Phytosanitary Measures - Safe use of
biological control**

**List of biological control agents widely used
in the EPPO region [PM 6/3(2)]**

NEMATODA

Heterorhabditis bacteriophora

Heterorhabditis megidis

Phasmarhabditis hermaphrodita

Steinernema carpocapsae

Steinernema feltiae

Last version: March 2002

Regulation of EPN's

▪ FLORA and FAUNA ACT, the Netherlands:

Nematoda (Entomopathogene aaltjes)

Strongylida – Heterorhabditidae

- Heterorhabditis bacteriophora
- Heterorhabditis megidis

Rhabditida – Steinernematidae

- Steinernema carpocapsae
- Steinernema feltiae
- Steinernema glaseri
- Steinernema kraussei

Last version: February 2, 2005

Regulation of EPN's

Need for harmonization

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

Regulation of EPN's

Potential risks

- **Producer, applicator:**

Take precautions as in all work situations and follow local “Occupational Safety and Health Acts” and “Working Conditions Acts”.

→ Do not regulate in this framework

Regulation of EPN's

Potential risks

- **Environment**
 - **non-native species**
 - **displacement**
 - **dispersal**
 - **non-target effects**

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 system: low costs**
- **Focus on non-native spp.**
- **Keep native spp procedure very simple**

Recommendations for regulation (2)

- **Regulate species, not strains, nor 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, and close to other macrobials**
- **Not under EU 91/414 as a microbial pesticide**
- **Use expert judgement and literature for risk assesment**
- **Develop appropriate test methods (only where needed)**
- **Accept mutual recognition (eco-regions, zonal registration)**
- **Create a positive list**

Recommendations for regulation (4)

Focus on Main Issues

- Establishment
 - Dispersal
 - Persistence
 - Non-target effects
 - Real risks
- After > 20 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**