

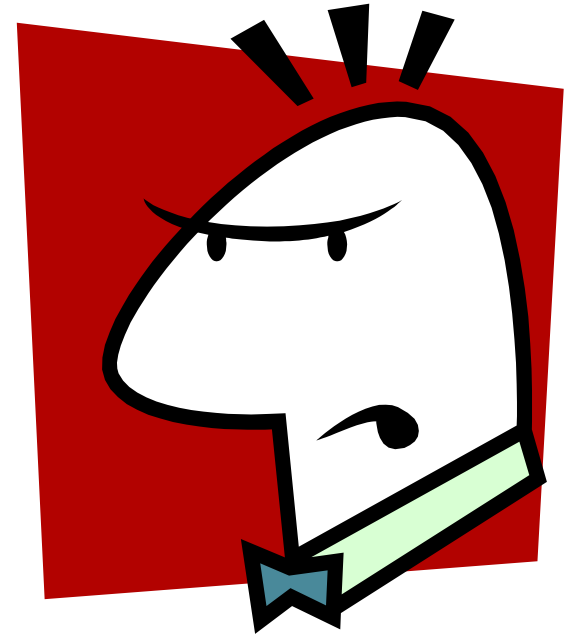
The Registration of EPNs a worldwide review of present regulations

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31 March 2006

Since 15 years Biocontrol Agents are more and more subject to regulation

- FAO Code of Conduct for the Export and the Release of BCAs
- IPPC and ISPMs
- Directive 91/414/EEC including **ALL KIND** of plant protection products
- OECD Guidelines
- national regulations



What is the present situation ?



Internationally,
and Locally

Internationally

➤ **COMPULSARY**

- International Plant Protection Convention
- ISPM No3 adopted in April 2005

➤ **NOT COMPULSARY**

OECD: Guidance for Information Requirements for the Regulation of Invertebrates as Biological Control Agents (EHS N°21 - 2004)

IPPC

- common and effective action to prevent introduction and spread of pests
- Promotion of appropriate measures for their control



- Biocontrol agents may be or become Pests !

International Standards for Phytosanitary Measures No 3 ISPM 3

« GUIDELINES FOR THE EXPORT,
SHIPMENT, IMPORT AND RELEASE OF
BIOLOGICAL CONTROL AGENTS AND
OTHER BENEFICIAL ORGANISMS »

ISPM No 3

- To facilitate the safe, export, shipment, import and release of BCAs : including IBCAs and EPNs
- Guidelines to national authorities (NPOs)
- Encourage responsible trade practices
- Provide risk management recommendations
- Promote safe use

PRACTICALLY REQUIRES REGISTRATION IN THE COUNTRY OF RELEASE

ISPM No3

- OBLIGE COUNTRIES TO REGISTRATION
- INCLUDING EPNs
- DO NOT SPECIFY
 - data required
 - procedures
 - fees

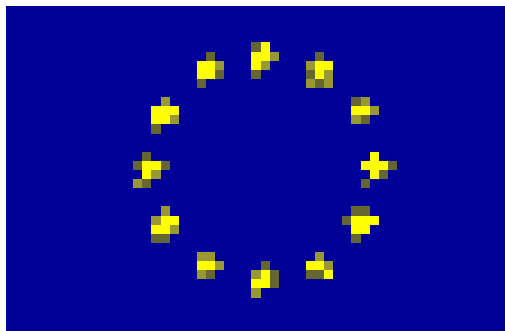
OECD

Guideline for IBCAs Data Requirement

- 4 Fields of consideration
 - Characterisation and identification
 - Assessment of safety and effects on human health
 - Assessment of environmental risks
 - Assessment of efficacy
- Almost only « available » information (no specific studies)
- EPPO and APHIS-USDA documents as reference for waivers, and sales permit (IBCAs already in use)
- No comment on implementation, procedures etc.

OECD Guidelines

- Provide a very « liberal » and « low cost » frame for the registration of IBCAs
- Will be soon enhanced with new Guide lines on « scientific » issues regarding Microbials such as : environmental safety, occupational and consumers exposer, metabolite residues, genetic toxicity, taxonomy, efficacy
- EPNs may be concerned as long as NPOs will or not look at symbionts



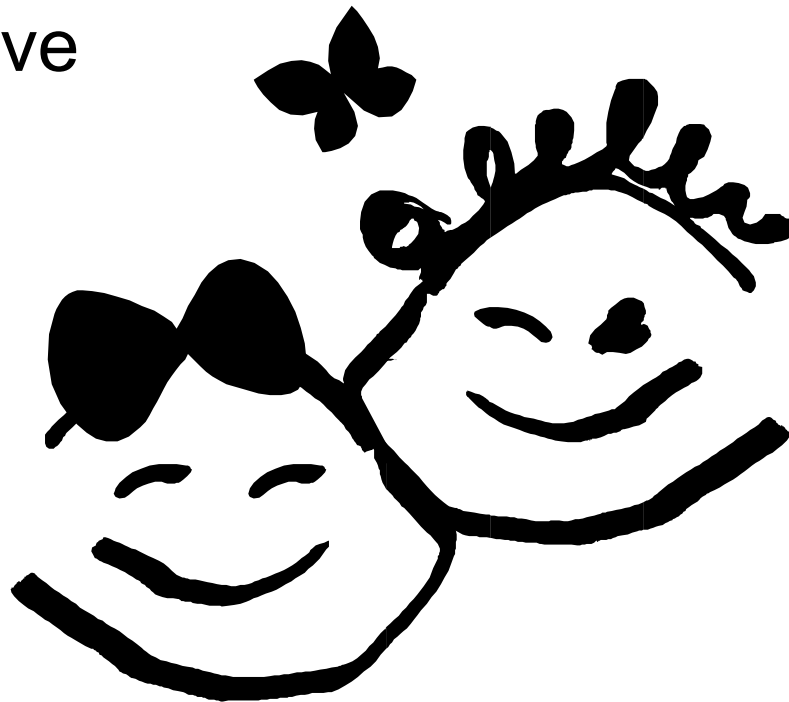
EU Level ?

- IBCAs are not covered by the « pesticides Directive 91/414/EEC



EPNs are part of Invertebrate Biocontrol Agents (IBCAs)

- EU did not consider IBCAs within the Directive 91/414
- Many countries have not decided upon registration, yet
- Other have a very « liberal » attitude



AND WHAT ABOUT INDIVIDUAL COUNTRIES ?



(This is not Wendy Sexsmith)

IBMA survey February 2006

24 OECD + 6 SE Asian countries

- registration for EPNs ?
- Based on OECD Guidelines ?
- Major requirements

SITUATION

- Although EPNs are sold in 50% of the countries only 30% have registration
- In OECD countries basic requirements are in line with OECD Guidelines (50%)
- EU do not regulate EPNs, but several European countries do it
- No registration in countries outside of OECD

Situation (2)

Most frequent requirements for Registration

- ✓ Detailed identification (70%)
- ✓ Available documentation on environmental risks (40%)
- ✓ Potential of establishment and dispersal (50%)
- ✓ Efficacy (70%)

Situation (3)

Data not frequently required

- Toxicity (5%)
- Benefits (< 5%)
- Tox (acute or chronic) (5%)
- Biology (20%)
- Quality control (15%)
- No clear differences between endemic and exotic species

CONCLUSIONS on REGISTRATION of EPNs

- confusion and case by case
- Flexible and supportive in the US
- Not considered by SANCO
- Most important criteria: **efficacy** (although unclear definition)
- Need clarification and support in Developing countries

4 RECOMMENDATIONS (to REBECA Project)

1. Consider the OECD guidelines
2. Make a clear cut between exotic and chronic species
3. Positive Listing (no registration needed)for the species which demonstrated good and safe performances over years
4. Consider some kind of Bio-vigilance (prevention of risks)



Thank You!

Akademik

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