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International regulation of Invertebrate Biological Control Agents

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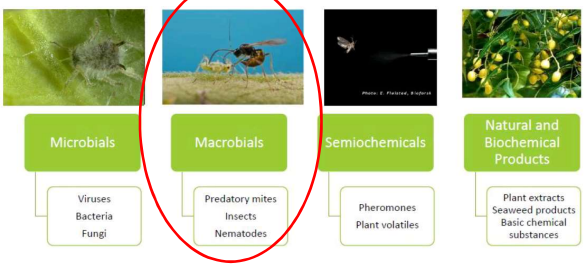
- International Biocontrol Manufacturers Association
- Worldwide association of Producers (and distributors) of Biological Control Agents
- 250 members
- Macrobials: 50 producers, most of them < 20 employees



Regulation of biological control agents

Why?

- Biological control is a safe alternative for pesticides…..
- Essential in production of safe food……
- Safe for the environment…..
- Promoted by governments (SUD directive EU)…..

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Regulation of biological control agents

Why?

- Increased concern about the environment
- Increased concern about Biodiversity

➢ General regulations have impact on biocontrol as well
  – Specific regulation required, to avoid overregulation

➢ Increases credibility of biocontrol industry

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Convention on the Biodiversity

- Convention on Conservation of Biodiversity
- Entity of the UN
- Established in 1992, Earth Summit, Rio de Janeiro
- Parties: 194 countries (except USA)

Objectives

1. The conservation of biological diversity
2. The sustainable use of the components of biological diversity
3. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources

Consequences for IBCA's

CBD 2002: '*prevent the introduction of all alien species and, when prevention fails, to control as far as possible species that threaten indigenous ecosystems, habitats or species'*

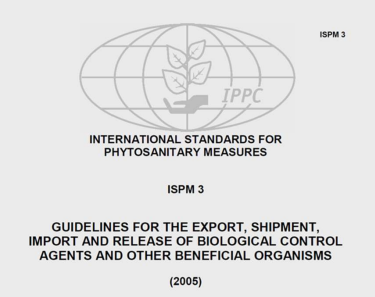
- Not appropriate for invertebrate biocontrol agents:
  - releases prevent use of chemicals that threatens biodiversity
  - Can be used to control invasive species
- Special regulation required

Biocontrol regulations

Base for regulation developed by International Plant Protection Convention (FAO):
ISPM 3 *Guidelines for the export, shipment, import and release of Biocontrol Agents and other beneficial organisms (2005)*

- Guidelines for risk management
- Responsibilities of contracting parties

Framework:
Regulation is arranged on national level



Potential risks

- **Human health risks** not considered to be of importance: *"not known except for some allergy in production of mites and nematodes"* (Ehlers, 2003)
- **Non-target effects:** *"More than 5000 introductions of about 2000 species of exotic arthropods in 196 countries during the past 120 years rarely have resulted in negative environmental risks"* (van Lenteren et al. 2006)
- "*Despite large scale releases of phytoseiids, and the establishment of key species, no cases have been documented that have showed any negative effects*" (Palevsky, 2015)
- The exception: *Harmonia axyridis*

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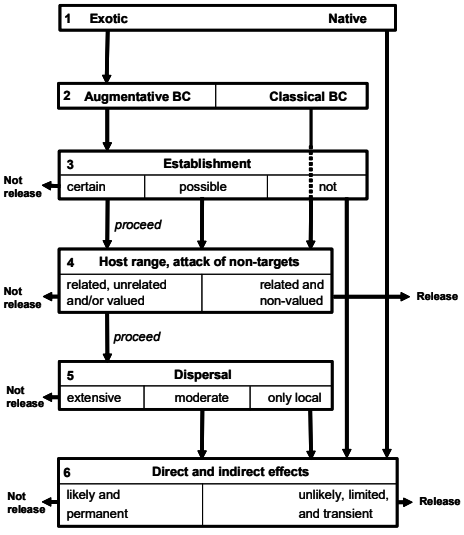
Environmental Risk Assessment for non-native species

Key features:

- Establishment : climate match, vegetation, hosts
- Host range : narrow -> wide
- Dispersal : flying, walking, size
- Direct/ indirect effects on non-target organisms

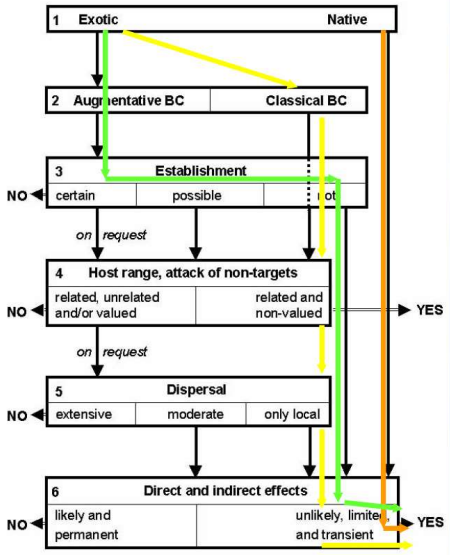
Source: van Lenteren *et al., Biocontrol* **48**, 2006

Environmental Risk Assessment: stepwise system



- Distinguishes between Exotic/Native, and Augmentative/Classical control
- Identifies key features of ERA:
  - Establishment
  - Host range
  - Dispersal
  - Direct/ indirect effects

Source: van Lenteren *et al., Biocontrol* **48**, 2006



Native natural enemy
all natives: safe

Exotic natural enemy for greenhouse use
if establishment impossible, usually safe
if establishment possible: more work!

Natural enemy for classical biocontrol
host range is most critical aspect

Van Lenteren, 2006

Europe

Biopesticides regulation EC 1107/2009

- Micro organisms and any other product of biological origin claiming to control pests
- Costly and lengthy procedure, too complex for biocontrol products
- Invertebrates not under this regulation
- Instead national regulation based on IPPC, different per country

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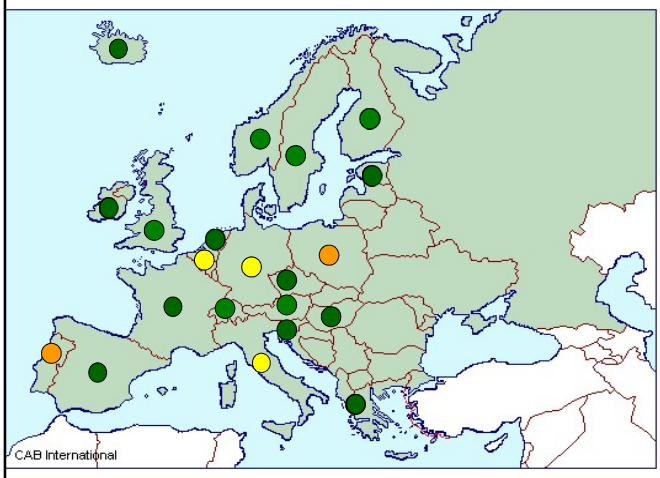
Status of national regulation in European countries:



- Implemented (16)
- In preparation (3)
- No regulation

Harmonisation of regulation:

- National regulations: Big differences between countries
- REBECA-project: Harmonisation of Regulation for biological control
  - EU project with input from regulators (EPPO), research (IOBC) and industry (IBMA)

REBECA Regulation of Biological Control Agents

- Resulted in Guidelines for information requirements
- Basic principle:
  Safe unless opposite is proven
- Accepted as EPPO standard in 2010

EPPO standard PM 6/2:

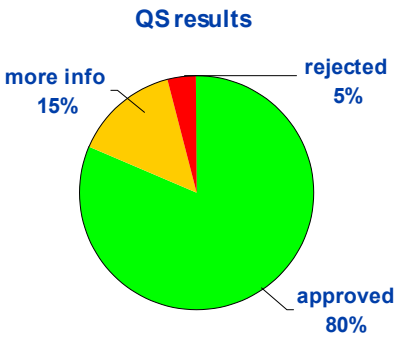
Guidelines for information requirements for import and release of exotic biocontrol agents (insects, mites, nematodes)

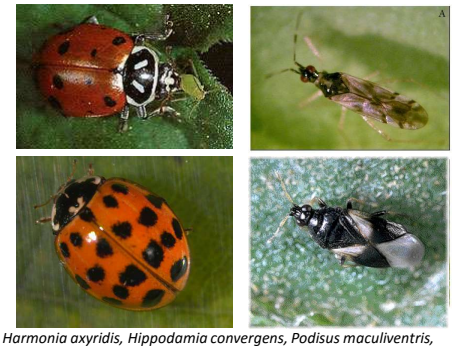
- Required information:
  - Basic biology
  - Intended use
  - Efficacy: not as base for permit!
  - Environmental Risk Assessment (ERA)
- For native species and species on positive list short process (no ERA!)

- Under EPPO = wider than Europe
- No law, no obligation by countries

EPPO standard PM 6/3: 'Positive list'

Quick scan results NW Europe - 150 species





Harmonia axyridis, Hippodamia convergens, Podisus maculiventris, Orius insidiosus, Dicyphus hesperus, Cotesia marginiventris, Amblyseius californicus, Encarsia hispida, Phasmarhabditis hermaphrodita, etc.

EPPO standard PM 6/3: 'Positive list'

List of biological control agents widely used in EPPO region, created in 2001

- Facilitates decisions on import/ release of BC agents within EPPO
- First listings based on expert judgement: Quick scans
- Joint EPPO-IOBC panel: updating of list
- Criteria:
  - Native in large part of EPPO region or
  - used in 5 EPPO countries for at least 5 years with
  - no reported negative environmental effects or significant non-target effect
- 135 species

The Netherlands

- Release of any spp forbidden by Nature Conservation law
- Except species on exemption list (all except new!)

For new species:

- Quick and dirty 'scan' based on available data from literature
- Additional tests if required
- Dossier in format EPPO standard 6/2
- Natives limited dossier; notification
- Application of dossier to Ministry of Agriculture
- ERA performed by Plant Protection Service (Envi)
- Answer within 8 weeks
- Permit for release for 5 years; afterwards on exemption list
- Both indoor and outdoor use

- No product registration

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Regulations for import and release of IBCA's in Kenya

- Full registration as Pest Control Product

Two steps:

- Environmental Risk Assessment by KEPHIS based on specific dossier > trial permit
- Efficacy Trials under supervision of KEPHIS
- Permit issued by Plant Protection Product Board

- 1-2 years
- Unlimited period
- Are at present considering to simplify system

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Bottlenecks in regulation:

- Precautionary principle: all natural enemies seen as potential IAS
- Lack of expertise by regulators

- Lack of taxonomic reports of presence of species in countries
- Lack of experience in Risk Assessment

- Procedures not transparent/ difficult
- Responsibilities not clear (envi/agri)
- Long process, esp. when product registration is required

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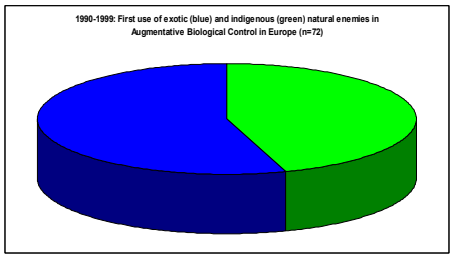
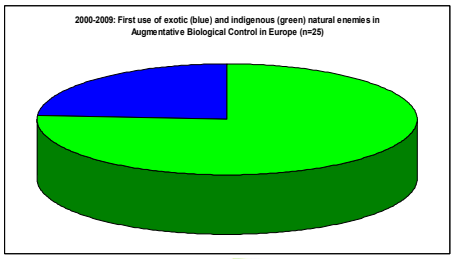
Additionally:

- Tendency to accept only native species (US) or even native populations (Fr)
- Not always possible:
  - Pests exotic: native species not always effective
  - Fragmentation makes biocontrol too expensive





Source: van Lenteren, 2011

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Consequences of overregulation for IBCA industry

- Reaction time increased
  - Increased time for research required
  - Hurdles of regulation
- Investment in time/ costs may be too high
- Promising candidates sometimes not developed to products
- Increasing problems to maintain IPM programs
- **Safety of food and environment is put into risk**

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Food for thought….

Best way to meet CBD goal = conservation of biodiversity:

or…

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Recommendations IBMA

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- Natural enemies require specific regulation, separate from (bio)pesticides
- Smooth and quick procedures

- Take risks proportionate, balanced to risks of pesticides
- Safe unless otherwise proven

- Build on experience of other countries
- Positive list species!
- Native species

Biocontrol:

The only risk is you forget it is safe

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Literature

http://archives.eppo.org/EPPOStandards/biocontrol.htm

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PM 6/2 (2)

Safe use of biological control
Sécurité de la lutte biologique

Import and release of non-indigenous biological control agents

Specific Scope

This standard gives guidelines for the import, release and required application procedures for non-indigenous biological control agents (BCAs).

Specific approval and amendment

Revision approved in 2010-09.

Introduction

Non-indigenous organisms, including biological control agents, may pose risks to agricultural and natural ecosystems if they establish in the environment. Their introduction into countries should be done with great care after assessment of the risks. The release ('Intentional liberation into the environment'; IPPC, 1995) of a non-indigenous biological control agent often follows a period in which relevant research has been carried out. The first import, for research, should have been carried out following the notification procedure of EPPO Standard PM 6/1 *First import of exotic biological control agents for research under contained conditions*, and the research will have provided information in support of the safety and efficacy of the organism when it is in due course released. This guideline is mainly concerned, therefore, with the release of biological control agents after a period of research, either in the importing country, or in another country, provided the EPPO environmental notification procedure has

The requirements for release of a biological control agent are more severe than for first import for research purposes. If the organism is to be released for classical biological control, it is intended that it should establish itself and control one or more pests, possibly permanently. If it is intended to be used for inundative release or for seasonal establishment, it will be released on an experimental scale first, then repeatedly at full scale[1] and the risks arising from this release should be estimated according to this Standard. The relevant precautions apply whatever the scale of the first release, as undesirable consequences may be irreversible.

ISPM No. 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*) provides that Governments should designate a National Authority responsible for implementation. For the purpose of import and release of non-indigenous biological control agents, this National Authority should institute an appropriate official procedure. Each country should decide what type of administra-

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ASSESSING RISKS OF RELEASING EXOTIC BIOLOGICAL CONTROL AGENTS OF ARTHROPOD PESTS

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Key Words environmental risk assessment, host range, establishment, dispersal, nontarget effects

■ **Abstract** More than 5000 introductions of about 2000 species of exotic arthropod agents for control of arthropod pests in 196 countries or islands during the past 120 years rarely have resulted in negative environmental effects. Yet, risks of environmental effects caused by releases of exotics are of growing concern. Twenty countries have implemented regulations for release of biological control agents. Soon, the International Standard for Phytosanitary Measures (ISPM3) will become the standard for all biological control introductions worldwide, but this standard does not provide methods by which to assess environmental risks. This review summarizes documented nontarget effects and discusses the development and application of comprehensive and quick-scan environmental risk assessment methods.