

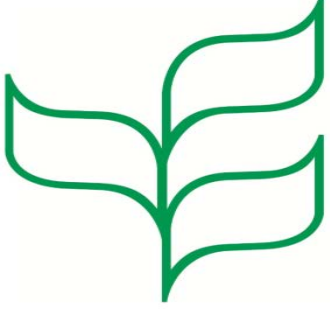


# Regulation of exotic IBCA's; status, hurdles and prospects

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EPPO/IOBC workshop Budapest,  
23 November 2015





## Convention on Biological Diversity

# International Convention of Biodiversity (CBD 1992)

Ratifications: (# 194) Almost all EU countries, S-AM, ~~(USA)~~

### **1 Conservation of Biological diversity**

*“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”*

### **2 Sustainable use of biological components**

### **3 ABS (Access and Benefit Sharing)**

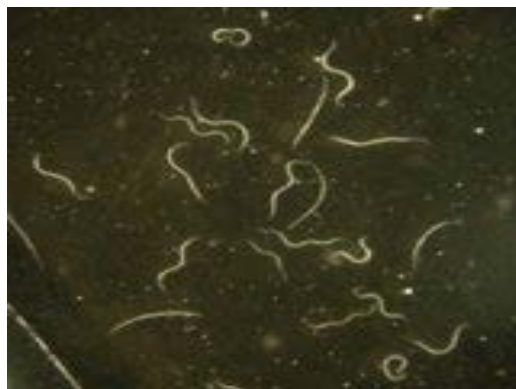


# SUD EC 128/2008

- Art. 14 *'Member States shall take all necessary measures to promote low pesticide-input pest management, **giving wherever possible priority to non-chemical methods** so that professional users of pesticides switch to practices and products with **the lowest risk to human health and the environment** among those available for the same pest problem*

# IBCA's

- Invertebrate Biological Control Agents include insects, entomopathogenic nematodes and predatory mites



# IBCA Regulation history:

- **1996** FAO ISPM 3 (IPPC)
- **1997** EPPO / CABI on Safety and Efficacy of Biological Control in EU: endorsement ISPM 3
- **1999** EPPO Guidelines for the first import of exotic BCAs for research under contained conditions
- **2000** EPPO Guidelines for import and release of exotic BCAs
- **2002** EPPO positive list with IBCAs widely used in the EPPO region
- **1998-2002** ERBIC; detailed criteria for RA and IBCA ranking (safety)
- **2003** OECD Guidance for information requirements for IBCAs
- **2003** IOBC/WPRS Commission for the Harmonisation of Regulation of IBCA's
- **2005** FAO: revised version of ISPM 3
- **2006** Bigler *et al.* 2006: book as framework for ERA of IBCAs
- **2006-2008**: REBECA (EU Policy Support Action)

## REBECA project (EU 2006-2008)

- Need for balanced and appropriate EU regulatory systems for import and release of BCA's
  - For biopesticides; aim was procedural improvements but not reached
  - IBCA's : EPPO guidelines
    - Human health risk: usually limited
    - Environmental risks of exotic species (CBD)

# How to perform ERA for IBCAs?

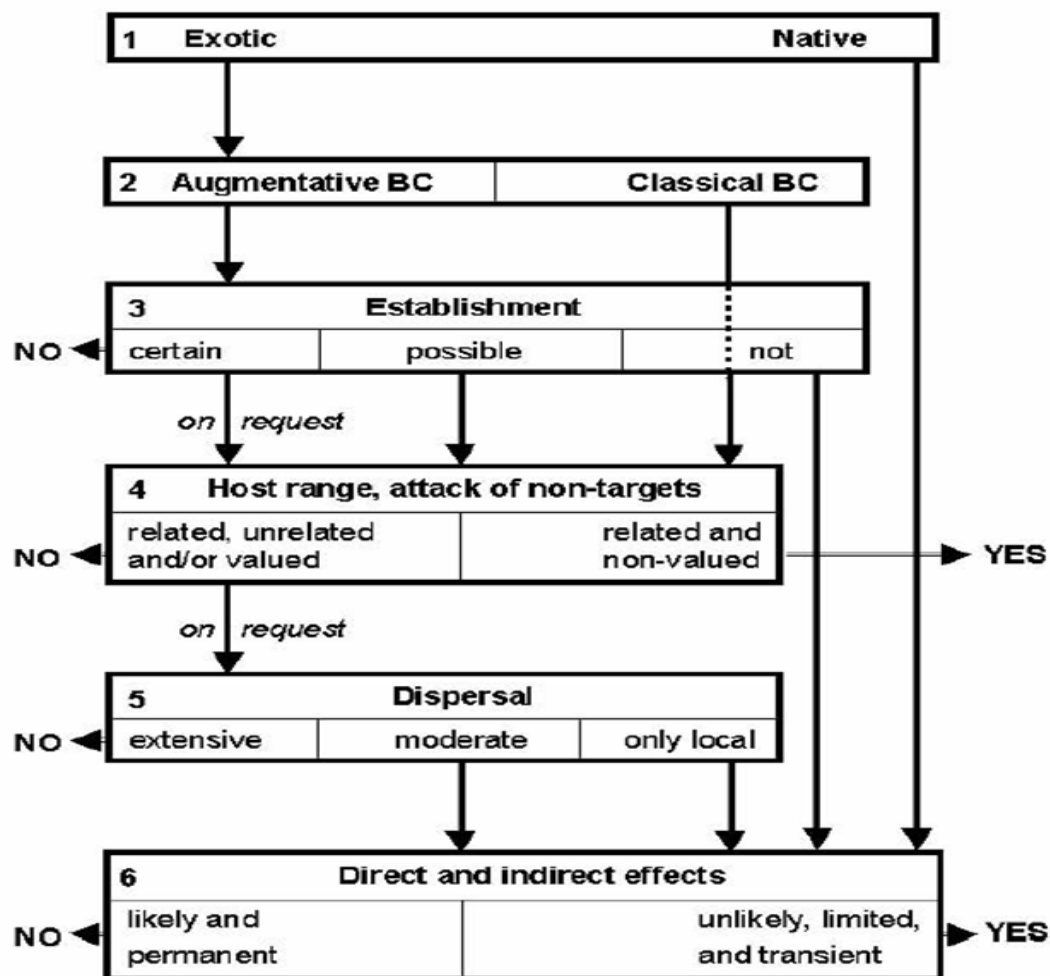
Identify risks of introducing exotic natural enemy

- **Establishment** and/or **dispersal** in non-target habitat
- Non-target **host range**
- (In) direct effects on **non-target organisms**

**Determine likelihood and magnitude of each of the risks**

**Quantify risk and apply cost-benefit analysis (also for other control methods!!!)**

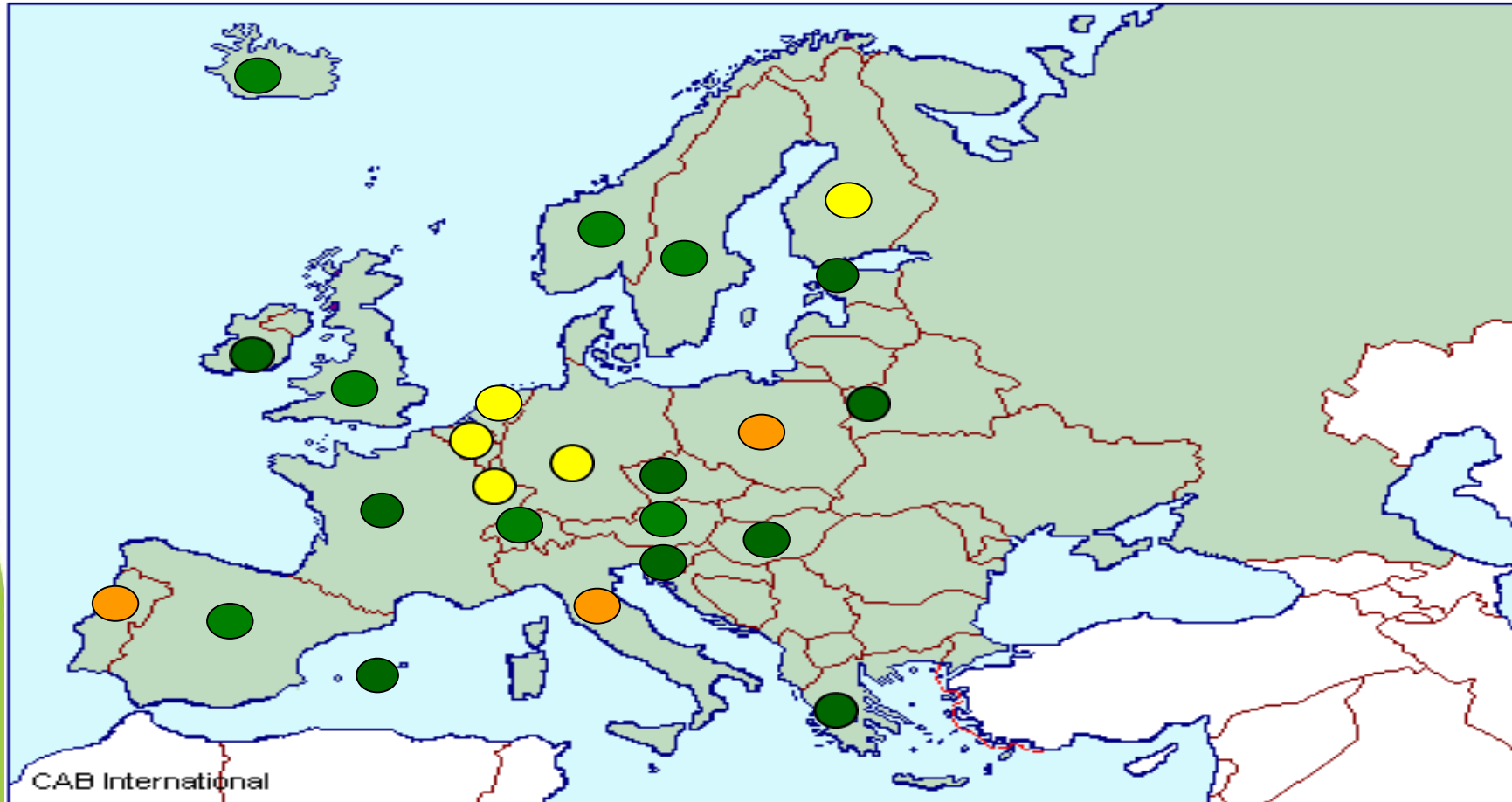
# Stepwise risk assessment : from 5 to 1 scheme



- Clearly good or bad species are discovered early in evaluation (saves resources)
- Only doubtful species go through whole evaluation
- Useful for quick scan or comprehensive evaluation



## Status of national regulation in European countries:



● Implemented (16)

● In preparation (2)

● No regulation

# International Regulation



- NAPPO region: NAPPO application: US, CAN and MEX
- Rest of the world : country specific ( often PRAs)



# Bottlenecks

- Lack of taxonomic reports
- All IBCA's are seen as potential IAS
- Variability in experience with authorities
- Procedure not transparent
- Responsibilities of dossier evaluation unclear
- Product specific regulation with biopesticide- like procedures
- Subspecies interpretation of native
- Lack of full implementation of EPPO guidelines
- Different formats of (EPPO) application form
- Unclearity about host range testing protocols

# 1 FR IBCA regulation: Interpretation of native below species level

- Positive (T0) list species x producer x origin
- Royal decree (° 31 January 2012 ) states : non native **organism**; not species
- Involved authorities: Min. Agriculture, Environment and ANSES as evaluation agency
- Interpretation of authority below species level

# 'National biodiversity'



# Considerations

- Added value for environmental safety?
- How to define 'national' species?
- Cut off criteria to distinguish based on molecular data?

# Position paper: Why 'national species' do not make sense in case of IBCA's

- 1. Widespread genetic exchange (highly mobile insects)
- 2. No added protection to the national flora and fauna
- 3. Seriously hamper the development of clean and safe alternatives for crop protection
- 4. Unfeasible to have production plant in each country
- 5. Unconstitutional in terms of European laws on free trade to favor national producers over other EU producers.

# IBMA position paper local IBCA populations is available



Group: Regulatory Affairs

Version 1

## Position paper local population of invertebrate biocontrol agents

The industries associated with IBMA produce a broad range of solutions for the biological control of crop pests and diseases. These products provide economically competitive alternatives to the use of chemical pesticides, and as such generate considerable ecological benefits. As an ecologically responsible industry it is obviously vital to us that our products are environmentally safe. For this reason, IBMA has early-on engaged with academic experts in the field of biocontrol to pro-actively develop stringent guidelines for ecological impact assessment of non-native species. These guidelines were published in as EPPO standards PM 6/1(1) First import of exotic biological control agents for research under contained conditions and PM 6/2(2) Import and release of non-indigenous biological control agent. Our industry has abided by these standards to warrant the ecological safety of our natural pest control solutions. We only produce and market natural species, using material for our rearing as it has been collected from nature. Our industry has an excellent record in providing environmental safe solutions for crop protection. By providing alternatives for chemical pesticides, important ecological benefits have been realized.





## 2: IBCA regulation ESP:

- Revised royal Decree '(O)MDF' (R.D. 951/2014)
- Efficacy data for new applications: TBD
- Studies on request for non-native species; although EPPO listed
- No adoption of the EPPO positive list as such

# 3 Procedural hurdles CH / AUS

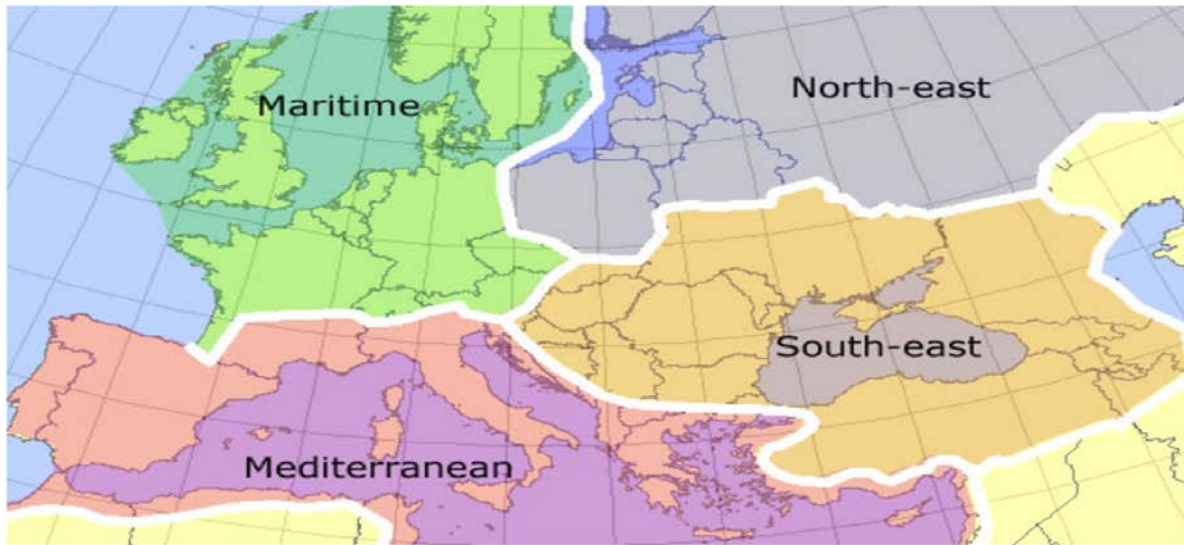
- Efficacy data per crop
- Invertebrate registration falls under national plant protection law and is treated in a biopesticide-like manner
- Procedures overshadow the fairly feasible content of a dossier

# 4 Finland, Latvia and the Netherlands

- Balanced registration application; based on EPPO list (PM 6/3)
- Clear procedures
- Open Communication with evaluators
- Application dealt with in timely matter

# Prospectives

- Harmonized IBCA regulation within an ecological zone context (relevant a/biotic parameters limiting species distribution)



Species distribution or environmental niche = abstract multidimensional space, in which a set of biotic and abiotic conditions allow a species to maintain a viable population (Hutchinson, 1957; Schnitzler *et al.*, 2012).

- Use EPPO list as a positive list with safe IBCA's
- Risk categories: ranking according to risk:
  - *Develop tools based on these categories: the safer the category, the lesser assessment required*
    - *For specialist parasitoids less data required as for generalist predators*



- Expected vs perceived risk

# Best way to meet CBD goals?

conservation of biodiversity

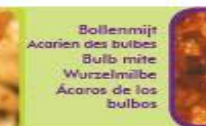
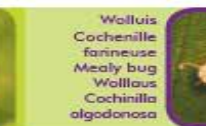
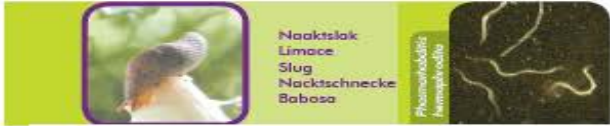
sustainable use of biological components



?



# Diverse portfolio for key pests



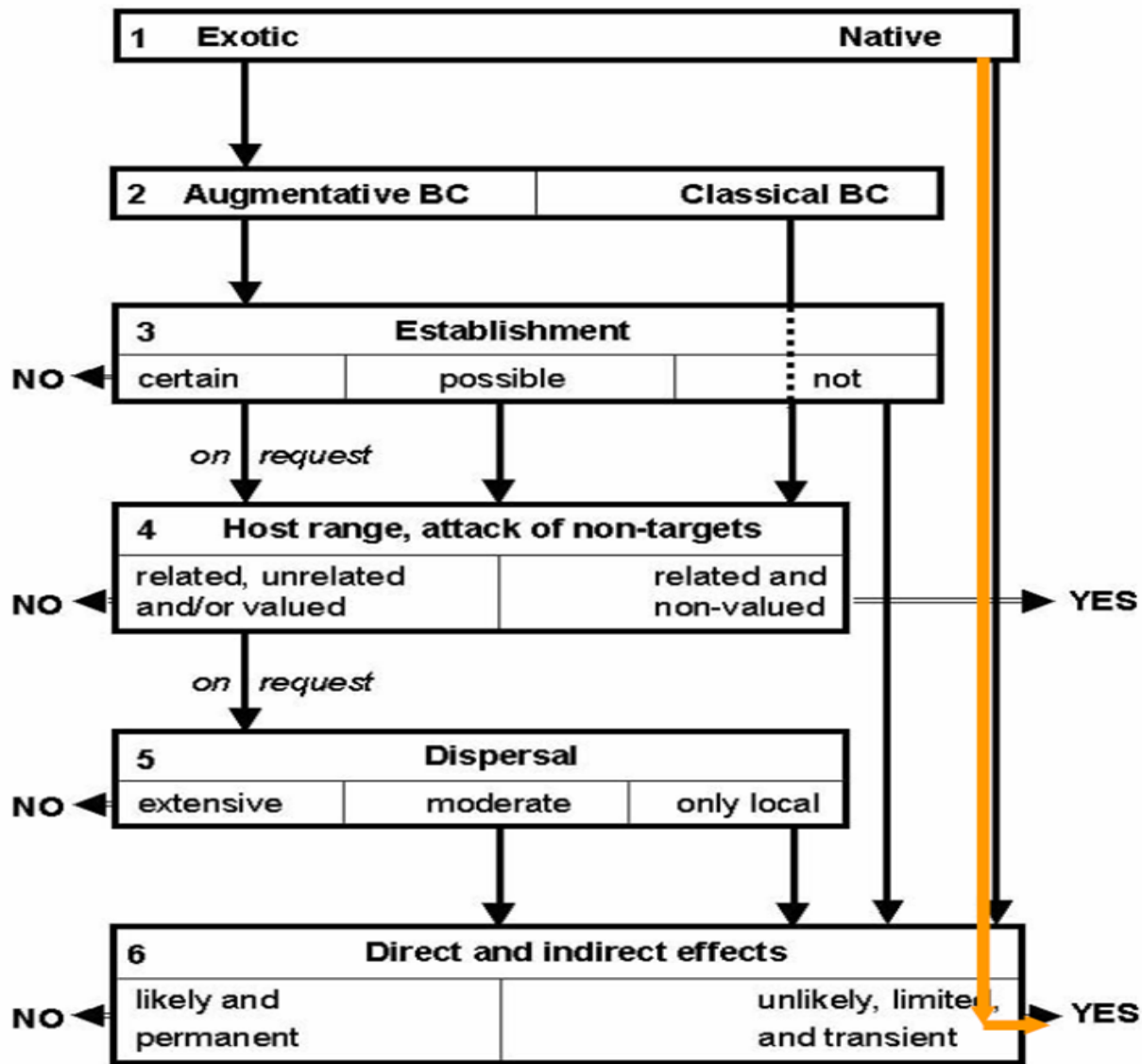


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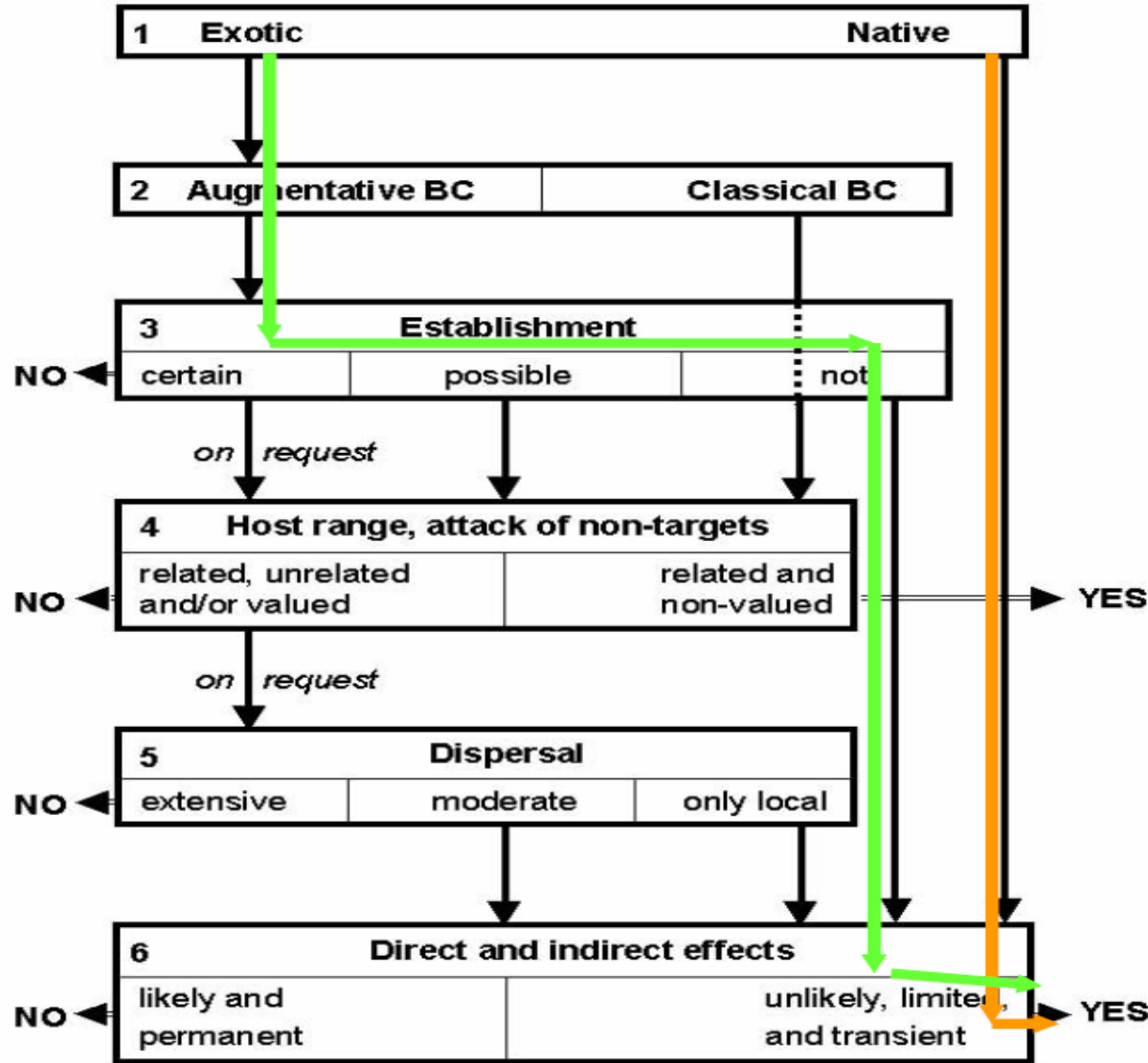
[Lieselot@biobest.be](mailto:Lieselot@biobest.be)







Native natural enemy:  
all natives (34 spp.): safe

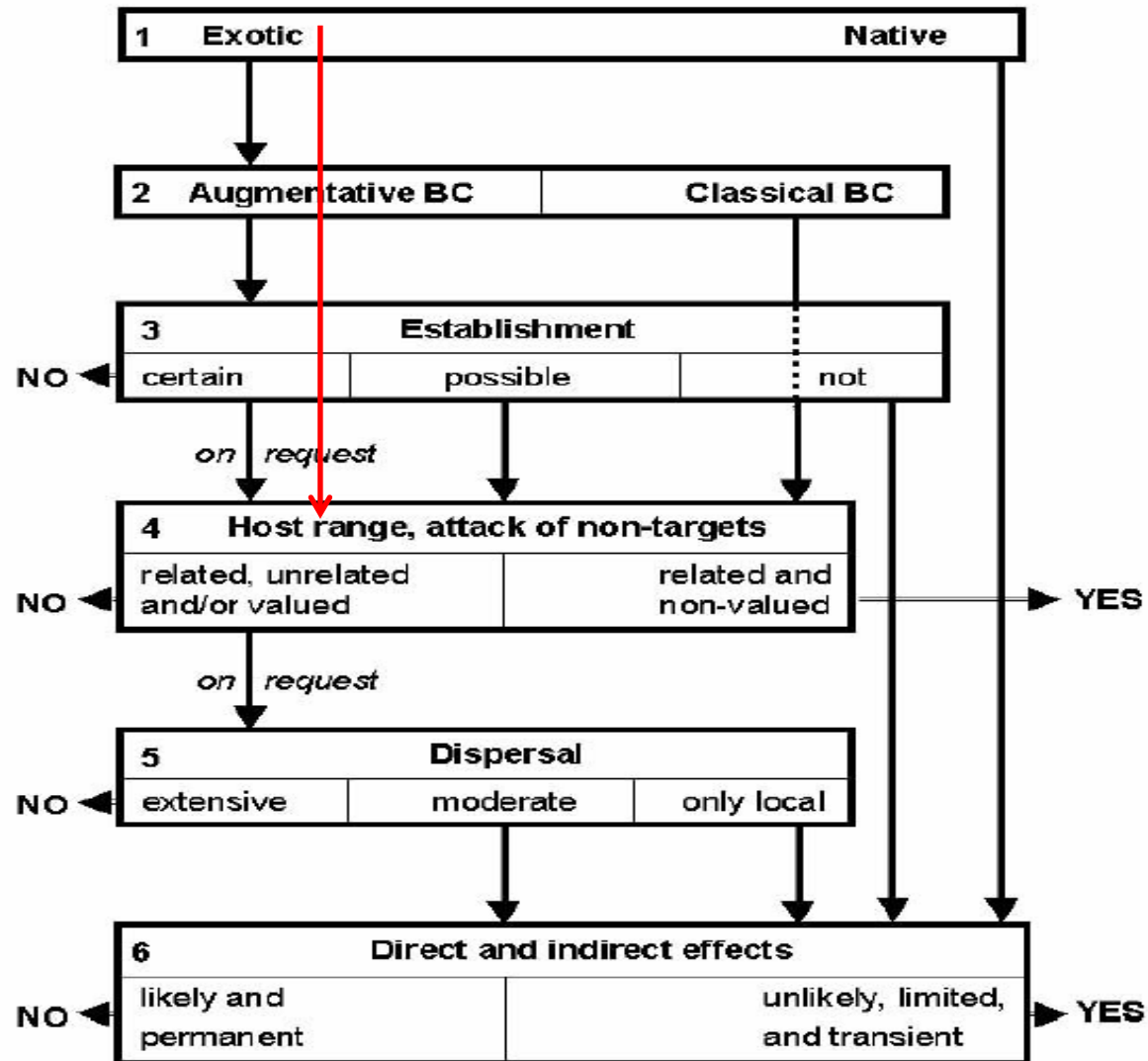


Native natural enemy  
all natives: safe

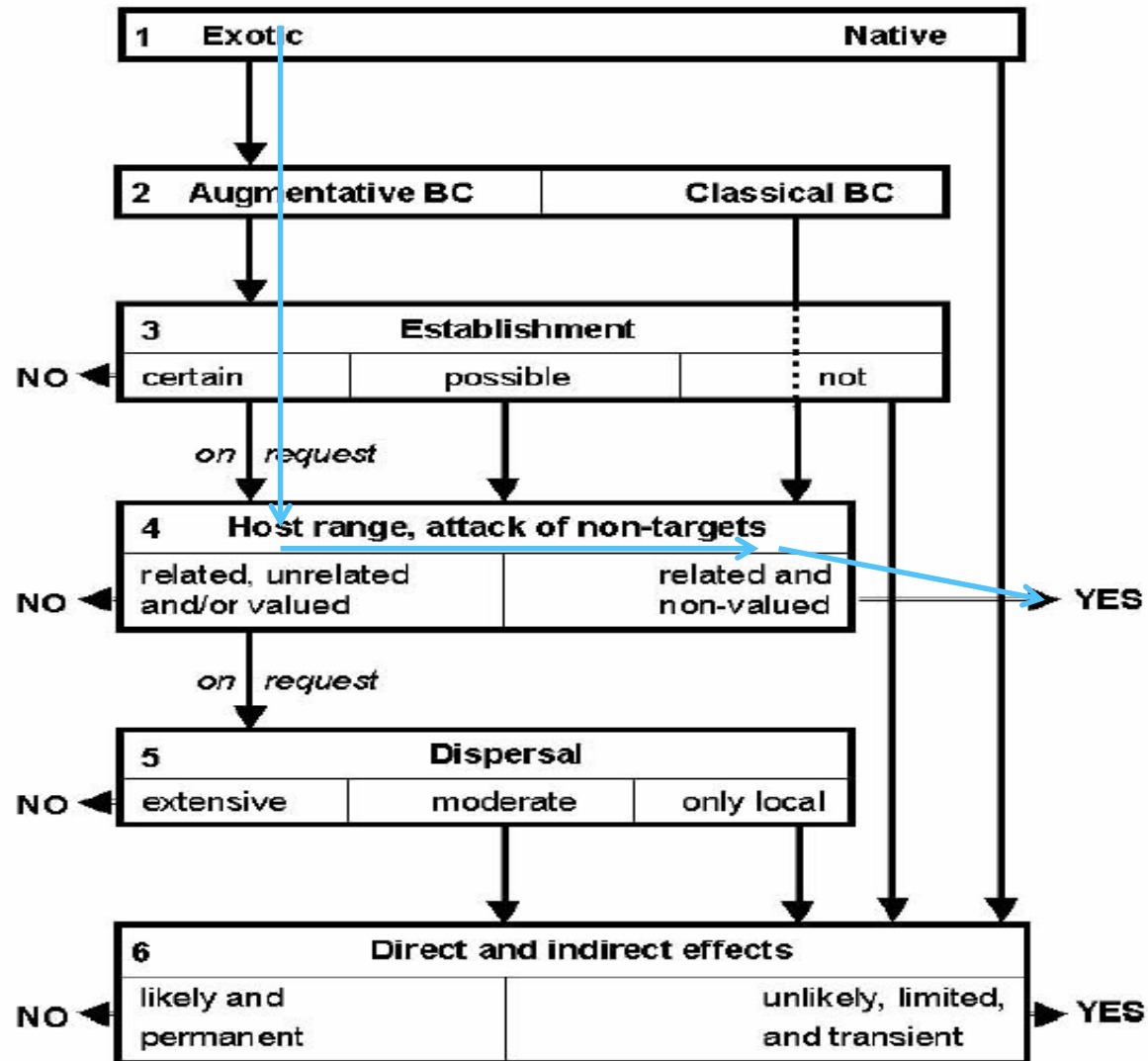
Exotic natural enemy for  
greenhouse use

If establishment impossible,  
usually safe

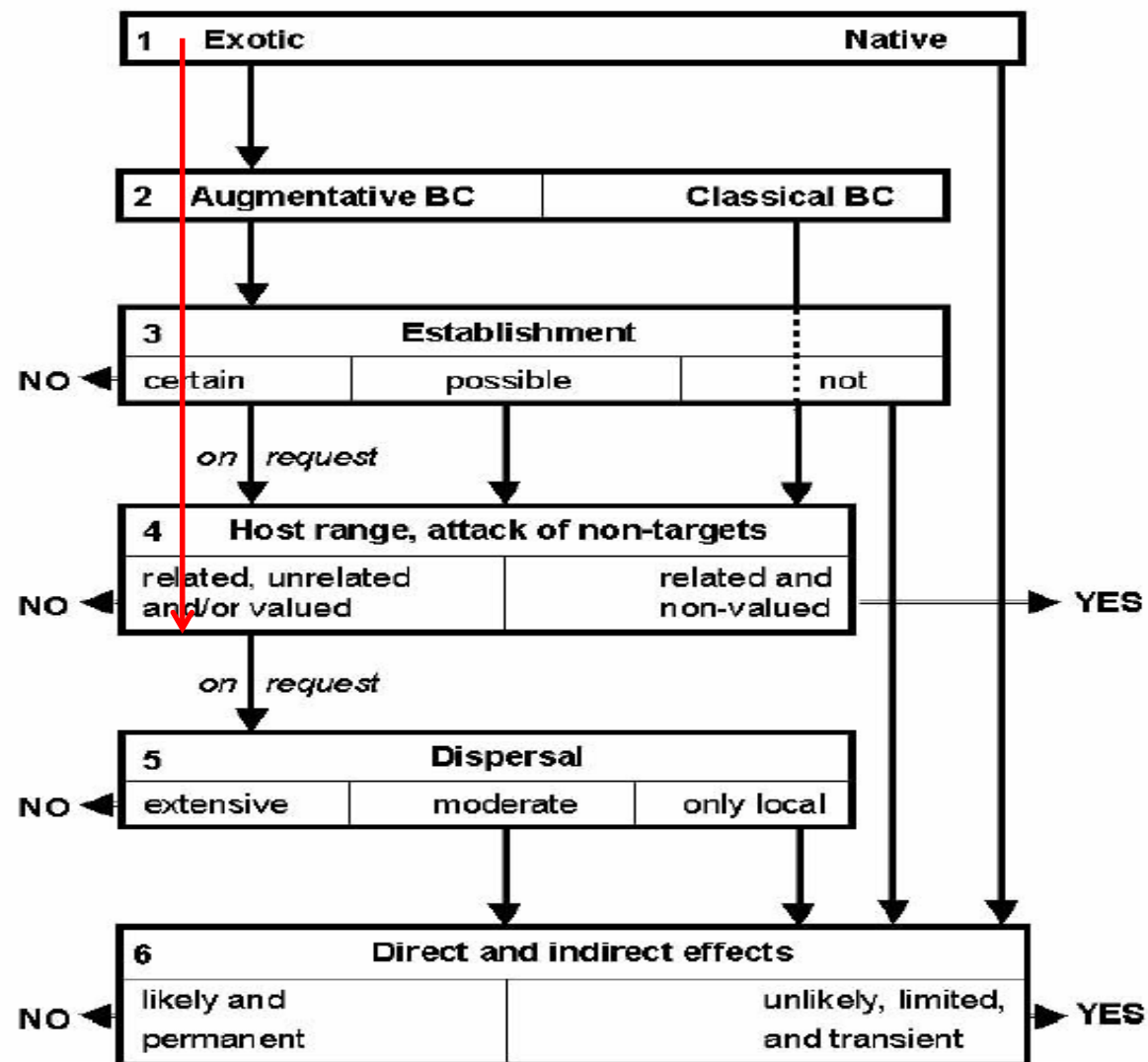
If establishment possible: more  
work!



- Exotic species for augmentative biological control that are likely to establish are detected very early in the evaluation process, and will be excluded from release without further studies



- Exotic species that attack only related spp. and do not attack valued non-targets are also detected early in the evaluation without the need to study dispersal and direct/indirect non-target effects; they can be released



Exotic species that attack related and unrelated non-targets and/or valued non-targets will be excluded from release without the study of dispersal and (in)direct non-target effects



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