



# Commission on Harmonised Regulation of Invertebrate Biocontrol Agents (CHIBCA)

**Convenor: Jeff Bale**

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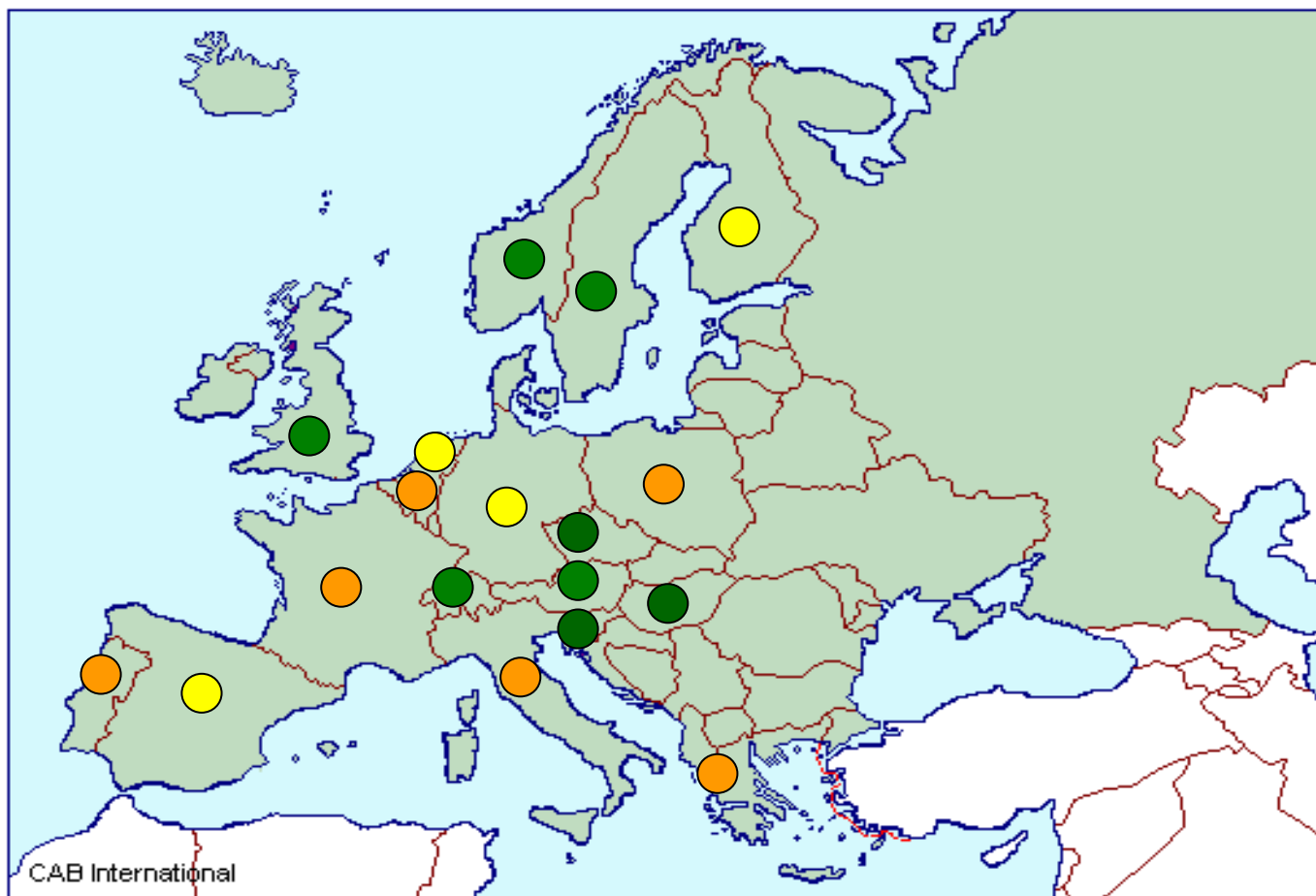
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# Invertebrates, Microbes, Botanicals and Semiochemicals



- Fundamental difference in regulation between groups of agents
- Microbes, Botanicals and Semiochemicals regulated by EU directive 91/414 – consistent across Europe, but can have expensive regulatory costs in some countries
- **Invertebrate BCAs – no EU directive, and variable regulatory policy in different countries**
- Relative success of invertebrate BCAs attributable to absence of coordinated ‘EU directive-based’ regulation – but ‘country-specific’ legislation causes problems

# Regulation of IBCAs across Europe in 2004



● Implemented (9)

● In preparation (4)

● No regulation (6)

# Looking back – but only 10 years ago



(CHIBCA founded in 2003)

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- **Fragmented regulation** across Europe
- EC (DG SANCO) confirmed **no prospect of EU Directive for IBCAs**
- **No consistency** in information requirements between countries
- **New dossier** required for each country
- **No agreed format** for environmental risk assessment (ERA)
- No published or accepted **methods** for ERA
- **No forum** for regulators to meet

# 1<sup>st</sup> Phase: Harmonising previous guidelines in one document and REBECA project



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## Review Article

### Guidelines on information requirements for import and release of invertebrate biological control agents in European countries<sup>1</sup>

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#### Abstract

Several international documents have been published in recent years with the objective of providing guidance to industry, biocontrol practitioners and competent national regulatory authorities on the regulatory framework for the import and release of invertebrate biological control agents (IBCsAs). As the scope and the level of detail given in these documents were diverse in many respects, it has been difficult for all stakeholders to apply such guidelines, and to integrate them in a harmonized way into national regulatory documents. At the request of several stakeholders, the International Organization for Biological Control of Nonxious Animals and Plants/West Palearctic Regional Section (IOBC/WPRS) organized an initiative with the objective of merging all relevant international documents into one document, to provide more specific guidance, and to harmonize the regulation of IBCAs in European countries and in other countries of the IOBC/WPRS. This document consists of five sections which together form comprehensive guidelines specifying the information required for regulating import and release of IBCAs.



2006-07

## Recommends

- an EPPO-IOBC Expert Group
- updating EPPO Positive List
- to make «permit application form» an EPPO Standard

2003-04 CHIBCA merged previous documents of FAO, EPPO and OECD

2005 Guidelines produced by representatives of industry, regulatory bodies and science coordinated by CHIBCA

# 2nd Phase: Joint EPPO-IOBC Panel on Harmonized Regulation of IBCAs



**EPPO-IOBC Joint Panel established 2007:** meetings held in Wageningen (2008), Engelberg (2009), Valencia (2010), Rotterdam (2011), Minsk (2012), next St. Malo Nov.2013

- **EPPO 'Positive List' reviewed and updated annually** – some species deleted from original list, new species added
- **Criteria** for additions and deletions reviewed and updated
- Rotterdam 2011: in conjunction with EPPO-IOBC Panel meeting, 1<sup>st</sup> Workshop for National Regulators
  - a) National regulations for IBCAs presented and application forms discussed
  - b) Risk assessment methods discussed
  - c) Data base of national regulators discussed

# 2nd Phase: Joint EPPO-IOBC Panel on Harmonized Regulation of IBCAs



- Minsk 2012: Discussion of the **use of Molecular tools** for species/strain identification of IBCAs as requested by some national regulators. Result is a scientific opinion in the form of a position paper of the Panel
- Minsk 2012: **“First Release Expert Group”** discussed and proposal made to be adopted?/rejected? in meeting 2013 in St. Malo

# Problems are still not yet resolved- work ahead



- **Little communication** between EU national regulators
- **Methods** for Risk Assessment not yet agreed
- **Adoption and use of EPPO Standard 6/2 (2)** as licence application documents with consistent information requirements across all countries
- **Concern of industry** - staff in 'regulatory offices' lack expertise to evaluate Risk Assessment data on new species
- **Advice on 'first release'** of new IBCAs – by creation of an 'Expert Group'