

International activities for the regulation of Invertebrate Biological Control Agents: why two meetings in Switzerland in summer 2004 ?

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International documents and activities on regulation of invertebrate biological control agents (IBCA)

- 1996 FAO Code of Conduct
- 1996 EPPO/CABI Workshop on safety and efficacy of biological control in Europe, UK
- 1999 EPPO Guideline for First Import of exotic biological control agents for research under contained conditions
- 2000 NAPPO Petition Guidelines for Release of Exotic Entomophagous Agents for the Biological Control of Pests
- 2001 EPPO Guideline for Import and Release of exotic biological control agents

International documents and activities on regulation of invertebrate biological control agents (IBCA) (continued)

- 2003 OECD Guidance for information requirements for regulation of invertebrates as biological control agents
- 2003 IOBC/WPRS Commission on Harmonisation of Regulation of IBCA (CHIBCA)
- Others (e.g. Canadian Review Process for Import and Release of New Entomophagous and Phytophagous Biological Control Organisms 2000)

Scope and objectives of the documents

1. Regulatory guidelines in which responsibilities of governments and national authorities are listed for import, export and release of IBCAs (FAO Code)
2. Guidelines on how to prepare dossiers for import and release of IBCAs (EPPO, NAPPO)
3. Guidance on information requirements for regulation of IBCAs (OECD)

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All documents are guidelines without advise on how to produce the data needed for regulatory dossiers and how to use them for environmental risk assessment

→ **methods to produce relevant data for ERA are needed**

Engelberg meeting in June 2004

Objectives

1. To present and discuss the contents of book chapters on **methods and environmental risk assessment (ERA)** of invertebrates used for biological control of arthropods
2. Exchange ideas and experience on methods for ERA of IBCAs
3. Discuss and review critical issues related to ERA of IBCAs

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Results

- Book on methods and ERA will be published by CABI in 2005
- Report will be published in Biocontrol News & Information (December 04)

Regulatory requirements are different for IBCAs between countries worldwide (incl. Europe)

- **Regulators will ask for different data and dossiers, i.e. companies will have to prepare several dossiers for the same IBCA**
 - **Data will be evaluated in different ways and conclusions from ERAs will deviate between counties**
 - **Investments in preparing regulatory dossiers will increase**
- **Harmonisation of IBCA regulation is needed (same dossiers submitted and evaluated in all countries)**

Table 4. Registration and evaluation criteria for micro- and macroorganisms used in crop protection in different countries (Bigler F. 1997)

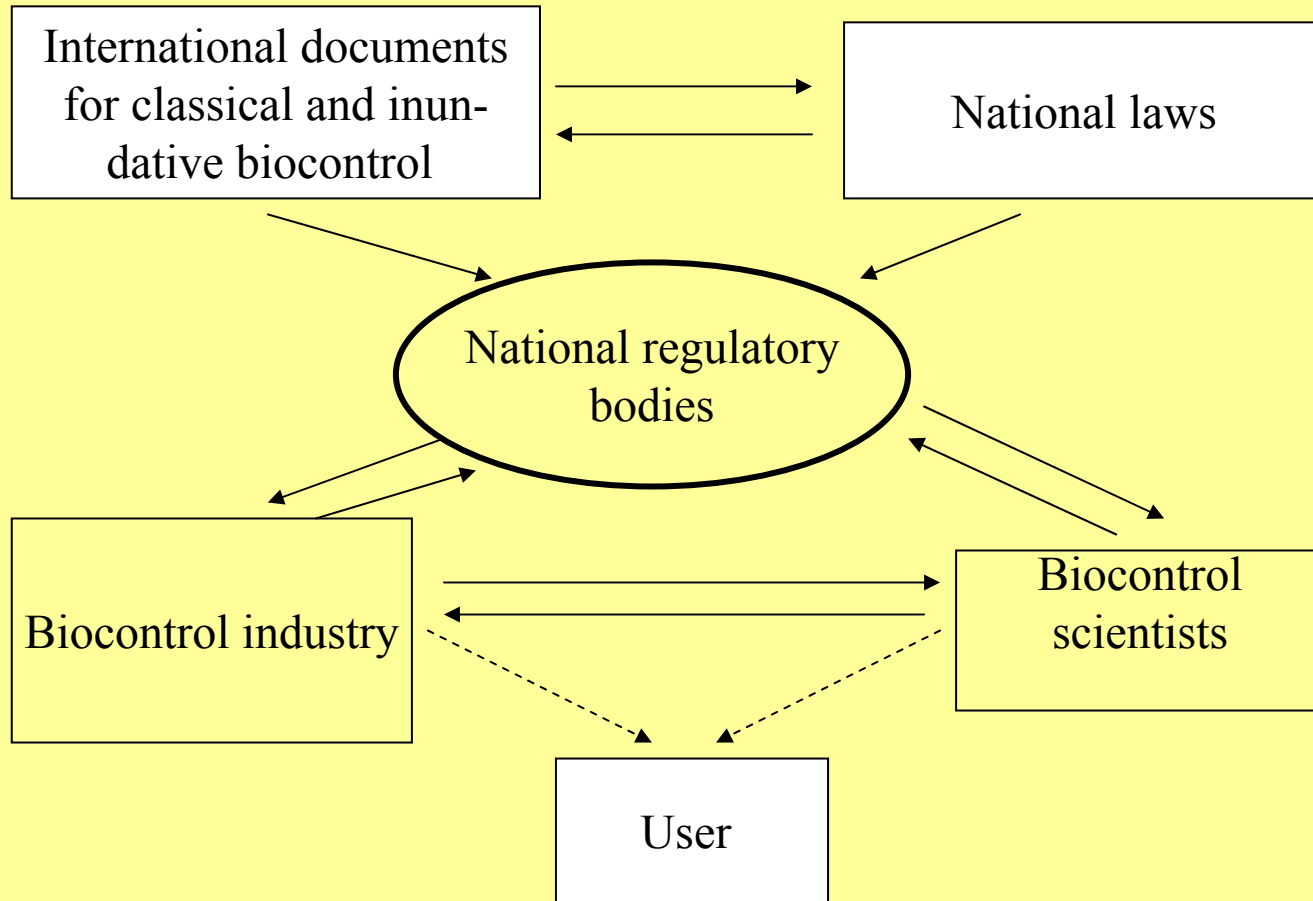
Countries	Microorganisms*		Macroorganisms		Remarks
	Efficacy	Ecotoxicology	Efficacy	Ecology**	
<i>European Union (EU)</i>	+	+	-	-	
Austria***	+	+	+	+	
France***	+	+	+	-	
Sweden***	+	+	+	+	since 1995
<i>Non-EU European countries</i>	+	+			
Hungary	+	+	+	+	since 1988
Norway	+	+	-	-	
Switzerland	+	+	+	+	since 1987
Australia	+	+	+	+	since 1994
Canada	+	+	+	+	since 1996
Israel	+	+	-	-	
Japan	+	+	+	+	
USA	-	+	-	-	

* Including products deriving from microorganisms (e.g. *Bacillus thuringiensis*).

** Mainly biodiversity issues considered.

*** Additional regulation for macroorganisms in contrast to other EU countries.

The context of harmonising regulation of IBCAs



Commercial use of invertebrates for inundative biological control

		Source
Species available on markets world wide	150 – 170	Bigler, 1997
Species available on the market in western Europe	72	van Lenteren, 1997
exotic to western Europe	39	
native to western Europe	33	
Species regularly used in greenhouses in Europe	33	Bolckmans, 1999
Species available on the market in Germany in 1998	64	Bathon, 1999
Species available on the market in Switzerland in 2003	37	Swiss Plant Prot. Index 2003

Micro- and macro-organisms registered in Switzerland 1995 and 2003

Group of organisms	Registered			
	Number of species		Number of products	
	1995	2003	1995	2003
Bacteria	1	2	11	18
Fungi	2	3	3	4
Viruses	2	2	6	7
Nematodes	3	5	6	8
Mites	3	3	4	9
Insects	12	22	28	41
Total	23	37	58	87

Zürich meeting in July 2004

Objectives

1. To compile information on current regulation of IBCAs in European countries
2. To discuss the concept of eco-regions in Europe for the use in regulation of IBCAs
3. To prepare detailed guidance documents on the regulation requirements for first import, new introductions, widely used and indigenous IBCAs
4. To update and improve the positive list of EPPO for safe IBCAs
5. To discuss and propose a consultation procedure for exchange of information and data between European countries

Zürich meeting in July 2004

Results

- 1. Compilation of regulatory requirements of IBCAs in Europe.**
- 2. Reports on procedures and data requirements for first import, release and safe use of IBCAs**
- 3. Decision to follow-up harmonisation activities for IBCAs in Europe (EU Coordinated Action)**

Conclusions

- 1. Regulatory requirements for IBCAs have increased worldwide over the last decade**
- 2. A „light form“ of regulation is needed that respects the interests of biocontrol companies, users and environmental concerns of the public**
- 3. Standardized methods to generate data for the dossiers will reduce investment and increase the quality of ERA**
- 4. Harmonization of regulatory requirements and consultation between national authorities will improve regulation and facilitate preparation of dossiers**