



# REBECA



**EU Policy Support Action  
Regulation of Biological Control Agents**

**[www.rebeca-net.de](http://www.rebeca-net.de)**

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# REBECA



One major achievement of REBECA was the initiation of a dialogue between all stakeholders on the regulation of Biological Control Agents



## The good news



It is now easier to register BCAs  
in Europe:

Knowledge on the safety was  
disseminated

Regulation will be more  
confident to accept waivers



# General Proposal



## How to accelerate regulation and reduce fees ?

No fees, support for SMEs, pre-submission meetings, definition on information for pre-submission meetings, QPS, more guidance documents, strict timelines, establish expert groups, centralize registration with more adapted legislative framework, reduce data requirements for efficacy



# General Proposal



## Comment on the new regulation

REBECA ...

supports mutual recognition in climatic zones

welcomes specific measures for low risk and basic substances

welcomes clear deadlines

welcomes reference to precautionary principle

Welcome increase in transparency

Specific measure for BCAs missing



# Microbials



**Baculoviruses will be listed on Annex I on the species level (no scientific reason why the whole group is not put on the Annex)**

**Precise identification very important**

**Pre-submission data set should be used to define waivers**

**Use available information on infectivity (Dir. 2000/54) to reduce data requirement on pathogenicity**

**Reduce data requirements on ecotox**

**Need for information on significance of bacterial metabolites, study on behaviour in the environment and effect on non-targets**



# Macrobials



**General decision on ERA methods and procedures**

**Application form and guidance document for completion**

**Proposal to update EPPO list**

**No recommendation how regulation of IBCAs should be regulated on a European-wide level.**



# Semiochemicals



**Collective listing of SCLP on  
Annex I**

**Low risk status for SCL  
pheromones**





# Botanicals



**SANCO 10472 should be used for all extraction methods and cover all plant parts**

**Low risk substances should be identified (all on SANCO 10472, 25b EPA list and substances with GRAS status)**



# Stakeholder interests



**Objective REBECA: Increase availability of safe biocontrol products in EU agriculture and forestry**

<b>Consumer</b>	<b>Farmer</b>	<b>Industry</b>	<b>Science</b>
<b>Safe food Protected environment</b>	<b>Profit Good PPP Sustainability</b>	<b>Profit IP Protection</b>	<b>Knowledge R&amp;D Funds</b>



# Future Activities



**Major problem is limited knowledge in all stakeholder communities**

**We need more information on risks and safety and make information available to all stakeholders**

**Communication will produce a more favourable environment for registration**

**Continue REBECA**

**COST Action? R&D projects**



**REBECA**

*Regulation of  
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**Thanks to the EU for the  
financial support**

**Thanks to many of you for your  
contributions**

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## History of Regulation



- Pesticide regulation has gradually become more stringent
- Development in close interaction with multinational agrochemical companies
- Regulation based on scientific reports of damages
- Pesticide regulation and its failures were among main stimuli for the emergence of the Precautionary Principle



# History of Biocontrol Regulation



- Regulation was **not** a gradual evolution involving industry
- Regulation was **not** based on scientific reports of damages
- BCAs have **no** evolution of regulation rules
- Rules based on regulation of chemical pesticides
- More adapted and more balanced approaches were rolled back with the introduction of 91/414
- With REBECA the situation is changing



## General Problems with Registration



- **Major obstacle: two level registrations - active substance at EU and PPP in all member states (additional 2 years)**
- **Countries vary in interpretation of guidelines**
- **Mutual recognition not well implemented**
- **Guidelines + requirements not set up for BCAs**
- **Efficacy trials are more difficult and costly for BCAs**
- **Regulation may be used to protect products**
- **When little knowledge and experience is available regulation adopts the precautionary principle**



## Precautionary Principle COM2000/1



- PP often used to introduce regulation on perceived risks
- Before PP is invoked, scientific data relevant to the risks must first be evaluated
- The general principles include:
  - proportionality
  - examination of the benefits and costs of action or lack of action
  - examination of scientific developments

If we follow this advice we must continue to improve our understanding of BCA risks and feed in new knowledge to change the system continuously



# Objectives



- Accelerate market introduction of safe BCAs
- Reduce costs for regulation
- Maintain or increase the level of safety
- Balanced regulation according to potential hazards
- Define “low risk products”, which might be exempted from registration
- Bring together stakeholders from industry, science, regulation authorities, policy and environment
- Disseminate relevant information on safety and regulation
- Propose research activities

# How did we work?



- 1. Identification of risks
- 2. Categorization of risks
- 3. Methods to assess risks
- 4. Proposals for improved regulation procedure
- 5. Review of costs of regulation
- 6. Cost-benefit analysis of regulation
- 7. Proposals on improvements of procedures
- 8. Dialogue between all stakeholders
- 9. Definition of knowledge gaps



# **REBECA**

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**BCAs can solve several problems in EU agriculture**

**Registration one reason for few products in the market**

**We need less rather than more regulation**

**Lack of knowledge and experience retards authorization**

**Accept experience and long term safe use in regulation**

**Rebeca could only been a starting point**

**Further activities in networking and R&D have to follow to make biological control a success story in EU for the benefit of consumers, farmers, SMEs and the environment**