



**REBECA**



# **Regulation of Biological Control Agents Objectives and Tasks**

**Workshop „Swiss Core“ Brussels:  
Safety of botanicals + semiochemicals  
June 13+14, 2006**

**Ralf-Udo Ehlers  
ehlers@biotec.uni-kiel.de**



## Call Text



### **EU-FP6-Specific Support Action 4**

**„Despite considerable research efforts on BCAs the number of such products on the market in Europe is currently still extremely low compared to USA + CAN. BCA cannot be treated like synthetic chemicals and need different approaches for registration purposes“**



# Registration keeps products off the market



- **Follows rules originally developed for synthetic pesticides**
- **Expensive considering the size of the market for BCA products (costs for registration > 2 million €)**
- **Time consuming: Cedomon (*Pseudomonas chlororaphis*) took 8 years to get on Annex 1 (EU Directive 91/414), national registrations have to follow**
- **No investor will provide funds for product development**
- **Currently no registration of new MBCAs by EU SMEs**
- **Almost all EU companies stopped R&D in MBCAs**



# IBCA Market

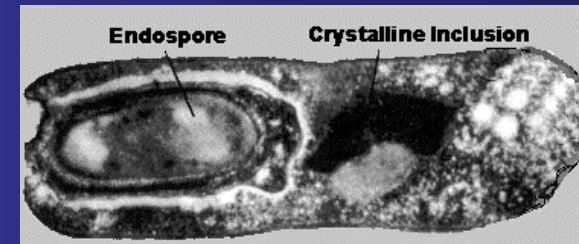


Increasing demand due to insecticide resistance and problems with residues

*B. thuringiensis* from 95% to 25%

Now 55% IBCAs with 200 million € turnover

Success is a result of no (low) regulation





## Regulation of BCA in EU



- **Regulation of BCA causes more harm to growers and consumers than benefit**
- **BCA are safer than alternative control measures**
- **Regulation keeps safe products off the market**
- **Old technology still in use**
- **Consequences:**
  - **illegal use of pesticides**
  - **problems with residues**
  - **no exploitation of safe control measures**



# How is regulation implemented ?



**When 91/414 was implemented there was no interest to discuss adapted regulation for biological control agents**

**Today someone says: “This might be dangerous”. EU then implements regulation ?**

**Example: In 2004 EPN (nematodes) included into the definition of MBCA in revision of 91/414**

**Implementation of regulation must be justified and based on scientific evidence**

**We need more transparency in SANCO !!!!!**



# Implementation of Regulation



- **Base regulation on risks analysis**
- **Before implementation perform trade-off analysis**
- **Authorities should not regulate trivial risks**
- **We need less bureaucracy, not more**
- **Introduce cost-benefit analysis of regulation**
- **Rapid intuitive judgements often operates as a substitute for more careful inquiry (SANCO decision to cover EPN under 91/414)**



# Botanials and Pheromones



- Do we need an expensive regulation process for product which have been used in other applications over long term without causing damage?
- Can we waive requirements for compounds found in our environment since the occurrence of mankind?
- Can we introduce the principle of long term experience of safe use or Qualified Presumption of Safety (QPS) into regulation management?
- Can we produce positive lists?



# **REBECA – Objectives**



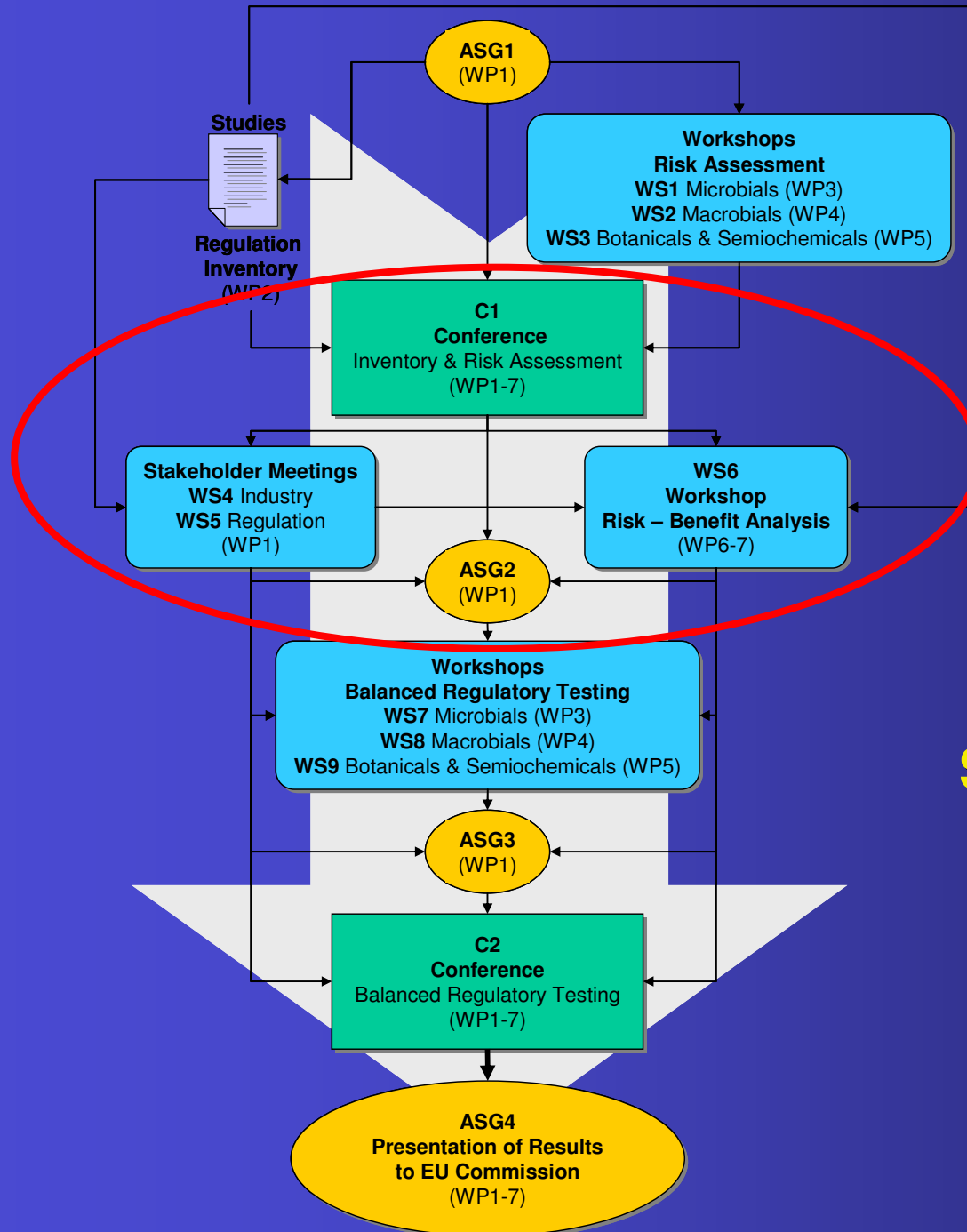
- **Accelerate market introduction of safe BCAs**
- **Reduce costs for regulation**
- **Maintain or increase the level of safety**
- **Balanced regulation according to potential hazards**
- **Perform a CBA and RTA of regulation**
- **Define “low risk products”, which might be exempted from registration**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



# REBECA Work Packages



- **WP 1: Management and co-ordination (Ralf-Udo Ehlers, CAU Kiel, D)**
- **WP 2: Current legislation practice (GAB + CABI + FIBL)**
- **WP 3: RA Microbial Biocontrol Agents (Hermann Strasser, LFU, Innsbruck, A)**
- **WP 4: RA Botanicals + Semiochemicals (Lucius Tamm, FIBL, CH)**
- **WP 5 RA: Macrobials (Jeff Bale, UOB, UK)**
- **WP 6: RTA and CBA of regulation (Heikki Hokkanen, UHEL, FIN)**
- **WP 7: Measures to accelerate regulation (Anita Fjelsted, DEPA, Copenhagen, DK)**



**Conference**

**Schloss Salzau**

**September 19-21, 2006**





# Workshop Objectives



- **Assess risks: magnitude, probability**
- **Get overview on risks to produce sensible priorities**
- **Assess tradeoffs and benefits of regulation: qualitative and quantitative analysis involving all affected stakeholders**
- **Propose sensible regulatory tools, minimize rather than maximize costs, maximize rather than minimize effectiveness**
- **Propose alternative regulation procedures and strategies**