



**REBECA**



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

**Workshop „Grauer Bär“ Innsbruck:  
Safety of MBCAs  
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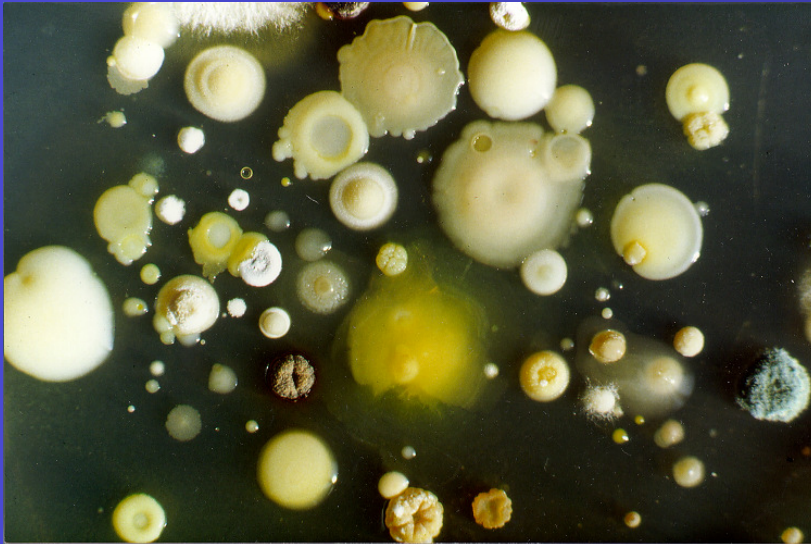
# Call Text



## **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“**

# Future Potentials MBCAs



Microorganisms from the rhizosphere of oil seed rape

We can only culture and study 5% of microorganisms in soil

Enormous potential for exploitation

MBCAs have an underestimated potential:

- They provide antagonists
- Their metabolites are used to develop new compounds (Spinosad)
- Their genes are used to make plants resistant (Bt)

Reasonable regulation will make possible the exploitation of MBCAs for agriculture use

# What is the current situation for MBCAs ?



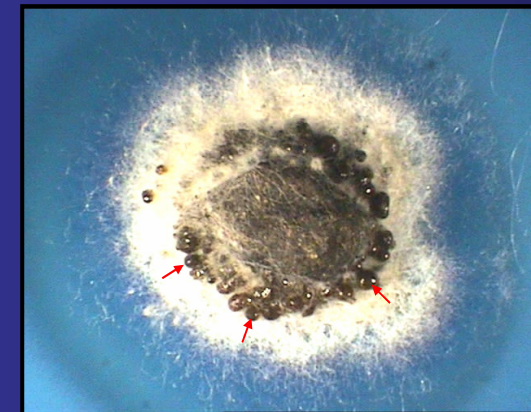
## Prophyta, DE (Contans, Bioact)



Das Pflanzenschutzmittel Contans<sup>®</sup>WG ist ein wasserlösliches Granulat zur Bekämpfung des Krankheitserregers *Sclerotinia sclerotiorum*. Das Präparat besteht aus den Sporen des natürlichen Bodenpilzes *Coniothyrium minitans*. Ein Gramm des Mittels enthält  $1 \times 10^8$  vitale Sporen.

*C. minitans* parasitiert die Dauerkörper des Krankheitserregers im Boden und tötet sie ab.

In Deutschland ist Contans<sup>®</sup>WG in allen *Sclerotinia*-anfälligen Kulturen als Pflanzenschutzmittel (zugelassen / genehmigt).



*Coniothyrium minitans* destroys sclerotia of pathogenic fungus

Company situated in new state: Special technology funds supported registration of Contans

Award by „German Foundation Environment“ makes possible the registration of Bioact

# Microbial Products listed on Annex 1



Bioagri, SE (**Cedomon**)

Verdera, FIN (**Prestop**)

Biobest, B (**PreFeral**)

Intrachem, I (**AQ10**)



**AQ10**<sup>TM</sup>  
Biofungicide



**All companies stopped product development**



# Cedomon Registration



**1996** Application EU registration for the bacterium *Pseudomonas chlororaphis*

**1999** Metabolite DDR identified

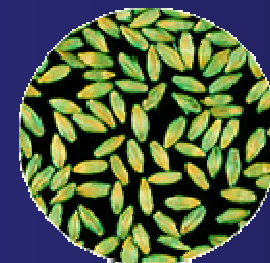
**2000** New data DDR generated and submitted

**2002** EU WG Evaluation

**2003** EU WG Legislation

**2/04** Back to WG Evaluation

**3/04** Accepted



# Cedomon Annex 1



- Bioagri owned by Swedish Farmers Cooperation Landmännen
- Registration Cedomon: > 2.5. million €
- Turnover 2004: 0.75 million €
- Turnover Imidacloprid 2004: 500 million €
- Registration 300 million €
- Compared to synthetic products costs for Cedomon were low
- But related to the turnover of biologicals they are too high



# Time frame (in months) for MBCA Registration Annex 1



Organism	EU	SANCO	EPA
<i>Paecilomyces fumosoroseus</i> (PreFeral)	05.94-06.01	85	60
<i>Coniothyrium minitans</i> (Contans)	09.97-12.03	63	23
<i>Pseudomonas chloroaphis</i> (Cedomon)	01.96-04.04	99	-
<i>Ampelomyces quisqualis</i> (AQ10)	02.96-10.04	104	?
<i>Spodoptera NPV</i> (Spodex)	07.97 -	> 101	12
<i>Gliocladium catenulatum</i> (Prestop)	03.99-10.04	67	13
<i>Bacillus subtilis</i> (Serenade)	05.00 -	> 67	14
<i>Pseudomyza flocculosa</i>	03.01 -	> 57	39
<i>Paecilomyces lilacinus</i> (Bioact)	04.02 -	> 44	21
<b>Average time period</b>		<b>&gt; 83,6</b>	<b>26</b>

**USA 59 Products - EU 5 Products**

# 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 into regulation management?



# Implementation of Regulation



- **Implementation of regulation must be justified and based on scientific evidence**
- **Authorities should not regulate trivial risks**
- **We need less bureaucracy, not more**
- **Rapid intuitive judgements often operates as a substitute for more careful inquiry (SANCO decision to cover EPN under 91/414)**

# REBECA Action



- **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**
- **Independent analysis free from biased judgement influenced by current regulatory situation**
- **REBECA should be an open forum to discuss possible alternatives to promote biological control and increase on safety of plant protection**

# Megaplan

- Introduction of participants
- Everyone identify risks, one risk per card
- Presentation of risk
- Group risks of all participants
- Discuss probability of occurrence and impact (0-5, none, remote... high)
- Choose one to present results to plenum