



REBECA



EU Policy Support Action

Regulation of Biological Control Agents

www.rebeca-net.de

**Ralf-Udo Ehlers
Inst. Phytopathology
University Kiel, Germany
ehlers@biotec.uni-kiel.de**



REBECA



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



REBECA



Today:

Presentation of results

Round table:

**Discussion on general aspects
to improve BCA regulation**

Tomorrow:

Details on proposals and discussion

Microbials (Royal)

Botanicals (Luxembourg)

Semiochemicals (Amsterdam)

Macrobials (T`Serclaes)



Stakeholder interests



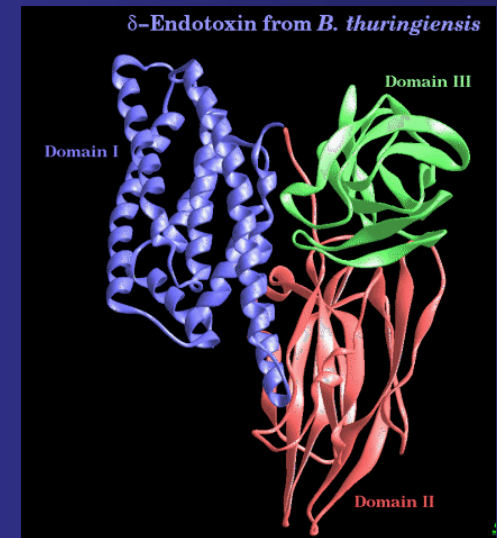
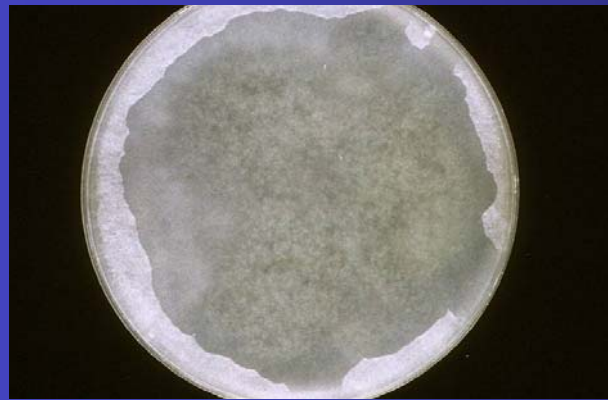
Objective REBECA: Increase availability of safe biocontrol products in EU agriculture and forestry

| Consumer | Farmer | Industry | Science |
|------------------------------------|--------------------------------------|-------------------------|------------------------|
| Safe food Protected environment | Profit Good PPP Sustainability | Profit IP Protection | Knowledge R&D Funds |

Biological Control Agents



- PPP of botanical origin
- Semiochemical, e.g. insect pheromones
- PPP based on viruses, bacteria and fungi
- Invertebrate BCAs (Macrobials)



Biological Control Agents



- Diverse group generally posing little or no risks to humans, non-targets and the environment
- Risk assessment case by case
- Many BCAs could be the solution of some major problems in plant protection
- However, there are few on the market
- Regulation is one, but not the only reason for low number of products



Growers under pressure



Few PPP overused, development of resistance, residue levels cannot be met, illegal use of PPP



Retailers lobby for biocontrol



**But they +
Greenpeace do not
know about BCAs**

tagesschau.de

Inland

Greenpeace-Test

Obst und Gemüse bei Lidl und Real am stärksten belastet

Obst- und Gemüsesorten in deutschen Supermärkten sind nach einer Greenpeace-Untersuchung häufig mit giftigen Pestiziden belastet. Die höchsten Werte wurden beim Discounter Lidl und beim Metro-Konzern mit dessen Handelskette Real ermittelt, wie die Umweltschützer mitteilten. Am wenigsten belastet war laut Greenpeace die Ware von Aldi, die übrigen Supermarktketten wie Rewe landeten im Mitte

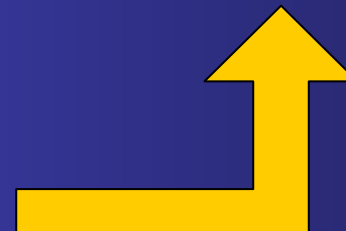


Greenpeace präsentiert Pestizid belastetes Obst



LIDL-Relation to Suppliers:

„For all fresh fruit and vegetables we accept only 1/3 of the allowable maximum residue levels according to German law“



BCAs to solve the problem?



Spain wants 38.000 ha of vegetable area transferred to IPM with a focus on biocontrol by 2010. Support of 1000 €/ha for BCAs





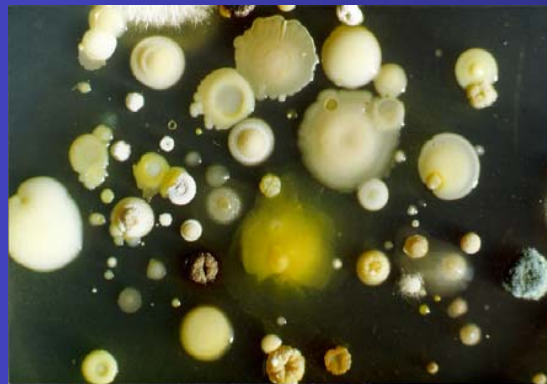
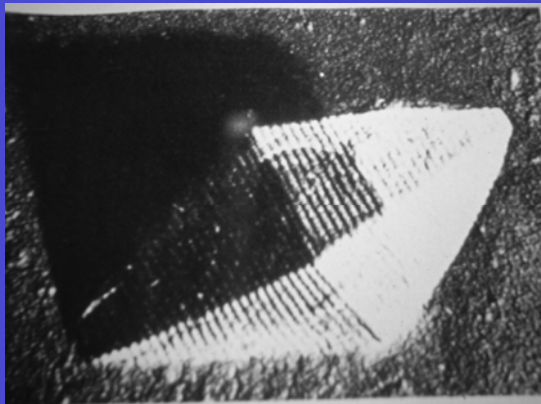
Consumers demand



Consumers demand organic products

EU self-supply at 45%

Huge demand for BCAs but we must set the conditions right so they can reach the market





Political agenda not met



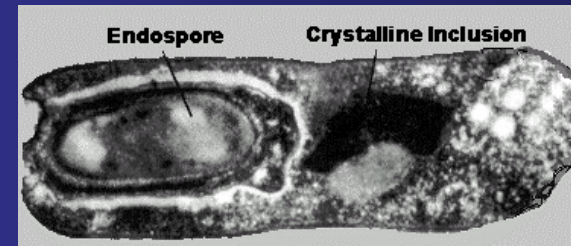
Reduction programs neglect potential of biocontrol

In MS + EU projects (e.g. Endure) biocontrol is of minor significance

Support to R&D and SMEs would certainly be helpful to improve the situation

Channel some of the millions the EU spends in agriculture into biocontrol!

Biocontrol Market 1985 to 2004



In EU Volume
doubled

B. thuringiensis from
95% to 25%

Now 55% IBCAs,
with 10%-20% yearly
increase

Microbials of less
importance –
consequence of
regulation?





The Global Market

The global market for microbial biopesticides was ~\$268 million at end-user level in 2005.

Biopesticides represent < 1% of the total global pesticide market.

Products based on *Bacillus thuringiensis* dominate the market; taking a 60% share.



Europe

Market for microbial- and nematode-based pesticides estimated to be approximately \$43m pa at user level in 2005. The potential remains high and opportunities exist which could raise the total market to \$200 million by 2015.

The fastest growing sectors of the European market have been in nematodes and entomopathogenic viruses; where sales in both may have doubled since 2000 to reach \$6 million and \$5.45 million respectively.

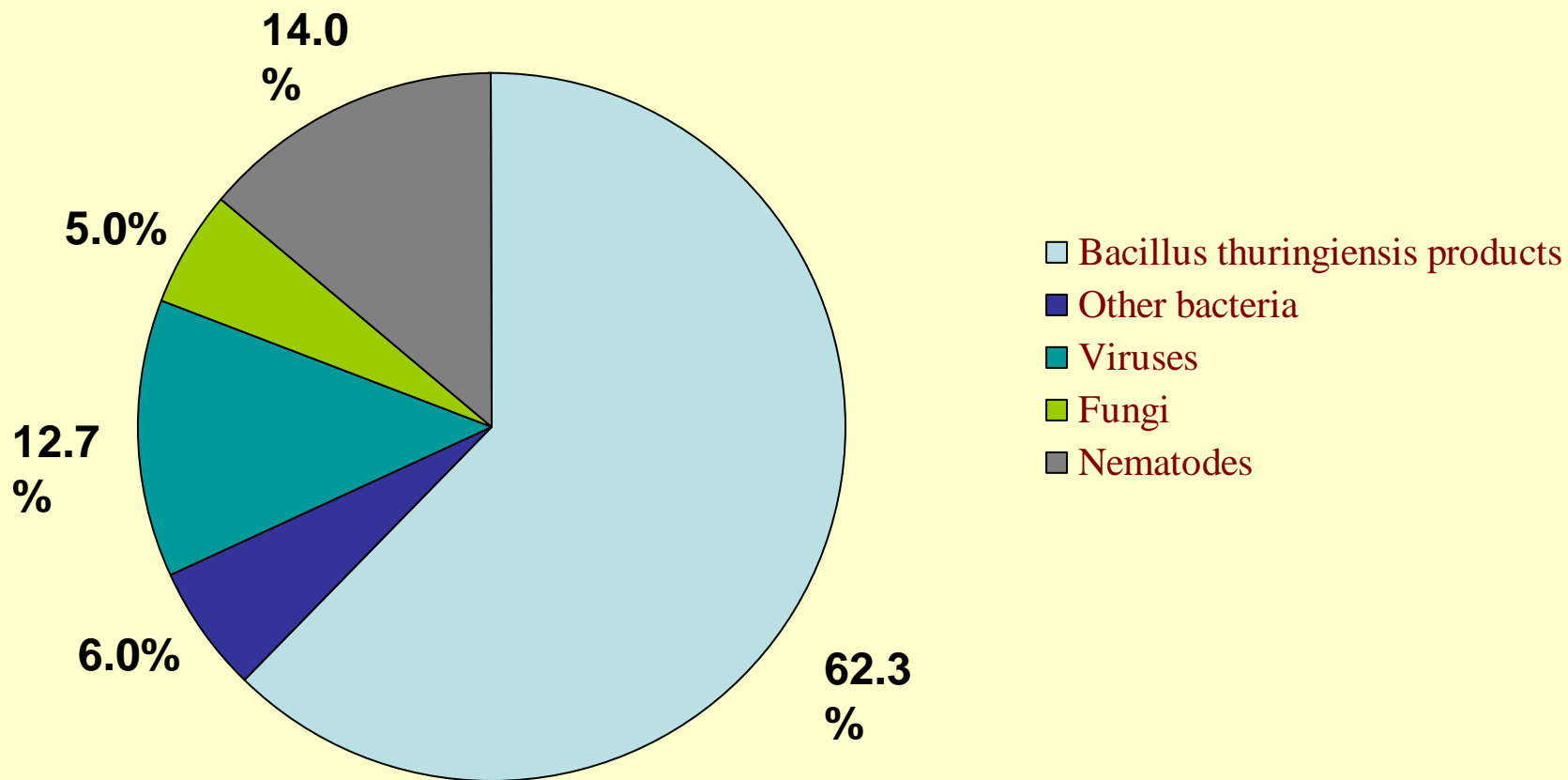
USA

The fastest growing sectors of the US market have been in mosquito control agents (in response to disease scare) and fungicidal products based on *Bacillus subtilis*.

The nematocidal product DiTera®, based on *Myrothecium verrucaria*, has shown significant growth and may be an indicator of a key market for the future. No application for EU registration.

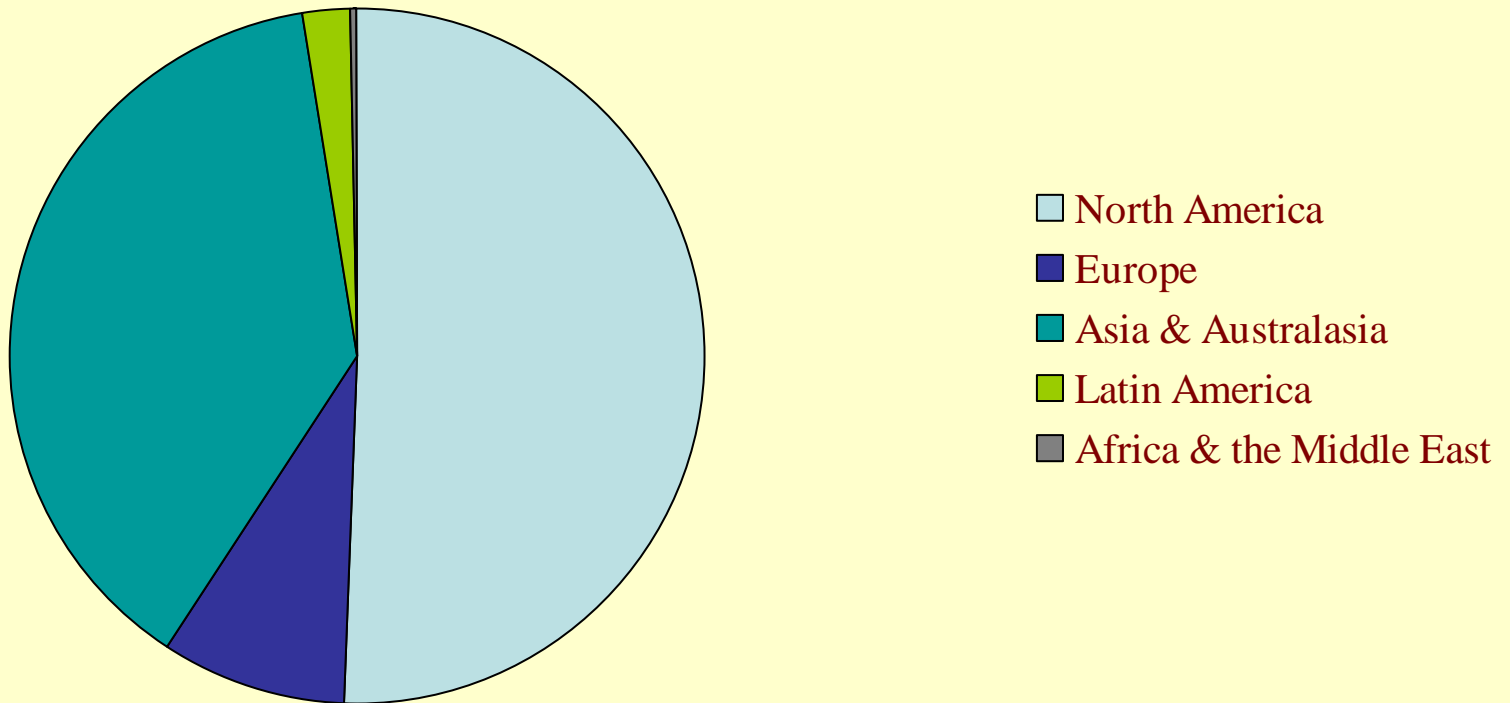


Estimated Sales of Microbial and Nematode-Based Biopesticides in the European Union (43 million US \$)



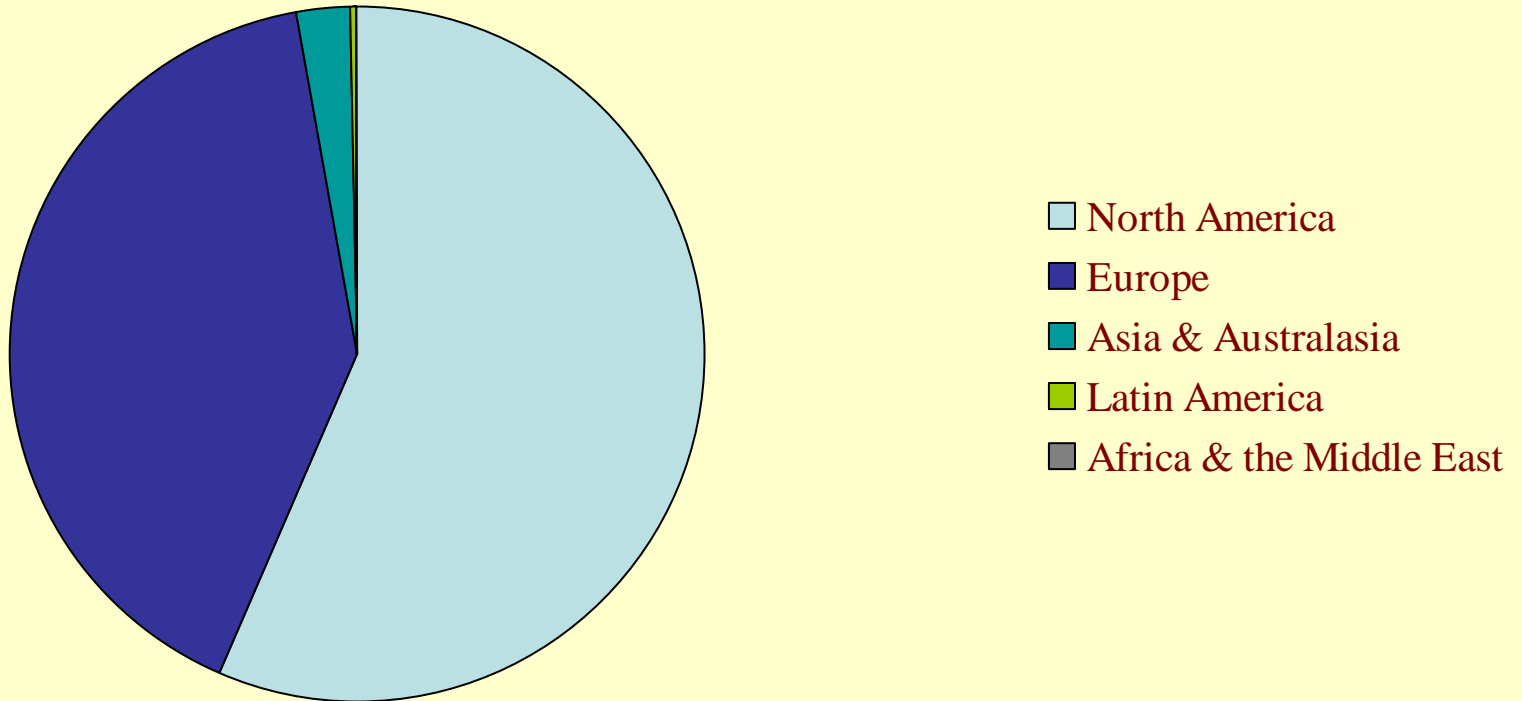


Estimated sales of products based on bacteria other than Bt (\$m)





Estimated sales of products based on nematodes (\$m)



Commercial problems with regulation



- **Costs and duration not predictable**
- **High cost (approx. 0.5 to 2.5 million €)**
- **Knowledge resources required**
- **Market size cannot support expensive regulation**
- **Registration is a blackbox: no investment into industry**
- **Barrier of entry for SMEs**

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

REBECA Call Text



EU-FP6-Specific Support to Policies 4

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

After 15 years of 91/414 the need for a review of regulation procedures for BCAs was realized

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

Workpackages



- **WP1: Action management and co-ordination**
 - CAU: Ralf-Udo Ehlers + Olaf Strauch * Miriam Döring
- **WP2: Review on current legislation and guidance practice**
 - GAB: Rüdiger Hauschild
 - CABI: Ulrich Kuhlmann
 - PRI: Antoon Loomans
- **WP3: Risk Assessment of microbial biocontrol agents**
 - LFU: Hermann Strasser
- **WP4: Risk assessment botanicals and semiochemicals**
 - FIBL: Lucius Tamm + Bernard Speiser
- **WP5: Assessment of protocols for macrobial invertebrate BCAs**
 - UOB: Jeff Bale
- **WP6: Analysis of drawbacks and benefits of regulation**
 - UHEL: Heikki Hokkanen + Ingeborg Menzler-Hokkanen
- **WP7: Measures to accelerate regulation**
 - DEPA: Anita Fjelsted

Thanks to Heike Kuhlmann (KCS)

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

*Regulation of
Biological Control Agents*



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



REBECA

*Regulation of
Biological Control Agents*



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

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

www.rebeca-net.de