



## **Deliverable 24**

### **Cost, trade-off, and benefit analysis**

#### **REBECA**

Regulation of Biological Control Agents

Specific Support Action

Project no. SSPE-CT-2005-022709

Contract Start Date: 01-06-2006

Duration: 24 months

Project Coordinator: Ralf-Udo Ehlers, Christian-Albrechts-University of Kiel.

### Document Classification

Title	Cost, trade-off, and benefit analysis
Deliverable	24
Reporting Period	2
Contractual Date of Delivery	
Actual Date of Delivery	28.03.2008

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Work package	WP6
Dissemination	Public
Nature	Report
Version	1
Keywords	

### Document History

*This document is based on the results of*

1. A survey conducted among 52 companies involved in BPPP in Europe
2. Series of REBECA workshops in 2006-2007

### Document Abstract

*This document briefly reviews discussions*

1. on how the level of regulation impacts the development and market access of BPPP
2. on whether the level of regulation has had an effect on the documented or suspected environmental or health hazards caused by BPPP
3. on the drawbacks of regulation in terms of consequences for plant protection, farmers, consumers and food safety.

## Table of contents

<b>Introduction.....</b>	<b>3</b>
<b>BPPP registration: company survey.....</b>	<b>3</b>
Time .....	3
Cost .....	4
Impact on R & D, and on company strategy .....	4
<b>Tradeoffs of regulations.....</b>	<b>5</b>
Biocontrol industry .....	5
Plant protection - farmers .....	6
Consumers and food safety .....	6
Environment .....	6
Evidence for trade-off effects:.....	7
<b>Cost-Benefit Analysis of Biopesticides.....</b>	<b>7</b>
<b>Conclusions .....</b>	<b>9</b>

## Introduction

The objective of this study was to analyse how the level of regulation impacts the development and market access of BPPP, and to analyse whether the level of regulation has had an effect on the documented or suspected environmental or health hazards caused by BPPP. Furthermore, a tradeoff analysis examined the drawbacks of regulation in terms of consequences for plant protection, farmers, consumers and food safety.

The first part of this study concerned a detailed survey among all the companies involved in BPPP development, registration and marketing in Europe. Several of the major companies were visited, and others were surveyed via a questionnaire sent to 52 other companies active in the BPPP area. The survey focussed on the time and cost of registration of BPPP, and the impacts of regulations on the R&D activities and the overall company strategies.

Company survey feedback was obtained from a total of 21 companies: ABITEP, Agraquest, Agrisense, Andermatt, Becker Underwood, Bioagri, Biobest, Biocare, CBC Europe, Denka, e-nema, Exosect, Futureco, Intrachem Bio, Isagro, Koppert, Prophyta, Sautter & Stepper GmbH, Trifolio, Valent, and Verdera.

## BPPP registration: company survey

### Time

Data on most important products (Annex I -listed) indicate that the mean registration time for EU Annex I inclusion is 75 months, while for US-EPA registration it is 28 months. Country registrations vary widely and range from a few months up to over 100 months, averaging around 24-36 months:

Country registrations, examples/means (in months; EU countries in **boldface**):

<b>AT</b> 19	<b>FR</b> 29	NO	15
BR 72	<b>GR</b> 7	<b>PT</b>	<b>27</b>
CA 17	<b>HU</b> 48	<b>SE</b>	<b>12</b>
CH 24	<b>IT</b> 14	<b>UK</b>	<b>22</b>
CN 18	JP		12
<b>ES</b> >34	MX		24
<b>FI</b> 12	<b>NL</b> 22		

## Cost

Results on registration cost show that EU Annex I inclusion has cost the companies about 1890 k€; out of that 970 k€ were external costs (fees etc.). The breakdown of total costs to different kinds of tests averaged as:

- efficacy tests 21 %
- toxicological tests 43 %
- ecotoxicological studies 23 %
- other required studies 13 %

## Impact on R & D, and on company strategy

R&D expenditure by the companies remained quite constant over the years, but in proportion of turnover it declined: means were  
1990: >>100% 1995: 83% 2000: 39% 2005: 14%

Information on the impact of regulatory costs and/or time on new R&D indicates that most companies still plan to bring new BPPP into market, while several others do not plan to invest into new R&D for BPPP. Products not requiring registration, of products (ai's) which already have been registered, have priority in the R&D of these companies. Several companies indicated that they would bring more BPPP into the European market if conditions for registration were more favourable; many replied that they prefer to focus on other geographical regions where the climate for this business is more favourable (North America, Asia ...). Three companies indicated that they had shelved BPPP mainly due to registration costs/time (4 products). These companies had spent on average 200 k€ in R&D on these products by the time of deciding to discontinue their commercial development. Furthermore, several companies do not plan to initiate new R&D on BPPP under the current situation, but their plans depend on "positive results from REBECA".

### Impact on new R&D

- several companies do plan to bring new BPPP into market
- new R&D has been started in 2000, 2002, 2005, 2006, 2006
- market entry for these expected in 2007, 2009, 2011, 2015
- R&D expenditure so far has been 15M€ in one case!
- several companies do not plan to invest into new R&D for BPPP, because of high registration costs. Products not requiring registration have priority in the R&D of these companies.
- several companies would bring more BPPP into the market "*if conditions for registration were more favourable*"

## Tradeoffs of regulations

A trade-off analysis examines the drawbacks and benefits of current regulation of biological plant protection products (BPPP) in the EU in terms of its consequences for plant protection, farmers, consumers and food safety. REBECA WP6 organized a workshop on the topic and conducted a survey among biocontrol industry concerning their experiences with regulation of BPPP and future plans concerning product development. A costly and lengthy registration of BPPP might restrict severely their market entry in the EU, and would lead to trade-off effects in areas such as farming activities, human health, environment, and commercial biocontrol activities. Furthermore, a benefit analysis will consider the benefits of regulations, e.g. for chemicals and for BPPP.

## Biocontrol industry

Costly and lengthy registration of BCA restricts severely their market entry in the EU and results in e.g.:

- Loss of competitiveness of biocontrol companies in EU
- Increased reliance on chemical control, increased problems with resistance, less sustainable crop management systems
- Farmers lack, particularly in fruit and vegetable, effective control measures, leading to > overuse of existing products > resistance > residues or use of illegal pesticides
- Higher costs for farmers, less efficient production if no effective PPP available
- Higher exposure of users to toxins
- High exposure of consumers to residues
- Organic farming has less alternative products
- No start-ups and spin-offs in biocontrol industry
- High fees of Member States result in companies marketing only major BCA; and biocontrol systems lack measures for less important pests > chemicals
- Regulation keeps smaller and more specific BCA from the market > return to broad spectrum pesticides
- Product innovations are not brought to the market, e.g. progress with new strains or new formulations, because of costs related to registration
- As costs and time related to registration can hardly be predicted, companies cannot produce business plans > without a business plan no venture capital > BCA industry remains a small business
- EU policy does not meet their objectives:
  - Reduction programmes
  - More organic growers
  - Safer food, less residues
  - Safer environment
  - More jobs
  - More SMEs
- Loss of competitiveness of the biocontrol sector in the EU
- No start-ups and spin-offs in biocontrol industry

- High fees of Member States result in companies marketing only major BCA; and biocontrol systems lack measures for less important pests > chemicals
- Regulation keeps smaller and more specific BCA from the market > return to broad spectrum pesticides
- Product innovations are not brought to the market, e.g. progress with new strains or new formulations, because of costs related to registration
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### **Plant protection - farmers**

Limited BCA availability affects farming:

- continued/increased reliance on chemical pesticides: pesticide sales (in tn) in EU15 increased by 12% from 1992 to 2001
- - increased difficulties to control pests due to pesticide resistance e.g. pollen beetle resistance to pyrethroids on oilseed rape, pests of protected crops e.g. in Almeria, Spain
- lack of effective controls esp. in vegetables and fruits
- overuse of existing products > rapid loss of compounds
- higher costs for farmers, less efficient production, if effective plant protection products are not available
- organic farming has less options for plant protection
- sustainability of farming systems suffers

### **Consumers and food safety**

Limited BCA availability affects human health, including applicators, bystanders, and consumers:

Pesticide residues in fruits and vegetables have been increasing during the past 10 years, as shown by data from Germany. In German supermarkets in autumn 2006, two percent (2 %) of vegetable and fruit samples from conventional production had residue levels exceeding even the Acute Reference Dose (ARfD). Additionally, 11% of samples labelled 'produced in Germany' contained residues of pesticides which are not allowed to be used in Germany (indicating illegal use).

### **Environment**

Limited BCA availability affects the environment via the negative externalities of continued use of chemical pesticides:

- contamination of biota, soil and water
- loss of biodiversity

## Evidence for trade-off effects:

- Some 60 BCA products registered in USA, EU-wide only 6
- Registration costs in EU average 1.9 million €, while average turnover per product is only around 0.2 M€
- Registration takes in the EU 75 months (mean), in the USA 28 months
- In the EU use of chemical pesticides has not decreased as planned
- Pesticide resistance problems are now more acute than ever (e.g., pollen beetle on oilseed rape)
- In German supermarkets, pesticide residues on vegetables and fruit have increased in proportion and severity steadily for the past 10 years; in autumn 2006 2% of samples had residue levels exceeding the Acute Reference Dose (ARfD)
- 11% of samples labelled 'produced in Germany' contained residues of pesticides which are not allowed to be used in Germany
- No new investments into BCA: 3 out of 5 major companies in the area do not plan to invest more into BCA because of the high costs and the long time needed for registration
- 3 companies had shelved some BCA products mainly due to registration hurdles: on average, 0.2 M€ was invested into R&D before deciding to stop
- Several companies indicated readiness to bring new BCA products into the market, if the conditions for registration were more favourable

## Cost-Benefit Analysis of Biopesticides

A workshop at Warwick HRI, UK, found 41 benefit and cost items relating to biopesticides. The balance of costs and benefits was found to vary substantially across the six stakeholder groups:

developers	-14
users/growers	-9
retailers	-6
regulators	-1
consumers	+2
opinion formers	+7

Thus, those who bear the private costs of development and application seem to have the most unfavourable balance of costs and benefits, while consumers of the final product and opinion formers have the most favourable balance. This emphasises the importance of considering the balance of private and public goods.

### ***Private vs. public benefits***

"The ratio between private and society benefits on UK wheat production is illustrative: for every £1 gained by farmers in private benefits in a move from conventional to

integrated farming (with reduction in pesticide usage), there are £6 worth of benefits to the society.”

“The environmental and socio-economic costs of pesticide use in the USA is more than double of that what is paid by farmers, and could be viewed as society subsidies to support this form of pest management.”

“Replacement of chemical pesticide treatments by biological controls would bring immense socio-economic benefits to the society: the benefits from controlling the pests would still accrue, but the negative externalities would disappear.”

Citations from Menzler-Hokkanen 2006: Socioeconomic significance of biological control. pp. 13-25 in Eilenberg & Hokkanen, An Ecological and Societal Approach to Biological Control. Springer.

**Risks related to BCAs** is another side of this issue, and have been addressed at a series of REBECA workshops in 2006. For microbial control agents the conclusions include that (i) the risks to human health are very low, (ii) main risks are to the environment (these may be perceived rather than real for many species), (iii) there is a need to separate ‘true risks’ from ‘perceived risks’, and then identify those risks that needed to be ‘regulated’. Among microbial control agents some are considered a risk because they belong to species, which has been identified as a human pathogen. However, it is often possible to distinguish between BCAs and clinical isolates with the help of modern molecular methods. These data can often indicate a phylogenetic separation of the BCAs from clinical isolates of the same species and sometimes even make possible the description of new species. Concerning botanicals BPPP the risks associated with their use may vary between very low and very high. Risks should therefore be assessed case-by-case. The discrimination of low risk substances from other substances should be the result of an assessment. Semiochemical-BPPP have low inherent toxicity and are expected to present a low risk. They modify behaviour of the pest species rather than killing them, they are more target specific than conventional insecticides, and are used at concentrations close to those in nature.

In the workshop reports, as described above, the assessment of risk (or identification of hazard) appeared however to be limited to the currently available, well known products, or organisms close to market, or those that have been researched for a long time as serious candidates for commercialisation. The discussion on risks might achieve other dimensions if there would be no regulations at all, or if the regulations would be significantly more relaxed than what we currently have. Attempts to commercialise organisms which currently stand no chance would likely take place. These include e.g. pathogens which are closer to vertebrate pathogens than those currently in use or in development (e.g., entomopox viruses). The question can be posed whether a less stringent regulatory system would allow the use of these products (even unrestricted use), and at what risk? There is a different approach to risk in ‘western’ societies, and in ‘developing countries’ (where do Russia, Ukraine, Cuba, Kenya, etc belong to, in this assessment? Poland?).

## **Conclusions:**

The current regulatory system for BPPP in the EU has numerous severe trade-off effects.

These contribute in several key areas to the EU not meeting their stated policy objectives:

- Pesticide reduction programmes
- Increasing proportion of organic production
- Safer food with less pesticide residues
- Safer and more diverse environment
- More jobs
- More SMEs