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Proposal for alternative regulation strategies

REBECA

Regulation of Biological Control Agents

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This document is based on discussion during the following workshops and conferences: (i) the Salzau conference in September 2006, the Porvoo workshop on cost-benefit and trade-off analysis, (ii) the Alès workshop on environmental risk assessment of microbials in June 2007, (iii) the final conference in Brussels 2007. Furthermore, the author reviewed the use of the 'precautionary principle' in the EU and the history of BCA regulation.

Document Abstract

Based on a comparison of the history of regulation of synthetic compounds and biological control agents (BCAs) it becomes obvious that regulation procedures for BCAs in Europe have not been introduced based on reports of damage, nor have they been a result of a gradual evolution in cooperation with industry and other stakeholders. The REBECA Action therefore proposes to continue the dialogue between stakeholders, which has been initiated by the Action, in order to develop innovative and more balanced approaches for the regulation of BCAs, which are more cost-effective and will accelerate market introduction of BCAs. A detailed analysis of the communication of the European Commission on the precautionary principle revealed that the rules laid down have not been applied to BCA regulation. Otherwise governments would have first analysed the risks and benefits of a regulation of BCAs and weighted trade-off effects. Since BCAs have a in contrast to chemicals a history of safe use, a more balanced regulation procedure would be appropriate. REBECA support the Parliaments view of the European Parliament, which proposes a separation of the legislation from synthetic compounds, because of the potential advantages for the market assess of low risk plant protection products. However, REBECA is aware that this would be long term project and the

problems for BCAs might remain unsolved. The Commission in its communication on the precautionary principle demands a re-examination of regulation measures based on new scientific results. Innovative and balanced regulation of BCAs will consider the real risks and allow for fast track systems for low risk products. Many registration requirements introduced for synthetic compounds might not be necessary for BCAs. A re-evaluation process should be accompanied by research projects to produce more data on the risks and safety aspects of BCAs. Finally it is outlined that current Common Agricultural Policy (CAP) promotes the reduction of pesticide use but does not consider BCAs as an alternative, although the potential for plant health and protection is immense. A promotion of biological control concepts must focus on the financial support of R&D in the evaluation of safety and risks and support SMEs in their attempts to register new BCA products.

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Introduction

Plant protection products (PPPs) can be harmful to humans and the environment. For this reason they need to be evaluated and authorised according to Directive 91/414/EEC prior to use. Authorisation for use is only given if unacceptable negative effects to humans and the environment can be excluded.

Registration of PPPs based on botanicals, semiochemicals and micro-organisms follows rules originally developed for the risk assessment of synthetic chemical compounds (Dir. 91/414/EEC). The data requirements for micro-organisms have been adapted twice. Due to the nature of the Biological Control Agents (BCAs), they usually pose less risk to users, consumers and the environment than synthetic chemical compounds. In risk analysis the major hazard is the loss of human lives. To our knowledge, never in the past has there been reported a loss of human lives due to the use of BCAs. But more than 300,000 fatalities per year are reported due to the misuse of synthetic PPPs (WHO, 2003: The world health report 2003: Shaping the future. WHO, Geneva, Switzerland). The environmental damages caused by biological control are of much less magnitude than hazards related with control measures based on the use of synthetic pesticides. Several specific traits qualify BCAs as low risk agents compared to synthetic compounds. For instance, their mode of action is usually much more specific compared to synthetic PPPs and consequently their environmental impact is limited. As they originate from nature they are bio-degradable. Compounds thus do not persist in the environment. Organisms are part of the environment and most micro-organisms are cosmopolitans.

The REBECA community has identified the regulatory requirements for BCAs as one of the major hurdles preventing the access of further of these generally safer PPPs to the market. Alternative measures are therefore urgently needed which

- are better adapted to carry out risk assessments for the specific risks of BCAs
- are more efficient for assessment of the real risks
- reduce costs related with the registration process
- accelerate the registration process

Prior to the proposal of alternative strategies, an analysis of the current situation will describe the status quo ante of the REBECA Action. Much of the conditions, however, prevail until today.

History of regulation of plant protection products

In Europe, PPP regulation was introduced in the 1960s. On initiative of the chemical industry, governments gave authorisation exclusively for those pesticides, for which evidence for their efficacy was provided. Environmental aspects were only considered in response to concerns about accumulation of the organochlorine insecticide DDT in the food chain. Since then PPPs posing unacceptable risks have been banned and/or substituted and chemical industry adapted to the increasing standards by monitoring safety aspects already at an early stage of product development. The history of regulation has been a process of replacement of one chemical group by another, which often exhibited another set of problems. This process was accompanied by the development of

more and more stringent rules taking into account scientific reports of damage caused by synthetic compounds and anticipated risks of new compounds. Governments responded to reports of damage with the development of new rules to ensure that similar impacts will not occur with new compounds.

Since the introduction of regulation, registration requirements and guidance documents had always been developed in consultation with multinational agrochemical companies. Other than regulation of synthetic compounds, regulations for biological plant protection products have not evolved within such a process:

- Regulation of biological PPPs was not a gradual evolution involving industry
- Regulation was not based on scientific reports of damages
- BCAs have no evolution of regulatory rules- Adapted and more balanced approaches existing in some member states were even rolled back with the introduction of Dir. 91/414 as a consequence of better harmonisation.

For example, in Germany, before implementation of Dir. 91/414, the requirements for PPP based on Granuloviruses were much reduced after the first file (*Cydia pomonella* GV) had been processed. With the implementation of Dir. 91/414, applicants had to provide a complete data set again.

Although not a good example for handling even minor risks, for many years Italy had no regulation for microbial BCAs in place. Companies only needed to use the scientific name of the agents on their products. *Bacillus thuringiensis*, *Trichoderma harzianum* and many other micro-organisms had been marketed without evaluation of safety data until 2006. No damage was recorded.

With the introduction of the EU regulation old active ingredients had to undergo the process of re-registration. This process is according to EU policy objectives targeting at the substitution of more risky PPPs. With increasing knowledge and scientific evidence about damage and potential risks of old synthetic compounds, a re-registration is a logic consequence. However, for biological control agents, which have been safely used for decades without any reports on damage and for which more and more knowledge has been gathered proving their safety, such a re-registration seems unnecessary. It is a consequence of handling biologicals like synthetic PPPs and is not based on scientific information on damage and risks. Biological control agents, which have not been applied for a re-registration, are not risky, but have a too small market to justify the registration costs and thus cannot be used in the future.

Compared to chemical industry, the participation of biocontrol industry in definition of regulatory rules was minor. One reason certainly was the rudimentary representation and low organisation status of the comparatively young biocontrol enterprises. Another was the low level of knowledge and experience available in these companies and also on the side of regulation authorities. Only a few years ago, the OECD asked for industry participation when discussing guidance documents for micro-organisms and invertebrates and only with the start of the REBECA Action, an intensive dialogue between all stakeholders in regulation of biological control agents was introduced, which was very well attended and resulted in a better circulation of knowledge and experience among all stakeholders.

Weighing the economic importance of biocontrol during the time of implementation of Dir. 91/414, one can understand why little emphasis was given to specify regulation for BCAs. However, this situation has now changed. Problems with chemical control compounds increase and growers in Europe are starting to experience the potential of BCAs. Biocontrol industry is flourishing with up to 20% increase in annual sales. Growers start to realize that BCAs have the potential to close control gaps and substitute some of the environmentally risky synthetic PPPs. In order to better protect consumers from residues of synthetic PPPs, avoid hazards for users of synthetic PPPs and preserve agro-ecosystems, a rapid market access of biological products would be desirable. A better adapted regulation procedure would help to reduce restrictions and ease the market access of environmentally sound biocontrol PPPs.

In view of the history of regulation of BCAs, the REBECA consortium proposes to

- continue the dialogue between all stakeholders
- critically review the existing regulatory practice
- develop new and innovative strategies for BCA regulation
- consider more adapted regulatory measures according to the real risks of BCAs

The Commission's communication on the precautionary principle

The precautionary principle is the basis of European risk management and is thus also applied for biological control agents. It is often mentioned that BCAs might possibly pose similar risks like synthetic PPPs or pose unknown risks we have not yet identified. These "unknown unknowns" are often a justification why the precautionary principle is executed on BCAs and why rules similar to those developed for chemical compounds are applied.

The decision making in regulation is based on data from investigations and applying experimental models for assessment of potential risks. Data are used to predict hazards and quantify probability of occurrence and the development of risk management strategies. However, the system could not always prevent hazards to the environment. Atrazines, for instance, were detected in the ground water and their use had to be banned. Only recently, Tolyfluanid-containing fungicides (Euparen®) were banned because the compound is metabolised in the soil to Dimethylsulfamid (DMS), which was detected in the ground water.

Also for these failures of the regulatory system to prevent hazards to the environment, it is becoming customary to demand the application of the precautionary principle for regulation of PPPs including those of biological origin. This new approach is becoming the basis of European regulatory systems and is reflected also in the Rio Declaration (1992): "in order to protect the environment, the precautionary approach shall be widely applied by states. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". The REBECA consortium could not identify major threats with serve consequences for humans and the environment related with the use of currently registered BCAs, micro-organisms that are currently reviewed in the list-4- process or invertebrate BCAs.

Regulation following the precautionary principle is often understood as a measure to exclude any possible risk or hazard? that could possibly occur, neglecting the dimension of the potential hazard and its probability of occurrence. However, risks are always on both sides of the equation and hence the idea of precaution guards against one set of risks while ignoring those, which occur when doing nothing. Some cures might be worse than the disease. A too stringent regulation of BCAs would protect the environment less than advertised. Trying to avoid any possible risks by BCAs will keep older, riskier technology in use (synthetic pesticides). The alternative to the use of BCAs is the continuation with synthetic compounds accompanied by all negative effects for farmers, consumers and the environment and externalized financial burden to the society (Waibel et al., 1999).

Within the EU Commission the interpretation of the precautionary principle is less treating the principle like a dogma but more as the beginning of a serious analysis of how to approach risks within the authorities dealing with risk assessment and management. The Commission published a communication on the precautionary principle (COM 2000-1) outlining the Commission's approach to use the principle and establishing guidelines for application. The Commission clearly states "that recourse to the precautionary principle presupposes that potentially dangerous effects ... have been identified and that scientific evaluation does not allow the risk to be determined with sufficient certainty." Is this an argument to demand the application of the precautionary principle for the regulation of BCAs? Risks related with the use of BCAs have been described and in many cases their dimension has been scientifically assessed. The RAFBCA project (QLK1-CT-2001-01391) worked on fungal antagonists and the ERBIC project (FAIR5-CT97-3489) on invertebrate BCAs. Both projects identified potential risks and also concluded on their dimension and probability of occurrence. Together with the results gathered and summarized by the REBECA Action (www.rebeca-net.de: Safety information) or the biopesticide fact sheets provided by the Environmental Protection Agency in the USA (<http://www.epa.gov/pesticides/biopesticides/#factsheet>) much information is available to conclude that regulation of BCAs can be based on scientific evidence and that we do not need to apply the precautionary principle. Thus we do not have so many "unknown unknowns" but rather a set of known risks with limited dimension.

The Commission's communication further outlines the general principles of risk management measures (COM (2000)1):

- proportionality
- non-discrimination
- consistency,
- examination of the benefits and costs of action or lack of action
- examination of scientific developments

Measures should be proportional to the desired level of protection and should not be discriminatory in their application. A comparable situation should not be treated differently and different situations should not be treated in the same way. Taking this principle literally, we must analyse whether the reduced risks related with biological PPPs paves the ground for the separation of the risk assessment practice of biological and synthetic products.

The Commission demands that "measures should be consistent with the measures already adopted in similar circumstances or using similar approaches." Biological PPPs

often only share their use in plant protection with synthetic compounds. Many other comparable agricultural practices are not regulated like BCAs. The use of organic fertilizers (containing a much higher amount of micro-organisms than used in biological control) is not regulated. Nitrogen-fixing *Rhizobium* bacteria are applied to seeds and are not regulated. In many countries the plant-growth promoting products are subject to lower level regulation. Even in food industry alternative approaches are successfully used. The "qualified presumption of safety" (QPS) concept provides a generic assessment system for micro-organisms deliberately introduced into the food chain. This system allows for experience to be introduced into the assessment and should be further elaborated for the assessment of plant protection products.

The Commission outlines as well that "measures....shall be re-examined and if necessary modified depending on the results of the scientific research and the follow up of their impact." As much more scientific information is now available this seems to be a good opportunity to review the legislation of BCAs and develop more balanced, better adapted and more cost-effective regulation procedures for BCAs.

The REBECA Action was a starting point to produce a network of all stakeholders involved in regulation of BCAs. Within the time frame of the Action, the activities concentrated on providing proposals for a short term improvement of the conditions. Further activities in the analysis of the risks and the development of innovative regulation strategies must now follow to provide the appropriate conditions for a faster development of biological control measures in European agriculture. The rules defined by the Commission need to be applied also to BCAs.

Reviewing the Commission's communication of the precautionary principles the REBECA consortium proposes to

- treat BCAs in a non- discriminative way
- considering their lower risk compared to synthetic compounds
- take into consideration experience and available data from comparative use
- re-examine measures based on new scientific results on the safety of BCAs

Cost-benefit and risk-tradeoff analysis prior to introduction of regulation

The Commission's communication further demands "a comparison between the most likely positive and negative consequences of the envisaged action and those of inaction in terms of the overall costs to the Community." This might be the major point in which the current system has failed. To avoid over-regulation with all its negative consequences, governments should first ask whether the benefits of regulation justify the costs of regulation. Such an analysis include a cost-benefit-analysis (CBA), which is supported by a risk-trade-off- analysis (RTA). Has the magnitude of risks related with BCAs ever been assessed prior to introduction of regulation measures? No, we lack precise comparative information.

Such an assessment should try to see if there is a human health risk or estimate the potential environmental damage. Where scientific knowledge does not allow for specific estimates, ranges should be identified. The first step is to explore the costs of regulation,

the second the benefits governments and the society gain from regulation. The probability of occurrence of the hazard will be of major value to analyse the magnitude of potential risks. The result of the CBA will answer the question: Do benefits of regulation justify costs of regulation?

Governments should then attempt to assess trade-offs, also in quantitative terms if possible. Risk trade-off is the chance that occurs when in a portfolio of risks a countervailing risk is generated by an intervention to reduce a target risk (Graham and Wiener, 1995: Risk versus risk - tradeoffs in protecting health and the environment. Harvard University Press, Cambridge, UK). Once trade-offs are identified in a quantitative or qualitative way, target risks and countervailing risks must be weighed and effected population (e.g. farmers vs. endangered species) be estimated. RTA can help to avoid the most serious risks on either side.

Some of the trade-offs can already be addressed. Risks related with BCAs are usually remote if compared to other risks our societies are dealing with and tend to accept, like synthetic pesticides, smoking or alcohol. Economic benefits of biological control are evident (Doleman, 1990: Benefits and costs of entomopathogenic nematodes: two biological control applications in China. Economic Assessment Series, ACIAR, Canberra, Australia; Cullen and Whitten 1995: In. Biological Control: Benefits and Risks, Eds.: Heikki M. T. Hokkanen, James Michael Lynch, Cambridge University Press) and the benefits by far outweigh the related risks, particularly when compared with damage and risks related to alternative chemical measures. By over-regulating BCAs potential risks are transferred to the environment and to other groups in society. If, as a consequence of too stringent BCA regulation, synthetic pesticides have to be used, farmers can be harmed, particularly those who apply pesticides in glasshouse environments, where they are intensely exposed to chemical compound. Thus we can conclude that over-regulation of BCAs will produce a contradicting situation: While policy and society demands a reduction of chemical control (EU Common Agriculture Policy - Agenda 2000), over-regulation of BCAs can result in a more widespread use of chemical control measures.

In order to avoid unnecessary over-regulation and related costs the REBECA consortium proposes to

- analyse costs and benefits prior to introduction of new regulation demands
- take into account trade-off effects of regulation
- minimize trade-off effects and maximize efficiency of regulation
- develop cost-effective procedures and accelerate the registration process

Stakeholders and conflicting interests

Conflicts about how risks should be regulated or the implementation of costly regulation procedures are often a result of wrong information policy by a small fraction of interest groups. It is important to ensure the public of what is discussed and decided and to integrate all stakeholders into the process of decision finding. Decision finding costs might be higher in the beginning, however, on the long term, a consensus will save resources as all stakeholders support the result. Stakeholders in the area of regulation of BCAs are

- scientists developing biological control products and strategies
- governments implementing legislation
- regulators dealing with the dossiers and transferring regulation into practice
- environmentalists organised in NGOs
- the retail sector and consumers of agricultural products
- farmers
- chemical industry
- biological control industry

The different stakeholders have overlapping and/or conflicting interests. Conflicting interests exist between some environmentalists and biocontrol industry when aspects of non-target effects are discussed. On the other hand, some environmentalists prefer less dramatic impacts of BCAs over broad-spectrum insecticides. During the REBECA Action it became apparent that some enterprises supported the introduction of regulation. These enterprises have registration departments with experienced personnel and know how to handle registration. As intellectual property can often not be protected in the area of biological control, registration is a measure to keep competitors off the market.

If governments and regulators implement regulation a conflict situation can evolve with industry, should the latter stakeholder be severely affected in its marketing activities. The dimension of this conflicting situation is also defined by the character of the regulation authority. In the USA, for instance, the Environmental Protection Agency (EPA), regulating biological and conventional plant protection products, has a profound interest in the promotion of biological control. This resulted in significantly more biological control products registered and a quicker market excess in the USA than in the EU. In Europe regulation is in the hand of authorities in charge of agricultural, environmental and health affairs. All three sectors have conflicting interests. Consensus finding is time-consuming. Often personnel dealing with files and monographs are experts in reviewing information on synthetic chemistries. If BCAs are regulated by these agencies, which lack background information on the risks of BCAs, the process of consensus finding will be particularly long and expensive and will result in exaggeration of risks. Lack of knowledge is resulting in overestimation of risks. The microbial biological control sector in the EU has significantly suffered from implementation of registration requirements following the rules developed for synthetic agrochemicals. Many potential products based on microbials are not submitted for EU registration due to costly data requirements. Many unnecessary data packages are required just because it is common practice to ask for them. In order to prevent bureaucratic hurdles and unnecessary consensus finding costs, attempts should be made to get regulation of BCAs into the hands of experts. Should European policy makers seriously want to promote the further introduction of biological control strategies, then they should take measures to equip authorities with more and with experienced personnel and include expert knowledge. They even might want to waive fees and support the data production necessary for the risk assessment. The REBECA consortium proposes to

- reduce consensus finding costs
- equip registration authorities with skilled personnel
- consider expert knowledge in the regulation process
- not allow abuse of registration system to protect markets
- waive fees for registration of BCAs
- support production of safety data

Cling together-swing together - separate legislation of BCAs from synthetic compounds

On Tuesday 23 October 2007, the European Parliament voted on a report on amendments to the directive on the sustainable use of pesticides (drafted by Christa Klass (EPP-ED, DE) under co-decision first reading). The Parliament also voted on a report on a draft regulation on the authorisation of new plant protection products (drafted by Hiltrud Breyer (Greens/EFA, DE) also under co-decision first reading. On Wednesday 24 October 2007, the Parliament voted on an own-initiative report by Irena Belohorská (NA, SK) on a proposed Thematic Strategy on the Sustainable Use of Pesticides.

The parliament's views included the following statements:

- The use of pesticides should be reduced.
- Low pesticide-input farming needs to be promoted, giving priority to non-chemical methods and meaningful support to organic farming. Member States should be required to set up National Action Plans for reducing pesticide use and the development of plant protection products with a low risk profile should be encouraged.
- Parliament voted on several restrictions of pesticide use, such as banning aerial spraying with pesticides, prohibiting the use of pesticides in buffer zones round water courses, restricting pesticides in parks and sports grounds.
- The problem of pests is likely to increase due to global warming, which is expected to lead to increased pest populations.

The European-funded Specific Support Action REBECA has studied the risk profiles and regulation procedures for invertebrate and microbial biocontrol agents, plant extracts and semiochemicals. REBECA believes that the use of such organisms and substances is in line with the European Parliament's policy on pesticide approval and use, as outlined above.

The parliament has expressed the view that priority should always be given to non-chemical methods of pest management (Amendment 51), and has added a new point 14a to Article 3 as follows: "The use of pest control and management techniques that do not have chemical properties: Non-chemical methods of plant protection and pest and crop management include rotation, physical and mechanical control and natural predator management"

In the view of the REBECA project, the summary of the above mentioned alternatives to chemical pesticides is incomplete, and the following non-chemical methods should also be mentioned explicitly:

- Use of invertebrate biocontrol agents,
- Use of microbial biocontrol agents,
- Use of plant extracts
- Use of semiochemicals

All of these methods are non-chemical in the sense that they either involve living organisms, or that they make use of natural substances (as opposed to «typical pesticides» which are synthetic substances that do not occur in nature).

It is obvious that Parliament members have not well considered biological control agents. Many might not even be aware of the rule covering BCAs under the same legislation like synthetic compounds. Thus they decide restrictions on the use of synthetic compounds not taking into consideration that they automatically apply also for BCAs. Politicians might be not aware of the trade off effects of their decision. As long as the legislation of synthetic compounds is not strictly separated from the legislation of biologicals, biological control will experience the same restrictions put on the use of synthetic compounds.

The Parliament discussed the new regulation which will follow Dir. 91/414. Industry stakeholders of biocontrol industry (IBMA) considered the discussions were so much concentrated on the regulation of chemical compounds that it was impossible to get attention for biological plant protection. Thus proposals for a more balanced regulation were not introduced by the IBMA. The new regulation proposes a compulsory mutual recognition of PPP if authorisation has been granted in a MS belonging to the same climatic zone as defined in Annex 1 of the new regulation. REBECA supports mutual recognition within climatic zones. Most microbial biocontrol agents are naturally occurring in all member states. Some organisms might be more restricted in their natural distribution by climatic conditions rather than by national borders. A mutual recognition would therefore be reasonable.

A major hurdle for BCAs is high costs related with the registration process. Regulatory requirements and associated fees are considered inhibitory to market development of BCAs. Biological agents are usually very specific in their mode of action. Consequently the potential market size is limited and often does not justify high registration costs. A mutual recognition would reduce registration effort in MS after the listing on Annex 1, as registration in three zones would be enough to cover the complete EU. Effort and time can be avoided by registration in just one MS in each zone. Unnecessary duplication of work and bureaucratic efforts are avoided. The speed of market introduction can be increased.

What is reasonable for biocontrol agents, might not meet the requirements for synthetic compounds: The latest discussion on the new regulation of PPP in the European Parliament is a good example how biological control is suffering from the development of more stringent rules for registration of synthetic compounds. Among Parliament members concerns exist regarding the mutual recognition and the loss of the possibility of member states to reject authorisation of a compound. One reason is the potential of ground water contamination. Some member states have no need to clean drinking water from pesticide residues and thus want to have a possibility to refuse authorisation in order to protect their ground water and avoid costs for cleaning. Consequently, these MS refuse the concept of mutual recognition unless such a system will include a possibility to avoid giving mutual recognition to products that may lead to contamination of the ground water. Thus decisions made to minimize risks of synthetic compounds make registration of BCAs more expensive and time-consuming.

As a consequence, a separation of the legislation existing for synthetic compounds would avoid bureaucratic hurdles which apply only for synthetic pesticides. Registration would be more balanced and can be adapted to the needs of BCAs should the legislation be separated. Instead much burden is carried on due to the application of rules developed for synthetic compounds and at each time the legislation of synthetic compounds is amended in the future the rules will be automatically applied to BCAs.

A legislation adapted to the potential risks related with the use of BCAs would be more flexible and allow for fast track systems for compounds or organisms which are obviously of low risk. It could waive data requirements for efficacy or ask for these data only after 5 years of use. In many cases the evaluation of the efficacy of biocontrol agents is not a straight forward trial like for synthetic compounds which possess biocidal characters. BCAs often lack these characters; have long term effects etc, which makes the efficacy trials very expensive and time-consuming.

At an early stage of the REBECA Action the participants decided to concentrate on proposals which could provide a short term improvement for the conditions of BCA regulation. Detailed proposals for a completely new system specific for the needs of biocontrol were not an objective of the Action. However, it should be taken into consideration whether within future activities a new legislation for biological control agents should be considered. The rapid introduction of BCA products and the promotion of biological plant protection would certainly benefit for a more specific registration procedure. However, REBECA is aware that this would be long term project and the problems for BCAs might remain unsolved within a separate legislation. Furthermore, a clear separation between chemical and biological agents might be problematic.

The REBECA consortium proposes to

- acknowledge the lower risk of BCAs in the development of new rules
- consider the possibilities to separate legislation of BCAs from synthetic compounds
- develop more flexible risk assessment procedures
- produce definitions for low risk
- introduce fast track systems for low risk products

Enhance dissemination of biocontrol concepts

Biological control is not yet recognized as a viable alternative to conventional PPPs. This makes policy approaches difficult to succeed. Some examples will describe the situation.

The European and National Parliaments are not aware of the benefits of biocontrol. Although their concepts and policy strategies want to avoid the use of chemical PPPs, the legislation is actually not promoting the use of biological control agents. Since the reduction of the use of chemical compounds is part of CAP, many national parliaments have introduced pesticide reduction programmes. However, hardly any of these programmes support the use of BCAs.

When REBECA asked NGOs to participate, members of Greenpeace and PAN (Pesticide Action Network) confessed that they had no expertise in the risks related with the use of BCAs.

Two years after introduction of BCAs in vegetable production in Spain, growers were asked for their opinion about biological control agents. They were very satisfied with their effect. On the question why they did not use them before, the answer was that they had not been informed about their potential and that they had considered BCAs to not be able to solve their problems.

It is obvious that the potential is neglected, the little information among users is often that these products are too expensive and do not work. Further networking and spreading of information on biological concepts and integration of BCAs into common agricultural

practice should be supported. Instead many reduction programmes try to reduce the amount of compounds sprayed and risk accelerating the development of resistance.

Financial support to biocontrol concepts

The Spanish government is currently supporting the introduction of BCAs into vegetable production with 1,000 €/ha in order to overcome problems with resistance against synthetic compounds, illegal use of non-registered products and residues in vegetable and fruit products. As a consequence the introduction of biological control agents in greenhouse production jumped from approximately 200 ha in 2005 to more than 5,000 ha in 2007.

Although the EU R&D Framework 6 concentrated on "Food Safety", little emphasis was given to research and development of biological control. Research in this area is less attractive than molecular genetics and transgenic plants. However, consumers in Europe prefer produce from organic farming and refuse consumption of transgenic food stuff. R&D in biological control uses well recognised, "traditional" techniques. However, the outcome and benefits to the society might be much more valuable. Should more funding go into the biocontrol sector, there would certainly be more products on the market and agriculture ecosystems will certainly be a safer environments with increasing biodiversity.

However, this goal can not be reached without further reduction of registration hurdles. Evaluating the results of the REBECA Action one aspect has become obvious: With increasing knowledge on the risks of BCAs the requirements are reduced and regulators are more confident to give waivers on certain non-relevant data requirements. The success in dissemination of results on the safety of BCAs during the REBECA Action was much based on the outcome of the EU-supported R&D projects ERBIC (on invertebrate BCAs) and RAFBCA (on fungal BCAs). In order to further reduce the registration requirements more data on their safety is desirable. Much of the information is already provided in the scientific literature. E.g., on the safety of *Bacillus thuringiensis* a comprehensive summary of published data is available. More studies providing information, results and experiences on other agents are needed to ease the registration process. For new and less investigated BCAs additional research funding is needed to produce the data on their safety.

Many applicants during the REBECA Action complained about lack of guidelines. In many cases guidelines are not applicable. Research into the development of methods and models including the drafting of guidelines for human risk assessment of microbial BCAs are urgently needed. It is comparably cheap to develop biocontrol strategies compared to the development of a synthetic PPP. But as markets are limited due to the specificity of most biocontrol agents, the return on investment is lower. Thus it might be reasonable for European societies to support the introduction of BCAs and promote the integration of biocontrol into IPM strategies by giving support to the production of safety data.

The REBECA consortium proposes to

- support knowledge transfer on BCA concepts to the farmers (from lab to farmer to fork)
- support development of risk assessment guidelines
- support closure of knowledge gaps on risks related with the use of BCAs
- take into account BCAs as potential substitutes for synthetic compounds
- focus on introduction of BCAs in reduction programmes
- support farmers during introduction of BCAs into IPM systems