

**Deliverable 30:**

**Strategy for implementation of results**

**REBECA**

Regulation of Biological Control Agents

Specific Support Action

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### Document History

The document is based on the recommendations from a questionnaire (“main obstacles and proposals”, 2006), as well as discussions and recommendations expressed at the following 8 REBECA workshops:

1. Innsbruck workshop on microbials April 2006;
2. Brussels workshop on botanicals and semiochemicals June 2006;
3. Salzau workshop in September 2006;
4. Regulators and industry workshops in Salzau June 2006;
5. Regulators workshop in Braunschweig, Germany April 2007;
6. Cost-benefit workshop in Finland May, 2007;
7. Brussels workshop on botanicals and semiochemicals June 2007;
8. Final conference in Brussels September 2007.

### Document Abstract

This document presents a list of all the REBECA proposals apart from the proposals on invertebrate BCAs, (please refer to deliverable 22 for information regarding implementation of proposals related to invertebrate regulation) and for each proposal it describes how it can be implemented, who will be the responsible partner for implementing it, and a suggestions for timeframe within which the process for implementation should be initiated and where relevant when it should be finalised.



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## Introduction

The aim of the REBECA project is to propose improvements in the registration process of biological control agents (microbials as well as invertebrate biocontrol agents), plant extracts and semiochemicals (here collectively called 'BCAs').

This document contains an overview of all the REBECA proposals which have been agreed upon within the group throughout the project period (apart from the proposals regarding invertebrate BCA). For each proposal the possible measures to obtain an implementation of the proposals are suggested; the partners that will be responsible and involved in the implementation process; expected timeframe for the initiation of the implementation.

The proposals and measures for implementation are listed in the following four tables:

1. General regulation of microbials, botanicals and semiochemicals
2. Microbials
3. Botanicals
4. Semiochemicals

The REBECA project also includes a workpackage on invertebrate biocontrol agents. The main proposal from that workpackage is the establishment of a pan-European regulatory system for invertebrate BCAs. The options for implementing such a system are described in a separate document (refer to Deliverable No 22).

## 1. General regulation of microbials, botanicals and semiochemicals

All the listed proposals in this first table have been discussed in details during several REBECA workshops. For further information about each specific proposal please consult the REBECA document: Proposals on how to accelerate regulation and reduction of fees (Deliverable No 27). This document contains a detailed background for all the proposals, further description of the proposals and lists of advantages and disadvantages of the proposals.

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<b>Improved communication between regulators and applicants</b>				
Pre-submission meetings shall be established as a routine in all EU Member States.	<p>There is a need for an EU guidance document. The Commission (DG Sanco) should initiate this work by asking a small expert group representing a few member states (alternatively ask a single member state) to prepare a first draft guidance document which will subsequently be discussed among all member states and finally agreed upon and taken note of by the Standing Committee of Food Safety and Animal Health.</p> <p>The guidance document should describe: the purpose of pre-submission meetings; a model describing how to carry out these meetings; and it should include specification for the pre-submission information package (see below).</p> <p>In case any expenses (travel expenses) will be involved in this work it should be covered by the Commission.</p>	EU and national level	<b>The Commission (DG Sanco)</b> , all EU member states	2008
Pre-submission information package	<p>A detailed description on how to prepare a pre-submission information package should be initiated by the Commission (DG Sanco) and developed by the same expert group as mentioned above. This description should be part of the above mentioned EU guidance document.</p> <p>A similar description exists in the US-EPA and in the Pest</p>	EU and national level	<b>The Commission (DG Sanco)</b> , all EU member states	2008

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
	<p>Management Regulatory Agency, Canada. These documents can be used as a basis for this work within EU.</p> <p>A first draft of such a pre-submission information package is described in REBECA Deliverable No 27.</p> <p>A more detailed proposal on a pre-submission information package for micro-organisms is described in the table on microbials below.</p>			
<p>Applicants given the opportunity of attending part time at expert/evaluation meetings</p>	<p>The usefulness of such a system will first of all have to be discussed by the EFSA, the Commission (DG Sanco) and member states. If it will be agreed to allow applicants attending part time at the expert meetings (which are normally hosted by the EFSA). EFSA should establish a routine where they prior to each expert meeting remind the Rapporteur member states responsible for the active ingredients listed on the agenda to consider whether it would be relevant inviting the involved applicants to participate in part of the expert meeting.</p> <p>The Rapporteur member state would subsequently be responsible for the communication and agreement with the applicant.</p> <p>The applicants would of course have to cover the travel expenses for attending such meetings them selves.</p>	<p>EU level</p>	<p><b>EFSA</b>, The Commission (DG Sanco) and all EU member states</p>	<p>2008</p>
<b>Improved communication between regulators of BCAs</b>				
<p>Enlargement of the OECD-BPSG and further activities to take place within the group</p>	<p>The OECD Bio-Pesticide Steering Group should be given higher priority by OECD member states. 1) Further experts should attend the meetings; 2) further resources from national regulatory authorities should be allocated to activities in relation to this group (expenses to attend meetings, expertise to develop guidance</p>	<p>OECD level</p>	<p>OECD-BPSG and the OECD member states</p>	<p>2008-...</p>

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
	<p>documents and papers for discussion in the group etc.); 3) Further meetings/workshops should be arranged within the group.</p> <p>An OECD-BPSG workshop will take place in Washington DC in April 2008. One of the main points on the draft agenda is increased communication between regulators including pre-submission meetings and pre-submission information package.</p>			
Further and more regular expert-/evaluation meetings on the specific groups of BCAs	<p>When active substances such as micro-organisms, botanicals or semiochemicals will be discussed in expert meetings, these meetings should be arranged specifically for each of these types of active substances, and the meetings should be arranged as often as necessary. Such meetings should be attended by people with high level of expertise within these particular fields. This will in particular be relevant during the evaluation of the 4<sup>th</sup> list substances, where specific meetings on microbials, botanicals or semiochemicals should be arranged.</p> <p>EFSA is responsible for planning such meetings and for inviting the relevant national experts.</p>	EU level	EFSA	2008
Establish expert groups for BCAs	<p>As soon as possible, the EFSA should ask member states to nominate national experts/regulators for three expert groups, since the EFSA does not have expertise to deal with these specialised fields:</p> <ol style="list-style-type: none"> <li>1. Microbials (such a group already exists and is established by the Commission, however the EFSA should take over this role and establish a formal group and further experts should be encouraged to join the group)</li> <li>2. Botanicals</li> <li>3. Semiochemicals</li> </ol>	EU level	EFSA	2008

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
	<p>One member state should be appointed as chair for the group.</p> <p>EFSA should make the necessary funding available for regular meetings within these groups.</p>			
<b>Lessons learned guidance documents from the 4<sup>th</sup> stage</b>				
<p>Lessons learned guidance documents to be used in pre-submission meetings to determine data requirements/ waivers and generic safety profiles</p>	<p>Member states involved in the preparation of 4<sup>th</sup> list DARs on microbials, semiochemicals and botanicals should write several lessons learned guidance documents that can be used by applicants and regulators evaluating such types of substances in the future.</p> <p>These documents should be discussed within the three expert groups established (semiochemicals, botanicals and microbials). If relevant, the documents could be further developed into OECD guidance documents. At least they should be communicated to e.g. the OECD BioPesticide Steering Group.</p>	<p>National level, EU level, OECD level</p>	<p>Coordination by the expert groups/chairs of these groups</p> <p>Rapporteur member states</p>	<p>2008-2009</p>
<b>Fees and financial support</b>				
<p>Fees for microbials and semiochemicals to be lowered substantially</p>	<p>A few member states take large fees for reviewing active substances of low risk (e.g. microbials) since often the work has to be carried out on a cost-recovery basis. The grower's organisations, consumer organisations and the industry should initiate political discussions within these member states in order to request further low risk products on the market and suggest reduced fees. In most cases a political decision to lower the fees has to take place.</p>	<p>National level</p>	<p>Grower's organisations, Consumer organisation, Industry, regulators, policy people.</p>	<p>2008- ...</p>

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
	Regulatory authorities and 'policy people' should take active part in such discussions.			
Financial support and guidance for registration of new microbials, botanicals and semiochemicals	<p>Only a few member states have a specific policy that supports an increase in the number of low risk products/alternative plant protection products on their market. The grower's organisations, organic farming organisations, consumer organisations and the industry should initiate political discussions within member states with the view to: get politicians and regulators to focus on the potential of these products; request the regulators to give higher priority to such products and to give further guidance to applicants of such product types; raise funds that can support the application process of such products.</p> <p>Apart from such activities at national level, international organisations (consumer organisations, grower organisations, NGOs, organic farming organisations) should initiate similar discussions at EU level.</p> <p>Regulators should take active part in such discussions. Further more regulators from member states where such activities have been initiated should regularly communicate the experience and effect of such initiatives to their colleagues.</p>	National level and EU level	National and international Grower's organisations, Consumer organisation, Industry, regulators	2008- ...
<b>Generic approach in risk assessment</b>				
Establish risk management strategies taking a generic approach wherever possible – evaluating certain active substances as a group	<p>When applicants submit applications for new BCAs they should in the dossier stress if they believe that certain part of the dossier is an issue that can be dealt with by a generic approach, (e.g. fungal metabolites) and the dossier should contain a detailed reasoning for this.</p> <p>Regulators should always be open for discussions with applicants on possibilities of evaluating certain active substances as a group,</p>	EU level	Applicants and regulators	2008 - ...

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
	e.g. microorganisms at a higher taxonomic level, certain semiochemical groups, etc. A more generic approach can take place for active substances when adequate experience and data is available for such generic evaluations.			
<b>Strict and short timelines</b>				
Strict and short timelines for the EU risk assessment as well as for national registrations should be included in the EU regulation	<p>Applicants and regulators should be in close contact prior to the submission of an application (pre-submission meetings etc.) which is likely to result in a submission of good and complete dossiers, which the regulators thus will find easy to evaluate.</p> <p>As mentioned above, an increased political awareness and support is likely to secure further resources for the regulators which will help them to be able to carry out the risk assessment within a short timeframe, provided the necessary data are included in the dossier.</p> <p>The alternative/low risk substances should be given high priority during the EU evaluations. Expert meetings discussing these product types should take place regularly and without delay. As already mentioned applicants should attend part time at such meetings to solve potential misunderstandings and answer questions right away, which is likely to speed up the procedure.</p> <p>Member states to agree on strict and short timelines for the EU and national evaluations/authorisations.</p> <p>In the new regulation to replace Directive 91/414/EEC strict timelines are included (also for national applications based on mutual recognition/zonal approach). However, this is still under discussion in Council.</p>	National and EU level	Applicants, regulators, EFSA, the Commission, member states	2008- ...

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<b>Efficacy evaluation</b>				
<p>Potential future introduction of efficacy evaluation into the EU evaluation needs to be accompanied by a guidance document on evaluation criteria in order to obtain a harmonised efficacy evaluation between the member states.</p> <p>Authorities should accept modified trial protocols, provided that the applicant can justify the modifications (e.g. for semiochemicals and microbials)</p> <p>Long-term effects on insect populations of e.g. semiochemicals or baculoviruses should as well be considered since the effect may not be observed until the next generation or the following year.</p> <p>Data requirements should</p>	<p>EFSA should establish an efficacy expert group consisting of efficacy experts from a number of member states and the EFSA. Through meetings and other means of communication this group should draft guidance documents describing requirements for efficacy data and criteria for BCAs. It should contain guidance for each of the three groups: microbials, botanicals and semiochemicals.</p> <p>The draft should subsequently be discussed among all member states and finally be taken note of by the Standing Committee of Food Safety and Animal Health.</p> <p>However, some of the suggested changes here will need to be included in the negotiations of the new regulation e.g.: the proposal of giving authorisations for 5 years followed by data on efficacy.</p> <p>A first guidance document/position paper on efficacy for microbials has recently been prepared by the OECD-BPSG.</p>	EU and national level	EFSA and member states	2008-2009

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<p>be flexible and adapted to the special properties of the particular type of active substance.</p> <p>Products with minor beneficial effects should be acceptable.</p> <p>If the active substance is not directly applied to crops (e.g. semiochemicals) there should not be a requirement for crop destruction after efficacy trials.</p> <p>To avoid unnecessary repetition of experimental work, the use of efficacy data from other areas should be actively encouraged</p> <p>For low risk substances, it should be possible to get 5 year registrations without presenting efficacy data. During the 5 years of market use efficacy data should be generated and subsequently be presented for further</p>				

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
registrations after the 5 years.				

## 2. Microbials

For further information about each specific proposal please consult the REBECA document: Proposals for improved regulatory procedures for microbial BCA (Deliverable 10).

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<b>Baculoviruses</b>				
Annex I inclusion of Baculoviruses at a higher taxonomic level than at isolate level	A REBECA proposal was discussed among all stakeholders at a REBECA meeting and afterwards in the EU Microbial Expert Group, where the proposal was agreed upon. This proposal has now been implemented. The first Baculovirus species ( <i>Spodoptera exigua</i> NPV) was included in Annex I, and came into force on 1 <sup>st</sup> December 2007. A guidance document on the procedure was taken note of by the Standing Committee of Food Safety and Animal Health in January 2008. The proposal has thus successfully been implemented.	EU level	REBECA stakeholders, EU microbial expert group, the Commission	2007
Proposal on threshold levels for microbial contamination in Baculovirus products	The above mentioned REBECA proposal contained a table with threshold levels of microbial contaminants. This part of the proposal as well as a Canadian proposal for an OECD guidance document on threshold levels of microbial contaminants in all microbial plant protection products should be further discussed	OECD and EU level	<b>OECD-BPSG</b> , EU microbial expert group	2008-2009

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
	within the OECD BioPesticide Steering Group. The output should be an OECD agreed guidance document on threshold levels for microbial contaminants in all types of microbial plant protection products.			
<b>Data requirements</b>				
Simplified dossier preparation based on a pre-submission information package	<p>The REBECA proposal with a detailed list of information/data required for the pre-submission information package for microbials should be further discussed within a specialised group such as the EU microbial expert group as well as in the OECD BPSG. There are two possibilities: preferably an OECD guidance document should be developed alternatively the EU expert group should develop a proposal for an EU guidance document which should subsequently be discussed among all EU member states and finally taken note of in the Standing Committee of Food Safety and Animal Health.</p> <p>The document should include criteria for waivers of data and a decision tree allowing applicants to submit a simplified dossier.</p> <p>The expenses for meetings required for the EU microbial expert group to discuss the information package should be covered by the EFSA.</p>	EU level or OECD level	<b>EU microbial expert group, OECD BPSG, EFSA, all member states, the Commission</b>	2008- ...
More specific data requirements/ deletion of some data requirements/ description of waivers for a number of data	After the adoption of a new EU regulation of plant protection products (expected in 2008), it is anticipated that within 18 months from the date the regulation will come into force the present EU data requirements should be revised and transferred into one/several EU regulations.	EU level	<b>EU microbial expert group, EFSA, all EU member states, The</b>	2008-...

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<p>requirements:</p> <p>Genetic stability</p> <p>Human infectivity and other toxicological data requirements</p> <p>Exposure data</p> <p>Sensitisation</p> <p>Metabolites</p> <p>Persistence in the environment</p> <p>Eco-toxicology and non-target organisms</p>	<p>It is therefore important that the EU microbial expert group soon should start discussions on certain parts of the data requirements taking into account the lessons learned since adoption of the present data requirements. A new proposal of data requirements should be proposed and discussed among all member states and finally adopted as a new regulation not later than 18 months after the new EU regulation of plant protection products have come into force.</p> <p>Apart of a slightly revised set of data requirements, a number of guidance documents should be developed. Partners, who should be involved in preparing such guidance documents is, apart from regulators and national experts, the industry (IBMA) and academia.</p> <p>The expenses for the meetings required for the EU microbial expert group to discuss the data requirements and the guidance documents should be covered by the EFSA.</p>		<p>Commission, Industry, Academia</p>	
<b>Low risk</b>				
<p>Developing a risk index to comparatively assess environmental risks posed by microbial and conventional pest control agents.</p>	<p>The tool could in the future be used to distinguish between high and low risk active substances/product types, and thereby indicate which active substances should be included into Annex I for e.g. 15 years as opposed to 10 years (according to the Commission proposal for a new EU regulation).</p> <p>It could help member states to distinguish between high and low risk products in case these member states would like to differentiate the taxes on pesticides and fees for evaluation and authorisation of products. Further more the tool could give guidance to growers that would like to comply with rules for IPM. This will be important after the framework directive of sustainable</p>	<p>EU/OECD level</p>	<p>OECD Risk Reduction Steering group and BPSG, The Commission, EU member states</p>	<p>2008 - ...</p>

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
	<p>use of pesticides have come into force.</p> <p>The proposal should be discussed in the OECD Risk Reduction Steering Group and among member states and the Commission during the period of negotiation of a new EU regulation.</p> <p>A seminar attended by the OECD Risk Reduction Steering Group and the Bio Pesticide Steering Group on “Identification of barriers and risks for low risk plant protection products &amp; biocides” is foreseen.</p>			

### 3. Botanicals

For further information about each specific proposal please consult the REBECA document: Improved regulatory procedures for botanicals and semiochemicals and list of knowledge gabs (Deliverable No 16).

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<b>Data requirements</b>				
<p>A new guidance document should cover all plant extracts.</p> <p>Relaxation on data regarding identification of plant constituents that are not the active substance. These substances should be characterized by group analysis.</p> <p>It should not be necessary to achieve 98% closure.</p> <p>Quality assurance/manufacturing methods: The methods of manufacture should be described in an adequate manner, taking into account measures to prevent the formation of hazardous microbial decay products during manufacture.</p>	<p>EFSA should as soon as possible establish an EU expert group on botanicals. This group, consisting of RMS from the 4<sup>th</sup> list botanicals, other experts from member states, the Commission and the EFSA, should during and after the EU evaluation of the 4<sup>th</sup> list botanicals further develop the draft document SANCO/10472 and subsequently ask the Standing Committee of Food Safety and Animal Health to take note of such a guidance document on botanicals.</p> <p>Expenses for the meetings required for the EU Botanical expert group to discuss the guidance document should be covered by the EFSA.</p>	EU level	EFSA and the EU Botanical expert group, all member states	2008 - ...

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<b>Low risk</b>				
Botanicals of low risk/concern should be identified early in the application/evaluation process and be subject to reduced data requirements	In general applicants and national regulatory authorities should meet early in the application process (at pre-submission meetings) and discuss this issue in order to agree on waivers. If specific issues need further discussion, these can be put forward for discussions in the EU Botanical expert group.	EU level and national level	Applicants, RMS, Botanical expert group	2008 - ...
During the preparation of the dossier as well as during evaluation and registration the history of safe use in plant protection should be taken into account as well as the use for other purposes (e.g. food ingredients)	Regulators and applicants should discuss this issue at the pre-submission meetings and later in the process within the Botanical expert group.	EU level	RMS and Botanical expert group	2008 - ...

#### 4. Semiochemicals

For further information about each specific proposal please consult the REBECA document: Improved regulatory procedures for botanicals and semiochemicals and list of knowledge gabs (Deliverable No 16).

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<b>The process of Annex I inclusion</b>				
Collective listing of Straight-chained Lepidopteran Pheromones (SCLP) in Annex I	As already mentioned, the EFSA should establish an expert group on semiochemicals as soon as possible. When the DAR for the 4 <sup>th</sup> list group of SCLP has been finalised the EFSA should initiate a discussion within the expert group on this issue (as well as the issues below). The group should communicate their conclusion to the Standing Committee of Food Safety and Animal Health preferably as a short guidance document which the Standing Committee should take note of.	EU level	EFSA and Semiochemical expert group	2008
SCLP should be regarded as low risk substances, as defined in the draft for the new regulation of plant protection products (art. 22 and 46)	This proposal should be discussed by the Semiochemical expert group after the finalisation of the EU risk assessment of the 4 <sup>th</sup> list SCLPs (and the new regulation has come into force).	EU level	Semiochemical expert group	2008-2009
<b>Data requirements for SCLP</b>				
Relaxations on the data required for the evaluation of "impurities" which are themselves	All the proposals regarding data requirements for SCLP should be discussed in the Semiochemical expert group (consisting of the RMS for the 4 <sup>th</sup> list SCLPs, the EFSA, the Commission and several experts from member states). Either specific data	EU level and OECD level	Expert group on semiochemicals, comprising: RMS, The EFSA	2008-...

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<p>SCLP</p> <p>Relaxation on request for 5 batch analysis for SCLP that are only rarely produced</p> <p>Relaxations on the data required for evaluation of SCLPs which are used in quantities comparable to natural emissions (up to 375 g/ha per year)</p>	<p>requirements for SCLP pheromones should be developed or an EU guidance document which should subsequently be taken note of by the Standing Committee.</p> <p>In order to obtain harmonisation, these issues should also be discussed within the OECD BioPesticide Steering Group.</p> <p>The OECD-Guidance document 12 need to be revised.</p>		<p>and the Commission.</p> <p>OECD-BPSG</p>	
<b>Data requirements for other semiochemicals</b>				
<p>Case-by-case relaxations on the data required for evaluation of other semiochemicals taking into account the natural emissions and the history of exposure to the substance.</p> <p>More generic relaxations on the requested data should be envisaged when 3-5 similar substances have been evaluated.</p>	<p>As soon as there will be adequate experience on such substances within member states/the EFSA these substances should be discussed in the Semiochemical expert group and a generic approach should be taken to the extent possible.</p> <p>The issue should at that stage also be discussed within the OECD-BPSG in order to obtain harmonisation.</p> <p>This activity is not envisaged to take place within the next couple of years.</p>	<p>EU level and OECD level</p>	<p>Expert group on semiochemicals, comprising: RMS, the EFSA and the Commission.</p> <p>OECD-BPSG</p>	<p>2010?</p>
<b>Harmonisation with biocides</b>				

Proposal	Measures to obtain implementation	Level of implementation	Involved partners	Timeframe
<p>Harmonisation in the data requirements of plant protection products and biocides since semiochemicals may often be used for both purposes (where semiochemicals are used in human or veterinary medicine, harmonization should also be envisaged).</p> <p>Joint dossier submitted for registration of a semiochemical for both purposes should be accepted</p>	<p>The Semiochemical expert group should discuss this issue and come up with a proposal of harmonised data requirements and dossier format which DG Sanco should forward to DG Environment with the view of having a discussion between the two DGs and experts and thereby obtain harmonisation.</p>	<p>EU level</p>	<p>Expert group on semiochemicals, comprising: RMS, the EFSA and the Commission.</p> <p>DG Sanco and DG Environment</p>	<p>2008-2009</p>

