

# Facilitating the registration of biocontrol organisms, plant extracts and semiochemicals in Europe



## Introduction

The legal regulation of plant protection products (Dir. 91/414/EEC) is a bottleneck in the market introduction of new microbial biocontrol agents, plant extracts and pheromones. In contrast, invertebrate biocontrol agents ("beneficials") are not registered at EU level.

The EU-funded project REBECA suggested improvements to accelerate the regulation process and make it more cost-effective, without compromises to the level of safety. Representatives of all stakeholder groups participated in the REBECA workshops. The EU Commission and Member States are encouraged to improve the registration of biocontrol organisms, plant extracts and semiochemicals at EU and/or national level.

The full proposals can be found at [www.rebeca-net.de](http://www.rebeca-net.de).

## Improvements of the registration process

An inventory revealed great similarity between the EU and the USA in formal data requirements, but notable differences in implementation. The registration process could be improved as follows:

- › Improved communication between regulators and applicants is a key factor (e.g. pre-submission meetings).
- › Improved communication among regulators would harmonize the approach taken in different Member States and speed up the process.
- › Strict timelines would provide better predictability of the length of the evaluation/registration process.
- › The requirements for efficacy evaluation should be flexible, and minor beneficial effects should be acceptable.

## Improvements for microbial biocontrol agents



- › Baculoviruses present no risk to humans and non-target organisms and should be registered at the species, and not at the strain level.
- › For bacteria and fungi, REBECA suggests a hierarchical procedure for risk assessment.

## Acknowledgments

We gratefully acknowledge the contribution from many colleagues who provided their expertise within the Specific Support to Policy Action REBECA "Regulation of Biological Control Agents" ([www.rebeca-net.de](http://www.rebeca-net.de)) and the financial support by the European Commission (SSPE-CT-2005-022709).

## Improvements for plant extracts



Plant extracts contain a vast diversity of substances, and often vary from one batch to another. Some botanicals are made from plants which are used as food or feed, or for medical purposes. REBECA recommends that:

- › Requirements on analytical methods are adapted for plant extracts.
- › Measures to prevent the formation of hazardous microbial decay products should be described.
- › Substances with a history of safe use should be considered as «low concern» substances, and be subject to reduced data requirements.

## Improvements for pheromones



Semiochemicals are applied at very low doses, comparable to natural emissions. They are applied in traps, so there is no contact with the crop. They have a non-toxic mode of action on the target pests and low toxicity to mammals. REBECA suggests various relaxations for semiochemicals, particularly for the widely used "straight-chained lepidopteran pheromones" (SCLPs).

## Improvements for invertebrate biocontrol agents (beneficials)



- › For northern Europe, it should first be tested whether the insect can establish in the environment (tolerance for winter temperatures). Without establishment, other effects are unlikely.
- › In southern Europe, the climate allows year round survival and reproduction, and establishment is more likely. Here, the assessment should focus on host range.
- › REBECA has produced a standardised "Permit Application" form and an accompanying guidance document, and recommends evaluation in collaboration with EPPO\* and IOBC\*\*.

\*European Plant Protection Organization

\*\*International Organization for Biological and Integrated Control