



Deliverable 17:

SWOT analysis on improved regulatory road map based on case studies for botanicals and semiochemicals

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	SWOT analysis on improved regulatory road map based on case studies for botanicals and semiochemicals
Deliverable	17
Reporting Period	2
Contractual Date of Delivery	Project Month 21, September 2007
Actual Date of Delivery	31 December 2007

Authors	Bernhard Speiser, Lucius Tamm
Work package	WP4
Dissemination	Public
Nature	Report
Version	
Keywords	Botanicals, semiochemicals, risk assessment, improved regulatory procedures, case studies

Document History

The document is based on the results of 3 workshops (Porvoo, Finland, 6-8 May, 2007; Brussels, Belgium, June 18-19, 2007; Brussels, Belgium, September 21, 2007) and of e-mail consultations in-between these workshops. Experts from science, regulatory authorities and industry attended the meetings and reviewed the minutes, which were used to produce this document.

Document Abstract

All REBECA proposals for adapted data requirements and regulatory procedures for «botanicals» and for «semiochemicals» (see deliverable no 16) were subjected to SWOT analysis. The potential impact of the proposals on duration of the registration process and on costs of registration were identified as the two key factors determining the strength or weakness of a proposal, while the ease or difficulty of implementation of proposals was identified as the major opportunity or threat of a proposal. The document contains two tables with an overall assessment of the proposals for botanicals and for semiochemicals. Another two tables contain a semi-quantitative impact analysis for selected cases (fenugreek, neem extract, quassia, lecithine and laminarine in the case of botanicals; SCLPs in the case of semiochemicals).

Table of contents

Methods.....	3
Overall assessment	3
Assessment for case studies	4
SWOT analysis for botanicals.....	4
Overall assessment for botanicals	4
Assessment for case studies in botanicals.....	5
SWOT analysis for semiochemicals	6
Overall assessment for semiochemicals	6
Assessment for case studies in semiochemicals	7

Methods

The concept of SWOT analysis (strengths, weaknesses, opportunities, threats) was developed by economists as an analytical tool for strategic management planning. To facilitate discussions with stakeholders, this general concept was adapted to the specific questions which are most relevant in the context of pesticide regulation. In consultation with stakeholders, the potential impact on duration of the registration process and on costs of registration were identified as the two key factors determining the strength or weakness of a proposal. The ease or difficulty of implementation of proposals was identified as the major opportunity or threat of a proposal.

Overall assessment

In a first step, all REBECA proposals concerning improved regulatory procedures for botanicals and semiochemicals were assessed as follows:

- **Implementation:** whether the proposal is easy or difficult to implement. All proposals involving changes in EU legislation were scored as difficult to implement, while proposals which can be implemented in the framework of existing legislation were scored as more easy to implement. Proposals which carry major costs for regulators were scored as more difficult to implement. The scoring is based on expert judgement, with emphasis on the arguments presented by the regulators present at the workshops.
- **Potential impact on the duration:** whether the proposal will reduce the duration of the registration process to a small or a large extent. The scoring is based on expert judgement, with emphasis on the arguments presented by the industry representatives present at the workshops.
- **Potential impact on costs:** whether the proposal will reduce the costs for the applicant of the registration process to a small or a large extent. This includes costs for producing studies and for dossier preparation, as well as registration fees. The scoring is based on expert judgement, with emphasis on the arguments presented by the industry representatives present at the workshops.

These analyses was performed during the workshops on 6-8 May, 2007 and on 18-19 June, 2007 and reviewed in e-mail consultation after that workshop and during the workshop on September 21, 2007.

Key to abbreviations: implementation

- *** Implementation of the proposal is easy and/or fast
- * Implementation of the proposal is difficult and/or slow

Key to abbreviations: Potential impact

- *** The proposal has a large impact (greatly reduces duration of the process / costs for the applicant)
- * The proposal has a small impact (slightly reduces duration of the process / costs for the applicant)
- The proposal has no impact (does not reduce duration of the process / costs for the applicant)

Assessment for case studies

In a second step, a semi-quantitative estimate of the impact of all REBECA proposals concerning improved regulatory procedures for botanicals and semiochemicals on registration efforts was made as follows:

- **Botanicals:** for five selected cases, the reduction of registration costs (as a percentage) was estimated. The scoring is based on expert judgement, with emphasis on the arguments presented by the industry representatives present at the workshops.
- **Semiochemicals:** for the case of SCLPs (i.e. the great majority of all pheromones currently used), the reduction of registration time and registration costs (as a percentage) was estimated. Where adequate, it was distinguished between Annex I inclusion and national registration. The scoring is based on expert judgement, with emphasis on the arguments presented by the industry representatives present at the workshops.

These analyses was performed during the workshops on September 21, 2007.

SWOT analysis for botanicals

Overall assessment for botanicals

REBECA proposal concerning ...	Implementation	Potential impact	
		on duration	on costs
guidance document for botanicals	**	**	**
further development of SANCO/10472	**	**	**
identification and analytical methods	***	***	**
manufacturing methods (material of origin)	***	**	**
manufacturing methods (HACCP)	***	*?	*
application and use of botanicals	***	*	*
identification of low risk/concern substances	*	***	***
risk assessment	***	**?	**
efficacy data (flexible trial protocols)	**	**	*
efficacy data (minor beneficial effects)	**	**	*
efficacy data (guidance for efficacy evaluation)	***	?	?
selectivity data	***	*	**

Assessment for case studies in botanicals

REBECA proposal concerning ...	Estimates of cost reduction for the following substances:			
	fenugreek	neem extract & quassia	lecithine	laminarine
guidance document for botanicals	20%	-	-	-
further development of SANCO/10472		-	-	-
identification and analytical methods	(20%)	20%	0%	10-20%
manufacturing methods (material of origin)	10%	5%	0%	10%
manufacturing methods (HACCP)	?	5-10%	0%	15%
identification of low risk/concern substances (considered as difficult to implement within a guidance document)	20%	0-50%	20%	0%
risk assessment (history of safe use)	>50%	0%-50%	10% (already waivers)	50%
efficacy data (flexible trial protocols)	0-5%	5%	5%	0%
efficacy data (minor beneficial effects)	0-5%	5%	5%	0%
manufacturing methods (HACCP)	?	5-10%	0%	15%

Comment by the botanicals working group

The assessment indicates that the registration costs for all five botanicals would decrease substantially, if the REBECA proposals were implemented. If the 'feasible' proposals are implemented, cost reductions between 50% - 80% seem achievable. However, even in a pessimistic scenario, cost reductions of 30% - 50% seem realistic. This progress could be achieved without any compromises to safety for operators or consumers. It is therefore concluded that the implementation of the 'REBECA proposal on facilitations in the registration requirements for botanicals' will reduce registration costs substantially and that therefore, the proposals should be implemented into the current regulatory framework as soon as possible.

SWOT analysis for semiochemicals

Overall assessment for semiochemicals

REBECA proposal concerning ...	Implementation	Potential impact	
		on duration	on costs
collective listing as SCLPs in Annex I	**	***	***
'low risk' status of SCLPs (under new legislation)	(***)	(**)	*
analysis of impurities	***?	*	***
number of samples to be analyzed	*/** ?	***	***
risk assessment of SCLPs	?	***	***
risk assessment of other semiochemicals	?	***	***
efficacy evaluation (flexible trial protocols)	***	*	***
efficacy evaluation (minor beneficial effects)	**	**	**
efficacy evaluation (data from other areas)	***	***	***
registration of semiochemicals	*	***	***

Assessment for case studies in semiochemicals

REBECA proposal concerning ...	Estimates of reduction of duration and costs for Annex I inclusion and national registration of SCLPs:	
	Annex I inclusion	national registration
collective listing as SCLPs in Annex I	Duration reduced to minimal; costs substantially reduced.	Reduction uncertain, depends on local procedure
'low risk' status of SCLPs (under new legislation)	No reduction	Duration: maximum 90/60 days (90 days for initial authorization per zone; 60 days for mutual recognition); cost reduction variable
analysis of impurities	A few 1000 EUR per substance	Not applicable
number of samples to be analyzed	uncertain	Not applicable
risk assessment of SCLPs	Duration reduced ca 70%; costs ca 25-50% (several 10'000 EUR per SCLP)	Not applicable
risk assessment of other semiochemicals	Similar to SCLPs	Not applicable
efficacy evaluation (flexible trial protocols)	Not applicable	Reduction variable, depends on local procedure
efficacy evaluation (minor beneficial effects)	Variable, depending on MS	Reduction variable, depends on local procedure
efficacy evaluation (data from other areas)	Not applicable	Reduction variable, depends on local procedure
registration of semiochemicals	Cost reduction ca 100'000 – 150'000 EUR per substance	Reduction variable, depends on local procedure