



Deliverable 4:

Minutes of ASG meetings 1-4

REBECA

Regulation of Biological Control Agents

Specific Support Action

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The action steering group met two times in 2006. The first meeting took place in January and the second meeting in September 2006

Document Abstract

The ASG is in charge of the scientific supervision, strategic recommendations of the Action, to set and monitor time schedules and to monitor the use of the REBECA budget. In the minutes of the meetings recommendations and advises of the ASG are down laid.

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Kick-Off and first Action Steering Group Meeting, 24.-25. January 2006, Salzau, Germany

Participants

Anita Fjelsted, Head REBECA WP7, DEPA, Denmark
Annette Schön, EU Project Management, CAU, Germany
Bernhard Speiser, FIBL, Switzerland
Denise Munday, Chair NBB Group of IBMA, Switzerland
Guido Sterck, Head IBMA Microbials WG, Belgium
Heikki Hokkanen, Head REBECA WP6, UHEL, Finland
Hermann Strasser, Head REBECA WP3, LFU, Austria
Jeffery Bale, Head REBECA WP5, UOB, United Kingdom
Lucius Tamm, Head REBECA WP4, FIBL, Switzerland
Maria Herrero, Global Regulatory Affairs Manager, Valent Biociences, Switzerland
Miriam Döring, REBECA Secretary, CAU, Germany
Olaf Strauch, REBECA Assistant Manager, CAU, Germany
Piero Venturi, European Commission, Belgium
Ralf-Udo Ehlers, REBECA Project Coordinator, Head WP1, CAU, Germany
Richard Greatrex, Head IBMA Macrobiales WG, United Kingdom
Robin Sheppard, Head IBMA Pheromones WG, United Kingdom
Rüdiger Hauschild, Head REBECA WP2, GAB, Germany
Ulrich Kuhlmann, Head REBECA WP2, CABI-Biosciences, Switzerland
Wyn Grant, Professor of Politics at Warwick, United Kingdom

Presentations:

All speakers agreed to publish the presentations of the Kick-Off meeting on the internet page (www.rebeca-net.de)

Ralf-Udo Ehlers: REBECA Objectives
Olaf Strauch: REBECA Project Structure
Piero Venturi: European Research Programmes related to Plant Protection Systems
Rüdiger Hauschild: EU Regulation of Biological Control Agents
Lucius Tamm, Bernhard Speiser, Rüdiger Hauschild, Wolfgang Oellrich, Ulli Kuhlmann:
Review of current legislation: What should be covered?
Denise Munday: IBMA White paper on the regulation of biologicals
Hermann Strasser: Workpackage Microbials
Lucius Tamm & Bernhard Speiser: Workpackage Botanicals & Semiochemicals
Jeffery Bale: Workpackage Macrobiales
Ulrich Kuhlmann: International Regulation Practice for Macrobiales
Heikki Hokkanen: Workpackage Cost-Benefit Analysis
Anita Fjelsted: Workpackage Measures to Accelerate Regulation

Agreements, announcements and recommendations regarding the project structure and management not noted in the technical annex of the contract

Meetings:

- Dates for the meetings suggested in the contract can be handled with certain flexibility.
- The risk assessment workshops (WS1, WS2, WS3) will be carried out before the C1 conference.
- Smaller extra-meetings between WPs can be organised if necessary in order to discuss different views of working groups.
- The C1 conference will be held on September 18-22, 2006 at Salzau, Germany.
- It was decided to hold the WS4 (stakeholder meeting industry), WS5 (stakeholder meeting regulation) and WS6 (risk benefit analysis) together with the C1 conference.
- The leader of WP6 (risk benefit analysis, Heikki Hokkannen) might not be able to attend the C1 conference.
- Participation at the workshops is mainly restricted to invited experts to maintain the working atmosphere.
- The conferences are open to interested experts.
- It was recommended to choose Brussels as a preferred meeting place in order to facilitate the participation of EU officials.
- It was recommended to choose meeting places located close to airports in order to promote the participation of regulation authorities.
- Costs for meeting places should be reasonable to stay within the available budget.
- The C2 conference on balanced regulatory testing will be held in or close to Brussels.
- The next and the final action steering group meeting will be held in Brussels.
- The expert list in the technical annex of the contract is open. Experts should be contacted directly by the WP leaders.
- Experts of the EFSA should be invited to the risk assessment meetings (at least for microbials, botanicals and semiochemicals).

Internet page:

- The internet page will be published first under www.rebeca-net.de because, the EU domains will be not allocated before the mid of April 2006. Later on the internet page will be moved to www.rebeca.eu.
- E-mail addresses on the webpage will be implemented in a way which makes them invisible for spam sending programs.
- A newsletter function will be integrated.
- Confidential documents will be not published on the web page.

Agreements, announcements, remarks and recommendations regarding the work-packages

WP2: Inventory of current legislation and guidance documents

- The inventory must be ready for the C1 conference.
- GAB, FiBL and CABI considered whether they should use a questionnaire. It was objected that this approach will depend too much on cooperativeness and quick response.
- Regulatory experts/officials will be identified and directly contacted for open questions.
- The project partners involved in the compilation of the regulation inventory should coordinate their work (approach regulation authorities ect.)
- The EU regulation practice will be compared to that of the Switzerland, USA, Canada, Australia, New Zealand.
- No EU member country rules must be considered for microbials, semiochemicals and botanicals.
- It was recommended to carry out detailed case studies comparing the registration requirements, time scale and costs for products registered in the EU and the reference countries.
- Microbial extracts will be covered by FiBL together with botanicals on a voluntary basis and not as a contractual obligation.

General remarks

- WP6 needs input and feedback from the other WPs (risks and benefits of BCAs, costs for registration ect.)
- WP7 needs input and feedback from the other WPs (regulation inventory, registration costs, risk assessment methods, lists for low risk products ect.)
- A strong lobby able to promote REBECA are food trading companies due to the public demand for food free of pesticide residues.
- Some participants supports the suggestion to establish international expert groups able to assess BCAs before registration according to 91/414 to enable fast track decisions.
- It was recommended to investigate if and how the QPS (Qualified Presumption of Safety) system can be applied on all groups of BCAs.
- The question was raised if the harmonisation process of the regulation of macrobials does make an EU directive necessary? No decision was taken how this should be followed up.
- Information on how low risk candidates are handled, are available from the EPA, Canada, Australia ect.
- Some participants support the thesis that the research for risk assessments should be publicly funded if there is no scientific evidence for major risks.

- It was suggested that lowering the registration fees for low risk products like BCAs need to be considered by EU member state governments in order to keep such product types on the market.
- It was suggested to consider weed biocontrol agents. No decision was taken how this should be followed up.

Action Steering Group Meeting, 22. September 2006, Salzau, Germany

Participants:

Anita Fjelsted, Head REBECA WP7, DEPA, Denmark
Bernhard Speiser, FIBL, Switzerland
Hermann Strasser, Head REBECA WP3, LFU, Austria
Jeffery Bale, Head REBECA WP5, UOB, United Kingdom
Lucius Tamm, Head REBECA WP4, FIBL, Switzerland
Olaf Strauch, REBECA Assistant Manager, CAU, Germany
Ralf-Udo Ehlers, REBECA Project Coordinator, Head WP1, CAU, Germany
Rüdiger Hauschild, Head REBECA WP2, GAB, Germany
Ulrich Kuhlmann, Head REBECA WP2, CABI-Biosciences, Switzerland
Wyn Grant, University of Warwick, United Kingdom

Preface

The action steering group met directly after the official end of the Salzau workshop in September 2006. Wolfgang Reinert from SANCO joins the ASG meeting only in the beginning for comments on the first topic.

Résumé of the Salzau workshop on 'Current Risk Assessment and Regulation Practice'

All participants agreed that it was a well organised and fruitful workshop. Wolfgang Reinert acknowledged the constructive working atmosphere in the working groups.

Annual Report

It was decided that a draft annual report should be delivered until the beginning of December 2006. Every workpackage leader should deliver a summary of the activities in 2006 all relevant documents (minutes of meetings, questionnaires, studies).

Responsibilities:

Olaf Strauch, Ralf-Udo Ehlers:

Annual Report Summary, Workpackage 1 report.

Rüdiger Hauschild, Bernhard Speiser, Ulrich Kuhlmann, Antoon Loomans:

Comparative Studies on the current regulation of BCAs (Workpackage 2)

The studies for microbials, botanicals and semiochemicals will be combined in order to avoid a duplication of work (Rüdiger Hauschild, Bernhard Speiser). Ulrich Kuhlmann will deliver comparative study for macrobials outside the EU and Antoon Loomans a comparative study for the EU member states.

Hermann Strasser, Olaf Strauch:

Workpackage 3 report

Lucius Tamm, Bernhard Speiser:

Workpackage 4 report

Jeffery Bales:

Workpackage 5 report

Heikki Hokkannen, Ingeborg-Menzler Hokkannen:

Workpackage 6 report

Anita Fjelsted:

Workpackage 7 report

Meeting schedule

It was decided to postpone the workshop on 'risk benefit analysis' to 2007

Future Activities

It was recommended to raise the awareness for the REBECA action in other stakeholder groups like environmentalists, food industry and retailers.

A plan for the REBECA meeting budget should be created until the end of the year.

Minutes: ASG Meeting, January 29, 2007, Kiel, Germany

Participants

Jeffery Bale, University of Birmingham, United Kingdom
Ralf-Udo Ehlers, Christian-Albrechts-University Kiel, Germany
Anita Fjelsted, Danish Environmental Protection Agency, Denmark
Rüdiger Hauschild, Head REBECA WP2, GAB, Germany
Heikki Hokkanen, University of Helsinki, Finland
Ingeborg Menzler-Hokkanen, Helsinki, Finland
Bernhard Speiser, FIBL, Frick, Switzerland
Hermann Strasser, Leopold-Franzens-University, Innsbruck, Austria
Olaf Strauch, Christian-Albrechts-University Kiel, Germany

Preface

This meeting was in place to

- summarize the results of the Action obtained in the first year (2006)
- plan the activities and time schedule for the second year
- preparation of the annual report 2006

Agenda

First topic: Get organized for the last year

1. Major achievements of REBECA in your field of responsibility
2. What needs to be done until the end of the action?
3. How is this organised? Workshops/Meeting, suggestions for 2007.

09:00 Hermann Strasser: Microbials

09:30 Bernhard Speiser: Botanicals Semiochemicals

10:00 Rüdiger Hauschild: Comparative Studies Microbials, Botanicals, Semiochemicals

10:30 Jeff Bale: Macrobiales

11:00 Anita Fjelsted: Regulator Proposals

11:30 Heikki Hokkanen: Risk-Benefit Analysis

12:00 Olaf Strauch: Internet page, Budget available for 2007

12:30 Final Discussion

Second topic: Annual report

14:00 Olaf Strauch: Status of the Report

14:15 Discussion

Third topic: Plan final Conference in Brussels 2007

14:45 Ralf-Udo Ehlers: Conference date and location

15:00 Discussion

Forth topic: Political strategy to promote easier registration for BCAs in Europe.

15:30 Discussion

18:00 Dinner

Micorbials:

1. Pessimistic experiences on the 4th list evaluation of microbials were reported.
2. A position paper on “**Relevant metabolites**” is still outstanding. Ehlers and Hauschildt will produce a structure for a position paper by Febr. 7 and Strasser will fill it with data and information by March 9, 2007. This position paper will be discussed and improved by e-mail correspondence with REBECA experts and Alan Vey (INRA), Tariq Butt (Swansea Univ.) Claudio Altomare (Institute of Sciences of Food Production of the Italian National Research Council, Bari), Fergal O’Gara (Cork Univ.), Trevor Jackson (AgResearch, NZ), Gabi Berg (Univ. Graz), Stefan Jaronski (USDA-ARS Montana), Tobias Längle (Agriculture and Agri-Food Canada, Ottawa); Ulf Heilig (IBMA). Results will be presented by Strasser at a REBECA session during the IOBC/WPRS working group “Insect pathogens and insect parasitic nematodes” meeting in Alés, France, 3-7 June 2007.
3. **Environmental aspects** like residue chemistry and environmental fate are issues which are of little concern for risk assessment of products containing MBCAs. However, regulation authorities in Europe often require proper ecotoxicological evaluations. EPA waived those studies in most cases. We think that sufficient data are available to be able to waive data on

the environmental and ecotoxicological effects of MBCAs. Strasser and Strauch are preparing a workshop to be held during the IOBC/WPRS working group “Insect pathogens and insect parasitic nematodes” meeting in Alés, France, 3-7 June 2007, which will present scientific knowledge in the field and discuss these aspects following the expert presentations. From the result of this workshop REBECA will prepare a position paper.

4. Review of test systems for human health risk assessment: Data are required for toxicity, pathogenicity, and infectivity. During the Innsbruck meeting it was discussed whether the test systems are accurate or adequate to assess risks related to the use of MBCAs. The following points should be discussed (the yellow marked are likely the most important points):

5 Toxicological and Exposure Data and Information on the Microbial Pest Control Agent

5.1 Summary: potential of microbial pest control agent to be hazardous to humans with consideration of its pathogenic potential, its ability to infect and pattern of clearance, and its toxicological effects

5.2 Occupational health surveillance report on workers during production and testing of MPCA, including information on: see IIM 5.2.1 to 5.2.4. Published reports of adverse effects, especially reports of clinical cases and followup studies. Proposed first aid measures and medical treatment.

5.2.1 The sensitisation and allergenic response of workers

5.2.2 Details on any occurrence of hypersensitivity and chronic sensitisation

5.2.3 Any significant clinical findings related to exposure, with special attention to those whose susceptibility may be affected.

5.2.4 Published reports of adverse effects, especially reports of clinical cases and followup studies; list databases and key words used in a literature search.

5.2.5 Proposed first aid measures and medical treatment

(5.3) Basic studies

(5.3.1) Sensitisation properties

5.3.2 Acute oral infectivity, toxicity and pathogenicity

5.3.3 Acute intratracheal/inhalation infectivity, toxicity and pathogenicity

5.3.4 Acute intravenous/intraperitoneal infectivity

5.3.5 Genotoxic potential, especially for fungi and actinomycetes: a discussion of the potential for genotoxin production based on the relationship of the micro-organism to a genus/species known to produce genotoxins. If a related fungus/ actinomycete produces a genotoxin, either an appropriate and sensitive analytical test (e.g. HPLC) must be done to detect its presence in the MPCA (for Canada), or genotoxicity testing is required (for EC).

5.3.6 Cell culture study, for viruses and viroids or specific bacteria and protozoa with intracellular replication

5.3.7 Short-term toxicity (including inhalatory short-term toxicity), pathogenicity, infectivity

5.3.7.1 Short-term toxicity, pathogenicity, infectivity (28-day minimum)

(5.3.7.2) Inhalatory short-term toxicity

5.4 Toxicity studies on metabolites (especially toxins)

5.5 Other/special studies

(5.5.1) Specific toxicity, pathogenicity and infectiveness studies

(5.5.2) *In vivo* studies in somatic cells

(5.5.3) Genotoxicity - *In vivo* studies in germ cells

5.6 Summary of mammalian toxicity and overall evaluation

- 7 **Toxicological Studies and Exposure Data and Information for the Microbial Pest Control Product**
- (7.1) Acute toxicity studies
- 7.1.1 Acute oral toxicity
- 7.1.2 Acute percutaneous (dermal) toxicity
- 7.1.3 Acute inhalation toxicity to rats
- 7.1.4 Skin irritation
- 7.1.5 Eye irritation
- 7.1.6 Skin sensitisation
- 7.2 Operator, bystander and worker exposure: monitoring data
- 7.3 Operator and bystander exposure: reporting of hypersensitivity incidents before and after registration
- 7.4 Safety data sheet for each additive
- 7.5 Supplementary information on all data points in part 7: Effects on Human Health, if it is recommended that MPCP be tank-mixed with an adjuvant or another pest control product.
- 7.6 Summary and evaluation of health effects

Possibly other test systems might be included. Hermann Strasser is planning a meeting in Innsbruck June 22 - 23, 2007 to prepare position papers and summarize research needs for test systems.

5. Virus document: **After comprehensive preparation and discussions during the Innsbruck and Salzau Workshops, Rüdiger Hauschildt has summarized the REBECA position paper on the regulation of Baculoviruses: Proposal on Facilitations in the Regulation of Plant Protection Products containing Baculoviruses. It was sent around to relevant organisations for comments. After receiving the comments, the document will be presented as an official REBECA position paper on the webpage. The document lacks the REBECA logo, which would better indicate that this is a result of the REBECA activities.**

Botanicals and Semiochemicals

SANCO 10472 was identified as a very useful approach. However, its scope in terms of plant extracts covered is currently very narrow, and the document could be improved by broadening its scope.

As the identification of a product as “Low Risk Product” is an “ex-post” evaluation decision, it is of little help for REBECA’s aim of facilitating BCA registration. Therefore, we need to consider also approaches which allow “ex-ante” evaluations (like the QPS approach).

In the draft for the new regulation “Basic Substances” (page 33 Article 23) are mentioned. These substances get an approval for an unlimited period of time. Important to mention is that the risk of these substances is assessed “ex ante”: “By way of derogation from Article 5, a basic substance shall be approved where any relevant evaluations carried out in accordance with other Community legislation, regulating the use of that substance for purposes other than as a plant protection product, show that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect

on the environment.” It was proposed to prepare a list of candidates for this list and consider public notifiers.

FIBL is planning a workshop for botanicals & semiochemicals in June in Brussels. Strategies will be outlined proposing alternative regulation strategies based on the results of the past workshops. These strategies will be subjected to a SWOT analysis.

During the Salzau workshop it was concluded that OECD 12 document on semiochemicals should be adopted within the EU regulation process. Ehlers proposes to reach an agreement on SCLP similar to that for the insect viruses. He also indicates that pheromone experts have indicated that coleopteran pheromones can be included as their structure is similar to SCLPs. These proposals can be discussed at the Brussels workshop in June.

Comparative studies on the current regulation practice

Inventory study on microbials was presented by Rüdiger Hauschildt. The study on botanicals and semiochemicals as well as general aspects of regulation was not ready yet but has been supplied in the meantime. It was proposed to include the conditions on microbial products in Italy into the study. A detailed analysis of waivers was provided by Bill Schneider during the Salzau meeting. This should also be included in the study. Data on number of employees at EPA might also help to show the differences in the systems. In the final document clear recommendations should be given which can be drawn from the results of the studies.

The study on macrobials was provided by Uli Kuhlmann summarizing the situation outside of the EU. The study on the situation in the EU by Anton Loomans was not provided and is still not ready. We expect it to be available by Friday, Febr. 8 to include it into the interim report.

Macrobials

Jeff Bale reported on the progress and future activities. WP 5 (Assessment of protocols for microbial invertebrate biocontrol agents) will carry out 3 small group meetings in 2007 prior to the second workshop in July.

1. March, 2007: Rotterdam, The Netherlands: Development of environmental risk assessment procedures (ERAs). About 10 experts are expected to participate.
2. April 10 - 12, 2007: CABI Delemont, Switzerland: Structure for safety data requirements to be used for maintenance and updating of the EPPO positive lists for beneficials. Few experts will prepare a document.
3. Preparation of a guidance document for regulators and industry based on the Bigler *et al.*, 2005 article in *Biocontrol News and Information*.

NB: A report of ERA for nematodes has been prepared by Ralf Ehlers and Itamar Glazer

The second workshop will be held in the period July 4 – 7, 2007, location yet to be confirmed. This workshop will discuss the recommendations emanating from small group

meetings and the 'Kuhlmann' template for a Europe-wide regulatory system for non-native species..

An important issue would be mechanism of implementing a pan-European system and whether this was best achieved on a voluntary or legislative basis. It was proposed that SWOT the possible alternatives (EPPO or EFSA or other organization) should be made before a conclusion was drawn.

Industry

Ehlers reported about discussions with industry representatives and IBMA UK, which proposed a meeting with industry representatives of companies which have a registration or have products in the process of evaluation. It should target discussions to reach an agreement on a common strategy for industry within REBECA. This meeting will be held in July and first meet in the 4 groups: Microbials (to be organized by Richard Greatrex), Microbials (Ulf Heilig and Ralf-Udo Ehlers), Semiochemicals (Owen Jones) and Botanicals (N.N.). Afterwards a plenum meeting will discuss the general items.

Regulation

Anita is planning several meetings:

1. Meeting for regulators of micro-organisms and semiochemicals (DG SANCO, OECD regulators, EFSA) 26 April in Braunschweig, Germany.
2. Meeting for regulators of micro-organisms before/after WS Innsbruck June 22 – 23 (DG SANCO, EU member states, EFSA)
3. Meeting for regulators of botanicals and semiochemicals before/after WS Brussels June (DG SANCO, EU member states, EFSA)
4. Meeting for regulators of invertebrate biocontrol agents before/after WS July 4 - 6 (EU member states) (Anita Fjelsted would not be able to attend/organise that meeting)

Issues to be discussed during these meetings:

EU evaluation process. Can it be changed? Can we speed it up? How?

Data requirements. Suggestions for further explanation/specification and changes

Survey reports for 4th list micro-organisms (table showing whether notifiers submitted studies/ literature/waivers on the various data requirements)

Compare and discuss survey reports for the fungi, bacteria and virus. Which conclusions can be drawn from the tables? Can they be used by future notifiers as indication of acceptability of waivers? Based on the information in these surveys, can we suggest changes to and/or more detailed specification of certain data requirements?

The possibility of preparing similar survey reports should be discussed among botanical regulators.

Lessons learned documents for semiochemicals and microorganisms. Agreement on authors, titles, timelines. The possibility of preparing similar lessons learned documents should be discussed among botanical regulators.

Increased co-operation and coordination on regulation of PPP and Biocides (between DG SANCO and DG ENVIRONMENT as well as national regulators)

OECD Biopesticide Steering Group (BPSG) papers on Contaminants and Genotoxicity

Discuss issues raised by several participants of the Salzau conference regarding the lack of knowledge/expertise/experience in the regulatory authority in highly specialised areas.

- Development of expert panels (EFSA)/centralised risk assessment and registration
- Training of experts
- Guidance documents (OECD, EU). Will they really help?

Communication between regulators and notifiers: What have we done and learned during our work with the 4th list substances?

Further discussions on the possibilities of reduction of registration fees.

Any further national/EU political development/discussions requiring further alternative products on the national markets?

Metabolites/toxins – which are relevant? Lessons learned during 4th list work.

Possibility of further harmonisation regarding efficacy data required

Analysis of drawbacks and benefits of regulation

A workshop is planned in Helsinki, Finland on May 9 – 11, 2007. The following structure is proposed:

1. Results of prior workshops on the identified risks of biological products will be presented
2. Results on a survey among several biocontrol companies on the costs of regulation will be presented
3. Workshop participants will be asked to summarize their thoughts on benefits and tradeoffs of regulation in smaller groups
4. Presentations from experts.
 - PSD and Goenog: Why have they initiated their programmes
 - SANCO: History and principles of regulation of BCAs
 - PAN: Risks related with alternative PPPs
 - IFOAM/FIBL: Need for plant protection products in Organic farming

- Risk perception in modern societies
 - Greenpeace: Illegal use of PPP and residues
 - EU and member state reduction programmes (ENDURE)
 - IBMA
 - Externalized costs of synthetic PPPs
5. Final discussions

General aspects

In general, all recommendations, studies, position papers etc. must clearly indicate that they are a product of the REBECA Action. Please use the REBECA headline and logo. The results of the Action will be published in a book. Publisher will be Springer in the Series "Progress in Biological Control". Negotiations are ongoing. Please refrain from publishing anything without prior agreement.

SANCO has invited us to discuss progress and future activities after submission of the report in March 2007.

Financial aspects were presented by Olaf Strauch. Due to fewer experts than expected and lower costs we spent 70.000 less than planned. No changes will be made to the individual partner's budgets. Several participants stressed that they spend much more time on the REBECA activity than planned and supported by the EU funds.

The final conference will be at the SAS Radisson Hotel in Brussels during September 20-21, 2007. At 13:00 the results will be presented to the Commission, policy makers and regulation. The meeting is open for participation of all stakeholders. We will limit the support to members and representatives of policy makers and interest groups. The meeting will start with a small lunch at 11:00. Industry will be invited to present some of their products. On the next morning detailed information will be made available in smaller groups divided according to the WPs. Final comments will be gathered during that meeting. The co-ordinators asked all partners to help in gathering contact addresses of politicians and interest groups.

We will meet with all participants and the Action Steering Group to prepare the meeting on September 10-11, 2007 in Kiel.

Minutes: ASG Meeting, September 10-12 2007, Kiel, Germany

Participants

Claude Alabouvette, INRA Dijon, France
Jeffery Bale, University of Birmingham, United Kingdom
Ralf-Udo Ehlers, Christian-Albrechts-University Kiel, Germany
Anita Fjelsted, Danish Environmental Protection Agency, Denmark
Wyn Grant, University of Warwick, United Kingdom
Rüdiger Hauschild, Head REBECA WP2, GAB Consulting, Germany
Heikki Hokkanen, University of Helsinki, Finland
Ingeborg Menzler-Hokkanen, Helsinki, Finland
Bernhard Speiser, FIBL, Frick, Switzerland
Hermann Strasser, Leopold-Franzens-University, Innsbruck, Austria
Olaf Strauch, Christian-Albrechts-University Kiel, Germany

Preface

This meeting was carried out in order to

- prepare the final conference of the Action in September 20-21, 2007
- agree on the content of a book and on a publisher for the REBECA results

Agreement on the conference programme for Brussels September 20-21, 2007

Presentations (September 20):

Chair: Gabi Berg (Denise Munday)

13:00

REBECA -Perspectives for safer plant protection
Ralf-Udo Ehlers, University Kiel, Germany

13:30

Trade-Off Effects of Current Regulation Practice
Heikki Hokkanen, University Helsinki, Finland

14:00

Risks and Regulation - Are they in balance?
Claude Alabouvette, INRA, France

14:30

Specific Proposals to Improve Regulation of Microbial PPP
Hermann Strasser, University Innsbruck, Austria

15:00 Coffee Break

15:30 Specific Proposals to Improve Regulation of Botanical and Semiochemicals
Lucius Tamm, FIBL, Switzerland

16:00 Specific Proposals to Improve Regulation of Macrobiales
Jeff Bale, University Birmingham, United Kingdom

16:30 General Proposals to Improve Current Regulation Practice
Anita Fjelsted, EPA, Denmark

17:00-18:30 Round Table Discussion

REBECA Proposal for Innovative Regulation of BCAs
(Moderator: Ralf-Udo Ehlers, University Kiel, Germany)

Wyn offers to do a language check of the presentations
All presentations needs to ready on September 17

Round table (September 20)

The round table will be chaired by Ralf-Udo Ehlers. He will introduce the participants (background and affiliation). In the beginning of the round table discussion each participant will ask for a statement regarding defined questions and the auditorium will be allowed to put questions to the participants afterwards.

1. Pendlington: What role can supply chain relationships play in encouraging the use of biocontrol?
2. IFOAM: What are the problems of using biocontrol in organic farming?
3. Denis Munday, IBMA: What can be done to improve the dialogue between regulators and industry?
4. Kersti G., KEMI: How can the dialogue between stakeholders be continued and with what objectives?
5. Steve L., CPL: What are the main limitations on developing the biocontrol business?
6. Meeussen, CTB, OECD: What are the opportunities and the problems of implementing the REBECA proposals?
7. Wyn Grant, Univ. W.: Why is there not more political support for biocontrol?
8. Environment, (Sharon Cheek?): What are the primary environmental benefits and concerns about biocontrol?

The round table discussion will be continued on the following topics:

- Identify which issues are most important in terms of developing biocontrol
- New regulations
- What would be easy to implement and what are the problem areas?

Workshops (September 21)

Microbials

Chair: Ralf-Udo Ehlers; Minutes: Olaf Strauch

- 8.30 Welcome. Introduce Panel: Anita, Claude, Heikki, Rüdiger, Hermann
15 Ralf Exclusion of topics
- 8.45 Rüdiger and Hermann
Checklist 30
Metabolites 30
Genetic stability 10
Ecotoxicology 20
- 10.30 Coffee break
- 11.00 Hermann + Claude: Identification of knowledge gaps: e.g.
Sensitisation
Heikki + Anita: Implementation and beyond REBECA
- 12.30 End of workshop. Lunch buffet.

Botanicals

Chair: Lucius Tamm; Minutes: Ingeborg Menzler-Hokkanen

- 8.30 Welcome. Participants introduce themselves.
- 9.00 Identification of 2 – 3 typical botanicals. Check, whether the REBECA proposals fulfil their aims in these cases. If necessary, improvement of the proposals.
- 10.00 What must be done for the implementation of these proposals?
- 10.30 Coffee break
- 11.00 Discussion of the IBMA proposal to introduce similar facilitations for “biochemical substances” as those described for botanicals.
1. What substances are covered by “biochemical substances” which are not botanicals, and vice versa?
2. Are the proposals for botanicals adequate to these substances?
3. How to proceed?
- 11.30 How to make progress with “standardized waivers”.
1. Issues of data protection
2. What can industry do? What can regulators do?
3. How to proceed?
- 12.00 Identification of knowledge gaps. Any other issues; feedback round.
- 12.30 End of workshop. Lunch buffet.

Semiochemicals

Chair: Bernhard Speiser; Minutes: ?????

- 8.30 Welcome. Participants introduce themselves.
- 9.00 Check, whether the REBECA proposals fulfill their aims for SCLPs. If necessary, improvement of the proposals.
- 10.00 What must be done for the implementation of these proposals? What can be done / what should be done at the level of biocides?
- 10.30 Coffee break
- 11.00 How to make progress with “standardized waivers”.
1. Issues of data protection
 2. What can industry do? What can regulators do?
 3. How to proceed?
- 12.00 Identification of knowledge gaps. Any other issues; feedback round.
- 12.30 End of workshop. Lunch buffet.

Macrobials

Chair: Jeff Bale; Minutes: Emma Hunt

- 8.30 Welcome and introductions
- 8:45 Discussion of circulated documents: Application Form
Guidance document
ERA methods (insects and mites)
ERA methods (nematodes)
- 10.30 Coffee break
- 11.00 Discussion: Methods for dissemination of recommendations to regulators

Preparation and availability of documents

The following documents will be available on the internet and be provided at the conference. All conference participants will be informed on September 17 that the documents can be downloaded from the REBECA web-page.

Macrobials:

Application form
Guidance document
ERA methods
ERA for nematodes
Positive List and Expert Group

Microbials

Deliverable 10
Baculovirus proposal

Botanicals & Semiochemicals

Deliverable 16

General proposals

Deliverable 27

Poster preparation

Each workpackage will produce 1-2 posters introducing the REBECA project and summarizing the results.

Introduction of the REBECA Action	Olaf Strauch, Ralf-Udo Ehlers
Regulation of beneficial insect, mites and Nematodes	Jeffery Bale
Regulation of virus	Rüdiger Hauschild
Regulation of bacteria and fungi	Hermann Strasser
Regulation of semiochemicals	Bernhard Speiser
Regulation of botanicals	Lucius Tamm
Trade-offs and cost-benefit analysis	Heikki Hokkanen
General proposals	Anita Fjelsted

A template for the posters will be prepared by Olaf Strauch. Posters need to be ready at September 17.

Agreed proposal for the REBECA Book

“Regulation of Biological Control Agents in Europe”

In Springer Series: Progress in Biological Control

Chapters General Aspects

Ehlers, Lüth: Biocontrol: Economic and Perspectives

Bode (Strauch + Ehlers): History of BCA regulation

Ehlers: Risks and trade-off analysis of regulation

Hokkanen: Cost-benefit analysis of regulation

Grant: Stakeholders and policy aspects

Hauschild+Tamm+Speiser: A Comparative analysis of regulation practice in the EU and other OECD countries

Reinert + Pitton: Proposal for a new EU regulation and potential consequences for biological control

Kuhlmann and Loomans: Regulation practice with invertebrate biocontrol agents in inundative and classical biological control

Tamm + Speiser: Regulation in organic farming

Chapters: Risks and risk assessment

Alabouvette: Microbial BCAs and risks

Berg: Bacterial ecology and risk aspects

Strasser + REFCAB: Toxicology of fungal metabolites

C. Regnault-Roger: Potential risks related to the use of botanicals and semiochemicals

DeClerk: The Harmonia invasion

Chapters: Proposals for innovative regulation procedures

Hauschild: Baculoviridae

Strasser, Ehlers, Hauschild, Fjelsted, Strauch: Bacterial and fungal BCAs

Speiser + Jones: Semiochemicals

Tamm: Botanicals

Bale: Macrobiales

Fjelsted: Proposals to accelerate EU regulation

ASG Meeting Copenhagen, November 12 + 13, 2007

Participants

Claude Alabouvette, INRA Dijon, France
 Jeffery Bale, University of Birmingham, United Kingdom
 Ralf-Udo Ehlers, Christian-Albrechts-University Kiel, Germany
 Anita Fjelsted, Danish Environmental Protection Agency, Denmark
 Rüdiger Hauschild, Head REBECA WP2, GAB, Germany
 Heikki Hokkanen, University of Helsinki, Finland
 Ingeborg Menzler-Hokkanen, Helsinki, Finland
 Bernhard Speiser, FIBL, Frick, Switzerland
 Hermann Strasser, Leopold-Franzens-University, Innsbruck, Austria
 Olaf Strauch, Christian-Albrechts-University Kiel, Germany

Preamble

The meeting was setup in order to discuss and to work on the content of the second periodic and final report. Furthermore, the content, editorship and publisher of a book were discussed.

Table on responsibilities for the second periodic and final report

For details please see the comments below. All draft versions of the deliverables should be available at the end of November. The draft versions of the chapters for the final report should be available at the mid of December. The final versions should be available at the mid of January. Every workpackage leader has to prepare a summary on the 2007 activities (please see the templates in the 'REBECA Activity Report 2007.doc'. Every REBECA member has to prepare the cost-statements.

Responsible person	Action to be taken Periodic report 2007	Final report
Anita Fjelsted	D27: Final version D28: Draft version D30: Draft version	General proposals New regulation Plan for implementation of results
Bernhad Speiser Lucius Tamm	D16: Final version D17: Final version D18: Final version D29: New Regulation	Botanicals Semiochemicals
Claude Alabouvette	D11: Knowledge gap: mixtures of micorbials	
Heikki Hokkanen	Minutes of the Porvoo Meeting D24: Draft version D25: Draft version	Risk benefit analysis Impact on industry

Responsible person	Action to be taken Periodic report 2007	Final report
Ingeborg Menzler-Hokkanen	D26: Draft version	
Hermann Strasser	D10: Explanation of every step in the metabolite assessment scheme D12: Draft version D28: Risk index	Microbials
Jeffery Bale	D19: Final version D20: Final version D21: Final version D22: Final version D23: Final version	Macrobials
Olaf Strauch	Updating Webpage D10: Final amendments D11: Draft version	Summary Objectives Microbials Impact on science Exploitable knowledge and its Use Dissemination of knowledge Publishable results
Ralf-Udo Ehlers	D29: Draft version	Summary New regulation Impact on industry Impact on science
Rüdiger Hauschild	D8: Final amendments D10: Baculovirus, final amendments	

Deliverables for the second periodic report

D5: Minutes of discussions on workshops and conferences

The Porvoo minutes are missing (will be delivered by **Heikki Hokkanen**).

D8: Inventory documenting the current regulatory practice and data requirements on microbials, botanicals, semiochemicals and macrobials

Inventory on microbials, semiochemicals and botanicals

The Commission criticized the table concerning the timeline registering microbials. The table should not be changed but the differences of the timelines in the USA and the EU and the reasons for delays should be commented more detailed. Some explanations should be included into the heading of the table.

The timelines for national registration should be mentioned. Regarding national registration prior to Annex1 inclusion it should be mentioned that this is only exceptionally authorized and if so usually only in the RMS.

It should be mentioned that in the comparison of the USA and the EU biocides are not included.

The amendments will be applied by **Rüdiger Hauschild**

Inventory for macrobials

The inventory on “regulation of invertebrate biological control agents in Australia, New Zealand, Canada and the USA: recommendations for Europe in its pursuit of a harmonised regulatory system” from Uli et al. will be replaced by the review article in J. Appl. Entomol.

D10: Proposals for improved regulatory procedures for microbial BCAs

Each step in the scheme on metabolite assessment should be explained in the text. Exposure is not considered in the scheme so far. Amendments will be applied by **Hermann Strasser**.

In some clauses the proposals can not be easily identified. This needs clarification. **Olaf Strauch** will deliver a draft for improvements and arrange final amendments with **Hermann Strasser**, **Claude Alabouvette**, **Anita Fjelsted** and **Rüdiger Hauschild**.

In the Baculovirus document it should be mentioned that a prior document, which was used to produce the EU guidance document, recommended the inclusion at the species level, whereas during the discussion at the Salzau meeting and in the final deliverable inclusion at the family level is prioritized. It might be mentioned that first virus products are already registered following that REBECA proposal. This amendments will be carried out by **Rüdiger Hauschild**.

D11: List defining knowledge gaps for microbial BCAs

The following knowledge gaps were identified:

1. Development for risk assessment methods better adapted to microorganisms
 - 1.1. Methodology to assess toxicity and toxigenicity
 - 1.1.1. Validation of described methods (RAFBCA)
 - 1.1.2. Development of new methods
 - 1.1.3. Validation of the assessment scheme metabolites
 - 1.2. Methodology to assess infectivity
 - 1.2.1. Using *C. elegans*
 - 1.2.2. Using other organisms
 - 1.3. Sensitisation
 - 1.4. Genotoxicity
 - 1.5. Non-target effects

2. Pathogenicity against non-targets other than humans
3. Natural occurrence and exposure (colonisation) of humans to microbials/metabolites (Danish epa already doing it)
4. Definition of low risk
5. How to assess mixtures of microbials in one product

Olaf Strauch will prepare a draft on points 1.-4. and **Claude Alabouvette** on 5. These drafts will be circulated to **Ralf-Udo Ehlers** and **Hermann Strasser**. The final version will be prepared by **Olaf Strauch**.

D12: Positive list for “low risk” candidates

Content:

- Baculoviruses
- Experts opinions on existing bacterial and fungal products (as presented in Salzau)
- List of all agents with a history of safe use
- Risk index examples

Hermann Strasser will prepare a draft, which will be circulated to Olaf Strauch, Rüdiger Hauschild, Claude Alabouvette and Anita Fjelsted at the end of November, and the final version.

D 19: Draft guideline for hierarchical regulatory system for microbial BCAs

Was up-dated by Jeff Bale and we will replace the old version with the new

D24: Cost, trade-off, and benefit analysis

Table of contents

- Introduction
- BPPP registration: company survey
- Time
- Cost
- R & D
- Company strategy
- Tradeoffs of regulations
 - Plant protection - farmers
 - Consumers and food safety

Objectives:

- (i) To analyse how the level of regulation impacts the development and market access of BCAs
- (ii) To analyse whether the level of regulation has had an effect on the documented or suspected environmental or health hazards caused by BCAs

A draft version will be produced by **Heikki Hokkanen** and **Ingeborg Menzler Hokkanen**.

D25: Report of WS 6 “Balancing the Benefits and Costs of Regulating Biological Plant Protection Products”

Table of contents:

- Background of the workshop
- Synthesis of the workshop outcomes
- Impact of regulations on BCA research and development, and market access
- Benefits and trade-offs of the current regulation system in the EU
- Environmental and health risks of different plant protection methods
- Avoiding the trade-off effects of regulation without losing benefits
- REBECA proposals for general improvements of the current EU regulation system

A draft version will be produced by **Heikki Hokkanen** and **Ingeborg Menzler Hokkanen**.

D26: Comparison of benefits/risks between different groups of plant protection products

Table of contents

- Introduction
- Compilation of documented and suspected risks from BCAs
- Review of risks from other PPP (or PP methods?)
- Chemical PPP
- Other PP methods
- Cost-benefit assessments of plant protection
- BPPP
- Chemical PPP
- Comparative assessment of benefits and risks of plant protection methods

Compilation of documented and suspected risks from BCAs
(data from REBECA workshops)

Review of risks from other PPP
(based on literature)
Chemical PPP
Other PP methods

Cost-benefit assessments of plant protection
(literature + Waibel's contribution in Porvoo)
BPPP

Chemical PPP

Comparative assessment of benefits and risks of plant protection methods
(similar to the ERBIC matrix & Laengle+Strasser)

A draft version will be produced by **Heikki Hokkanen** and **Ingeborg Menzler Hokkanen**.

D27: Proposals on how to accelerate regulation and reduction of fees

For the final version the 'questionnaire on main obstacles and proposals' will be added as an annex and the tables on fees will be included into the introduction of the chapter on fees. This will be done by **Anita Fjelsted**.

D 28: Specification of "low risk products"

Content:

- Documentation of the discussions on "low risk agents", questionnaire on "low risk products"
- Link to D12, D18 and macrobials positive list (D21)

Anita Fjelsted will deliver a draft on these topics until the end of November.

- Definition of low risk (before and after risk assessment)
- Comparative risk assessment (biologicals chemicals)

Hermann Strasser will deliver the risk index publication covering these topics

The draft version will be circulated to all REBECA partners and the final version will be prepared by **Anita Fjelsted**.

D29: Proposal for alternative regulation strategies

Content:

Topics current situation:

Risk perception and risk management in modern societies
History of regulation and BCA regulation since the Stockholm conference
Changes which occurred during the timeframe of REBECA
Comment of the Commission on the Precautionary Principle
Short falls of regulation according to the PP
QPS versus PP
Swedish proposal
New Regulation and linkage of BCAs with synthetic chemicals in jurisdiction

Enforcement of waivers

Topics future perspectives:

- Consideration of BCAs in action plans for pesticide reduction programmes
- Link with NGOs and MEPs
- Improve networking
- Support research into new methods and guidelines for human risk assessment of microbial BCAs
- Call text: BCAs should not be regulated like synthetic chemicals
- Develop BCA specific legislation
- Propose a more flexible system
- Priority for low risk candidates
- Fast track systems
- Better adapted data requirements
- Give area-limited and time-limited authorisation and monitor effects
- Waive data requirements for efficacy and ask for after 5 years of use

Ralf-Udo Ehlers will work on a draft and circulate it to all. **Bernhard Speiser** will support him with a list of the actual parliament and commission decisions with relevance for BCAs.

Comment to parliament decision

On Tuesday 23 October, 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). 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, 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 biocontrol agents, microbial biocontrol agents, plant extracts and semiochemicals (=pheromones and other substances affecting behaviour of crop pests). 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). With the exception of invertebrate agents, all of these control measures are subject to the same regulation framework as conventional pesticides under Dir. 91/414 and will be similarly treated under the proposed amendments.

The REBECA project concluded that these methods present a low risk to humans and the environment. REBECA also concluded that current regulatory procedures present a major hurdle to the introduction of new microbial biocontrol agents, plant extracts and semiochemicals into the European market. REBECA therefore proposes a number of improvements in regulatory practice (for details, see the project website www.rebeca-net.de). Many of these proposals fall within the framework of the proposed new pesticide regulation.

D30: Plan for implementation of results

Contents:

Introduction

Table General regulation of microbials, botanicals and semiochemicals

Table Microbials

Table Botanicals

Table Semiochemicals

Anita Fjelsted produced a draft version.

The final activity report

Definition of chapters and responsibilities

Content

Summary (Olaf, Ralf)

Objectives (Ralf, Olaf)

Risk benefit analysis (Heikki, Ingeborg, Wyn?)

General proposals (Anita, Bernhard)

New regulation (Ralf, Anita, Bernhard, Wyn?, Rüdiger)

Microbials (Hermann, Olaf, Claude?)

Botanicals (Lucius, Bernhard)

Semiochemicals (Bernhard, Lucius)

Macrobials (Jeff, Uli, Antoon, Ralf)

Impact on industry (Heikki, Ralf, Ingeborg, Lucius (impact on farmers?))

Impact on science (Olaf, Ralf, Hermann, Claude?, Bernhard, Lucius, Heikki)

Plan for using and disseminating the knowledge

Exploitable knowledge and its Use (Olaf)

Plan for implementation of results (Anita, Olaf, Wyn?, Ralf)

Dissemination of knowledge (Olaf)

Publishable results (Olaf)

COST Statements

Olaf will send the sheet for cost statement and the sheets for the hours.

Jean-Francois Maljean will be contacted by Ralf regarding the following questions:

Is it necessary to submit a final and a periodic report?

If and how is it possible to distribute the unused money between the participants which spend more man-month than covered by their budget?

Is it necessary to submit a cost-statement on 2007 and an additional cost statement on 2008 (01.01-15.02)?

Is it possible to carry out a further ASG meeting in January 2008?

Book

The alternatives to have one or several editors were discussed. The majority of the participants voted to have only one Editor (Ralf-Udo Ehlers). Springer offered to publish the book.