

**Deliverable 9:**

**Interim report on relevant risks and tools  
to determine risks of microbial BCAs**

**REBECA**

Regulation of Biological Control Agents

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### Document History

The document is based on the results of 2 workshops conducted in Innsbruck, Austria, April 12-13, 2006 and in Salza, Germany, September 18-22, 2006. Experts from science, regulatory authorities and industry attended the meetings and reviewed the minutes, which were used to produce this document.

### Document Abstract

The risks of Microbial Biological Control Agents (MBCA) are listed and weighted regarding their potential impact. The major risks were identified. In the document criticism and recommendations regarding the improvement of the risk assessment methods are discussed. Baculoviruses were identified as safe active ingredients for plant protection products and the rationale for waiving some data requirements under Annex II b of Directive 91/414 regarding these organisms are given.

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## Introduction

The objective of the Action REBECA is to accelerate the regulation process for BCAs in Europe and make it more cost-effective without compromises to the level of safety. An important part of the Action is the review of potential risks of BCAs. Authorities should introduce regulation based on real risks. Consequently, any recommendation how to regulate BCAs should be based on existing risks in order to provide proposals for a balanced risk management.

The report is based on the outcome of 2 workshops conducted in Innsbruck, Austria, April 12-13, 2006 and in Salzau, Germany, September 18-22, 2006. Experts from science, regulatory authorities and industry were involved (see Annex 1: list of participants Innsbruck). At the meeting in Innsbruck, presentations introduced into the control potentials of microbial plant protection products, experiences with registration of MBCAs, current regulation procedures and requirements (see Annex 2: list of presentations Innsbruck). Afterwards participants split into smaller groups dealing with the different MBCAs (viruses, bacteria or fungi). Each participant was asked to define the major risks related with the use of MBCAs. Then the groups tried to categorize risks according to the possible impact and likelihood of occurrence. The results were afterwards presented and discussed in a plenum session. After the meeting minutes were circulated and suggestions for changes were included into the the minutes (see Deliverable D5).

In Salzau, the results of the Innsbruck meeting were presented (see Annex 4: list of presentations Salzau) and the afterwards discussed within an expert group (see Annex 3: list of experts microbial products Salzau). Special attention was given to risk assessment strategies and a comment to the OECD draft on contaminant levels. Results were afterwards presented and discussed in the plenum and minutes were circulated to workshop participants for further modifications.

## Identification of potential risks

Until today, no hazards have been reported from the use of microbial BCAs (MBCAs) as plant protection products in the EU. In general, those microbial BCAs registered for use in plant protection are not infectious when non-target organisms are exposed to. Nevertheless, measures are indispensable which allow identifying microbials which are pathogenic or toxic to non-target organism in order to prevent the registration of products, which cause intolerable hazards.

REBECA participants identified two major potential hazards related to the use of MBCAs. One is the potential infectivity/pathogenicity against non-target organisms including humans and the other is related to the potential of micro-organisms to produce toxic metabolites which may pose intolerable non-target effects. Furthermore, micro-organisms could be recognized as potential sensitizers and allergens. The risks related to microbial BCAs are listed in Tables 1 to 4. Proposals

for waivers and comments are included and the risks were categorized (high, medium or low).

## ***Virus products***

On the basis of the current knowledge on the infectivity and pathogenicity of baculoviruses (1, 2, 3), participants proposed an exemption for data requirement. Baculoviruses are pathogens of insects and highly host specific. In most cases, the host range is restricted to few species within one genus, sometimes even to a single species. Consequently data requirements related to non-target effects for this virus group can be waived and it was recommended to list baculoviruses as species in Annex I.

**Table 1: Risks associated with viruses (excluding product formulation)**

Risk	Impact	Suggested waiver	Comments
<b>Adverse effects on human health</b>			
Pathogenicity	Low	For Baculoviruses all data requirements are covered within the OECD consensus document (1).  In case of new virus products NOT based on baculoviruses, cell culture studies must exclude interaction with mammalian cells and activation of retroviruses.	Baculoviruses are not pathogenic to vertebrates or non target invertebrates.
Toxins Non-viable residues	Low	For baculoviruses all data requirements are covered within the OECD consensus document (1).	Baculoviruses do not produce any toxin
Sensitisation	Low		Available methods are not suitable for micro-organisms. New methods need to be developed.
Allergenic effects	Low	For baculoviruses all data requirements are covered within the OECD consensus document (1).	Suggestion: Waive the requirements for the investigation of allergenic effects since all living organisms can cause such effects and allergic people can protect themselves.
<b>Adverse effects on the environment</b>			
Adverse effects on non-targets	Low	Baculoviruses are highly target specific and thus no negative impacts are known.	
Persistence	Low	For baculoviruses all data requirements are covered within the OECD consensus document (1).	
<b>Genetic instability</b>	Low		Suggestion: Risks of reduced effectivity and altered specificity due to a genetic instability should not be a part of regulation since it is controlled by quality control measures. The producer demonstrates his ability for monitoring the genetic stability by appropriate quality control methods.

**Table 2: Risk associated with the production and application of virus products**

Risk	Impact	Suggested waiver	Comments
<b>Adverse effects on Human health</b>			
Sensitisation	Low		Since viruses are produced <i>in vivo</i> , sensitisation (due to skin and inhalation exposure) might be caused by residues of insect origin.
Microbial contamination	Low		Human pathogens must be excluded. Food safety standards are sufficient to exclude risks. So far no defined thresholds are given for microbial contaminations in plant protection products, but an OECD paper is discussed (5). The occurrence of contaminations must be controlled for each product batch (quality control issue). Applicant should verify that the quality control methods are sufficient to secure the food safety standards. Standard operation protocols to detect contaminants must be provided.
<b>Adverse effects on the environment</b>	Low		Risks due to additives are low as long as low risk formulation components are used and low amounts are applied in the environment, which is generally the case to date

### **Bacterial and fungal products**

Experts emphasized a general rule important for the risk assessment of products based on micro-organisms. Since micro-organisms are part of the natural environment, the evaluation of risks associated with the application of micro-organisms always needs to be related to the natural exposure of non-targets. If the naturally occurring exposure to a micro-organism is high and regular, than the risk associated with an artificial application can be assumed to be negligible.

**Table 3: Risks associated with bacteria or fungi (excluding product formulation)**

Risk	Impact	Suggested waiver	Comments
<b>Adverse effects on Human health</b>			
Pathogenicity Viable residues	High	No impact on humans if the strain is not growing at temperatures above 35°C.	Considering animal ethics, unnecessary replicates of already performed risk assessment studies should be avoided. It was questioned whether determination of clearance after intratracheal application provides additional safety information compared to the acute toxicity studies.
Toxins Metabolites Non-viable residues	High	No impact if no toxic effects reported for the formulated product.	
Genotoxicity	High	No impact if Ames-test with the culture supernatant is negative.	

Sensitisation	Low		Available methods are not suitable for micro-organisms. New methods need to be developed. It was suggested to waive data requirements for sensitising properties since all living organisms may cause sensitisation.
Resistance to antibiotics	Medium		Due to the risk for infection of immune suppressive patients, data on susceptibility to antibiotics should be provided.
<b>Adverse effects on environment</b>			
Adverse effects on non-targets	Medium		Only organisms relevant for the intended use should be tested.  The origin and mode of action of the MBCA must be considered.  Fungal MBCAs produce toxins in interaction with the target. The toxin content in the product is usually low. Some toxins are also produced during <i>in vitro</i> culture. Consequently, exposure of humans resp. non-targets to toxins are usually negligible.
Persistence	Low	No impact if the MBCA is autochthonous in the application area.  No impact if there are negligible non-target effects.	Persistence is not seen as a risk but a benefit. The control activity of MBCAs is usually slower compared to chemical pesticides. Persistence for at least several weeks is required to achieve control effects. Roots need to be colonized for sustainable protection.  Knowledge on the general occurrence of the MBCAs and background levels should justify waiver.  MBCA populations decline over time. Abundance of MBCAs is negligible compared to the natural microflora.
<b>Genetic instability</b>	Low	Hazards due to genetic instability have not been reported for MBCAs  Risks are related to reduced effectivity	All micro-organisms have mechanisms of genetic recombination. MBCAs are not particularly different from other microbes.  Altered control potential due to a genetic instability is part of quality control. Producer should demonstrate the ability to monitor the product stability.

**Table 4: Risks associated with the production and application of bacteria or fungal based products**

Risk	Impact	Suggested	Comments
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		waiver	
<b>Adverse effects on Human health</b>			
Sensitisation	Low		Assessment only necessary for unknown (so far not tested) additives. As the formulation may affect interactions with skin, determination of sensitisation should be done with the product
Microbial contamination	Low		See comments for viruses.
<b>Adverse effects on the environment</b>	Low		Assessment only necessary for unknown (so far not tested) additives.

Micro-organisms can produce toxic metabolites and these metabolites can be part of the mode of action against the target pest. Metabolites of micro-organisms are usually of major concern during the risk assessment. Most metabolites have no or little effect on non-targets but can have potential effects on targets. Toxic metabolites can be an important active ingredient of a BCA product. Even if there is no direct toxic effect of the microbial BCA product, toxic metabolites can be produced in the environment at the point of application or activity of the micro-organisms. As a general rule, relevant metabolites are produced in contact with the target organism. All natural products (including metabolites) are biodegradable and disappear within a short time in the environment. The assessment of risks should be done in relation to the mode of action of the BCA, the potential propagation of the micro-organism in the environment and in relation to the natural background level. Furthermore, the biology of the investigated micro-organism should be taken into account. E. g. secondary colonizers, which invade ecological niches already established by other microbes, are more likely to produce toxic metabolites than primary colonizing microbes.

The potential risks for the environment were considered as low. Major hazards for soil microbiota caused by the application of micro-organisms have not yet been reported. Currently several projects in the EU are carried out, investigating the influence of microbial BCAs on soil organisms. Two projects are performed in Sweden (MASE: "Microbial Activity for a Sound Environment" and DOM "Domestication of Microorganisms"). At the Ministry for the Environment (RIVM) in The Netherlands, at the University of Warwick in the UK, at the Leopold-Franzens-University Innsbruck and University of Technology Graz in Austria projects also review the possible impact of the release of MBCAs on the environment.

## Assessment methods

In general the participants agreed that bacterial and fungal BCAs have to be evaluated on a case-by-case basis.

## Assessment of infectivity

The current regulation process requires extensive studies on infectivity, pathogenicity, and toxicity. REBECA experts agreed that human pathogens are well described and documented in the relevant literature and databases. On the basis of

this knowledge microbes are categorised into 4 risk groups (Directive 2000/54 EC). This Directive (6) is aiming at protection of workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work. If a biological agent is included in risk group 1, it is unlikely to cause human diseases. In that case no special measures are required according to the Directive to prevent or reduce the risk of exposure to such an organism (article 4, clause 1). Only general principles of good occupational safety and hygiene should be followed. All micro-organisms used in registered plant protection products to date belong to the risk group 1.

In Dir. 2000/54 only organisms categorized into the groups 2-3 are listed. This means: "In line with the scope of the Directive, only agents, which are known to infect humans are to be included in the classified list. Animal and plant pathogens which are known not to affect man are excluded". It can be concluded that the risk for infection of humans by micro-organisms is very well known and that the EU and the Member States already made a decision concerning this risk regarding the exposition of workers. This classification should also be applied to micro-organisms used in plant protection products.

REBECA experts concluded that more emphasis should be given to the clinical findings and published reports on adverse effects of the species of a MBCA during the risk assessment procedure. It was questioned whether the classification of a micro-organism into group 1 delivers at least the rationale to waive the risk assessment requirements regarding extensive infectivity studies of the micro-organism.

In the EU Member States adaptations of Dir. 2000/54 EC exist (6). For example in Germany the so called Directive TRBA 466 (7) for bacteria and 460 (8) for fungi are used, listing as well group 1 organisms. A quite similar categorisation of micro-organisms as used in the EU is used in the USA and by the WHO (9). The European Federation of Biotechnology is developing a classification scheme which includes as well the potential for environmental hazards.

Despite the group 1 classification further key indicators for the human (mammalian) safety of MBCAs are:

- no growth at  $>35^{\circ}\text{C}$
- no clinical reports and indications in relevant scientific literature or databases
- data on susceptibility of MBCA to chemotherapeutics (antibiotics)

The potential of nosocomial infections of immuno-compromised patients by MBCAs was discussed. These infections are a result of treatment in a hospital or a healthcare service unit, but secondary to the patient's original condition. Nosocomial infections are alarming as antibiotic resistance has widely spread. Data on the susceptibility of the MBCA to common antibiotics can minimize the risk of nosocomial infections. Reports on infections of immune suppressed patients, however, should not hamper registration of a micro-organism for use in PPP, since contact of immune suppressed patients to PPP should have to be avoided in any case.

Should tests with mammals are necessary, intraperitoneal injection studies with rats or mice were considered to be the best currently available test system for the infective potential of a micro-organism. Intratracheal instillation is used to test the pulmonary toxicity and infectivity. This application method, however, can cause serious clinical symptoms even in the control population making an interpretation of the obtained data difficult. It was questioned whether clearance studies provide significant information beyond results obtained from investigations on oral or intraperitoneal application. The participants agreed that the current system for the assessment of risks for human and animal health caused by microbial BCAs needs a revision.

As one possible alternative test organism for the infectivity/pathogenicity assessments for microbials, the nematode *Caenorhabditis elegans* was suggested. *C. elegans* is already used to assess the toxic and infectious potential of opportunistic pathogens, e. g. in clinical studies regarding cystic fibrosis (10). Toxicity can possibly be assessed in the same test system. Currently, preliminary investigation on the use of this nematodes as test system are underway at the laboratory of Gabriele Berg (TU-Graz, Austria). Other test systems basing on cell cultures, *Artemia* and *Daphnia* have been proposed by and subsequent to the RAFBCA project (11, 12, 13, 14).

### **Assessment of toxicity**

Toxicity is related to chemical compounds. They can also originate from microbial production. Toxicity is thus related to metabolites produced by the MBCA. If no relevant metabolites can be identified, no further data requirements should be necessary. Regulation requires sufficient data to produce recommendations on the ADI, AOEL, NOEL etc if relevant metabolites are identified. Experts discussed how toxic effects of MBCAs can be assessed. Feeding assays with rodents are used for the assessment of human and animal health risks. However, results can be misleading and provide false negative results as reported for the *Bacillus cereus* group enterotoxin, which is not affecting rats. Similar problems can also occur with rabbits or mini-pigs. The Danish EPA is not asking for oral toxicity studies on rats for products containing *B. thuringiensis* (Bt) anymore. Bt also belongs to the *B. cereus* group and thus needs to be tested for the production of the enterotoxin.

Micro-organisms are known to produce several metabolites. Task of the risk assessment is to identify relevant metabolites. In general, it is not possible to assess the effect of all metabolites produced and excreted by a micro-organism, since there are too many and the metabolic activity varies depending on the growth substrate. A risk assessment based on single metabolite is usually also not feasible. Metabolites known to be produced by the bacterial or fungal species and which are toxins or have other adverse effects, and which are contained in the product or accumulated under application conditions must be assumed as relevant.

It was suggested that instead of assessing single metabolites it would be more practical and cost effective to use culture supernatants or crude extracts or the

culture or the formulated product. In this way also interactions of different toxins and interactions with the product formulation would be included in the assessment.

Furthermore, the origin of the micro-organism (natural occurrence, ecological niches) can deliver information which indicates the potential to produce toxic metabolites. Secondary colonizers, which invade ecological niches already established by other microbes, are more likely to produce toxic metabolites than primary colonizing microbes.

As the result of the EU Project RAFBCA on production of metabolites by certain fungal MPCAs, the potential for exposure to their metabolites is considered to be low. There is scientific evidence that no major concern exists for human and environmental safety. Therefore, it was concluded that REBECA will produce a guidance document on fungal metabolites using the RAFBCA project and other relevant information for the registration process.

Regulation now in use requires that if the MBCA is related to producers of genotoxins, genotoxicity must be tested. Expert toxicologists mentioned that guidelines on the assays are not clear and methodologies suggested not updated and inadequate (4). Phrasing seems very difficult as the matter is complex. Major difficulties are expected from the production of pure compounds to be used for monitoring of substances and assays. It will need highly knowledgeable chemists and produce high costs therefore excluding this approach. The testing of crude extracts might be an alternative approach to test for genotoxicity.

### ***Environmental risk assessment***

Data requirements on non-target effects should be always related to the exposure, which depends on the application method (use in soil or plant surface, seed treatments etc.). Waivers on data requirements for some of the environmental risks are often accepted based on the possible exposure. In many instances where and when a micro-organism is used as an MBCA, the micro-organism is already present in the environment and has demonstrated no adverse effects. Furthermore, the living form of the agent in most instances will usually not replicate in the absence of the specific target pest (e.g. insect host). Metabolites are biodegradable and we have no evidence for bioaccumulation.

It was mentioned that it is unlikely that a MBCA will have long lasting effects on the soil microbiota, because the soil community is very stable. So far only transient effects have been observed. Natural (temperature, humidity, rainfall) or anthropogenic influences (manuring, crop-rotation, tilling) have a more severe impact on the microbiota than the application of MBCAs. This makes it difficult to assess the influence of MBCAs.

It was questioned whether earthworm tests and tests on soil microbiota are reasonable, as no influence on non-targets in the soil was reported. No earthworm pathogens have been reported.

Alternative systems should be evaluated (*C. elegans*, protozoan test). Currently a study about the influence of MBCAs on soil biota is carried out by Jacequeline Scheepmaker (RIVM, The Netherlands).

The experience from the 4th list evaluation can be used to facilitate and refine reasoned cases for waivers. It is envisaged by the regulatory authorities to compile a “lessons learned document”, when the 4th list evaluation is finished.

### **Microbial contaminants**

The OECD produced a Draft Issue Paper on “Contaminant Limits for Microbial Pest Control Products” (5). During the REBECA meeting in Salzau, September 18-22, 2006, this OECD paper was commented.

The consensus view of the REBECA experts is that products based on microbial biological control agents should not contain human pathogens as listed in the OECD paper and should contain low levels of contaminating micro-organisms.

The OECD paper identifies a major risk posed by contaminating micro-organisms in MBCA products and proposes the introduction of clearly defined contamination levels, attested by results of quantification and identification of microbials in the products.

This view was not shared by all experts. Some doubted that a major risk exists and feared that further regulation steps might result from the discussion of the OECD paper without providing evidence that a real risk can be identified. The experts did not know of any report, which documents a risk with professional MBCAs due to higher levels of contaminations or human pathogens. Consequently, it was questioned whether the introduction of more requirements than the existing is justified.

The presence of microbial contaminations in MBCAs products depends on the production method and the formulation of the product. Most bacterial and many fungal BCAs are produced in liquid or solid culture under sterile conditions. Growth of contaminations during the production process in that case is generally not tolerable because production will fail or is less economic. Manufacturers of MBCAs follow standard rules to exclude contamination during the production process. Any production batch with a significant level of contamination is excluded from marketing because it will fail product quality levels. It is therefore in the interest of the manufacturer to exclude contamination during any step of the production process and standard operation protocols exist which can easily avoid the occurrence of contaminating micro-organisms during production.

Once it comes to downstream processing, the material is exposed to the ambient microflora and contaminations can enter the product. Bacteria and fungi are common in the air, in process water, in formulation materials and on surfaces of machinery.

However, the risk for contamination with human pathogens in manufacturing of microbial biocontrol micro-organisms is not higher than in food and feed industry or other manufacturing processes. It is therefore not reasonable to introduce stringent legislation and rules than in other industry sectors.

The presence of few contaminating microbes is not a problem as long as the storage and transport conditions prevent growth of contaminants. Professional producers take measures to avoid the growth of contaminating microorganism in the product in order to maintain the product quality and shelf-life. Products are either dried to reduce the water activity below a level which allows growth of microorganisms. Dry products maintain their level of contaminants once the product is packed. Liquid formulations can be stabilized by lowering the pH or addition of preservatives or products are kept cold to avoid fungal and bacterial growth. Addition of preservatives often excludes biocontrol products from use in organic agriculture. Growth of most microorganisms (except anaerobic bacteria) is also prevented when products are formulated or packed avoiding the access of oxygen. In some cases an expiry date indicates until when the product quality can be guaranteed.

Thus contamination is usually avoided during production and kept at low levels during downstream processing, storage and transportation. The experts concluded that from the description of the production procedures, regulators should be able to assess whether a risk for contamination exists, which is higher than in food industry or handling of other organic materials. An analysis of the microbial contaminants of formulation material should accompany registration documents to exclude that risky micro-organisms are introduced with these additives. The complete microbial analysis of each production batch is not recommended as it would cause additional costs and is in many cases not feasible. The assessment of rare microbial contaminants ( $10^3$  cfu/ml or less) in a bacterial or fungal culture with  $10^9$  or more cells per ml might be difficult if not impossible as these contaminants will be lost during the dilution prior to plating for cfu counts. Levels of contaminating micro-organisms as defined in the OECD draft (5) are possibly difficult to detect in microbial products containing up to  $10^{11}$  cells/ml of the MBCA even if selective media are available. Particular if the MBCA is a coliform organism it will be difficult to distinguish it from other bacteria. The application of standard methods used for the examination of water and food might therefore not be applicable. It is recommended to predominately ask producers to introduce measures as part of their standard protocol suitable to avoid contaminations and provide expiry dates for the product instead of contamination levels.

The situation is different for products based in baculoviruses. Products based on viruses are until today produced in vivo. As baculoviruses are multiplied in living insects, microbial contaminations during the production process cannot be avoided. However, since viruses can not grow on artificial media, standard methods for the detection of contaminants can be used. During a REBECA virus workshop in Salzau conducted with experts from science, regulation authorities and industry, participants agreed on the following maximal contamination levels:

Mesophiles  $10^8$  CFU/mL, *Bacillus cereus*  $10^7$  CFU/mL, *E. coli* none in 1 g, *Staphylococcus aureus* none in 1 g, *Salmonella spp.* none in 25 g. Yeast and moulds should be visually monitored during production and the evaluation should be based on levels that occur. These contamination levels are in accordance with the current state of the art regarding production methods and application rates of virus products and should replace the recommendations given in the OECD paper.

### **Assessment of efficacy**

Data on efficacy are necessary for national registration. Uniform principles for efficacy data exist, but they just state that efficacy must be assessed in comparison to reference pesticides as it is the case for any (chemical or biological) new pesticide. Efficacy of BCAs is sometimes lower than recorded for chemical pesticides. Biological control, however, is not a single target approach but a complex strategy triggering also other, naturally occurring control systems. Many rapporteur MS accept 50-60 % efficacy, but there are exceptions. In general, companies think that it is acceptable to provide efficacy data. However, GFP is very expensive and certified GEP should be accepted as a substitute for GFP. Industry referred to the praxis in California (USA), where efficacy tests are carried out by extension service and do not require GFP/GEP.

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## Acknowledgements

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## **Annex 1: List of participants Innsbruck Meeting**

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## Annex 2: List of presentations Innsbruck

All presentations are available on the REBECA webpage ([www.rebeca-net.de](http://www.rebeca-net.de)).

### Short introduction in current MBCAs in market (problems in registration, potential hazards, fate and behaviour)

[Welcome and introduction](#) *Hermann Strasser*, LFU-Innsbruck, Austria  
[Experience in microbial registration](#) *Guido Sterk*, Biobest N.V., Belgium  
[Fungi against insects](#) *Hermann Strasser*, LFU-Innsbruck, Austria  
[Fungi against plant pathogens](#) *Marina Niemi*, Verdera Oy, Finland  
[Bacteria against insects](#) *Sergio Franceschini*, Intrachem s. r. l., Italy  
[Bacteria against plant pathogens](#) *Margareta Hökeberg*, BioAgri AB, Sweden  
[Virus](#) *Martin Andermatt*, Andermatt Biocontrol AG, Switzerland  
[Objectives of REBECA and the group work](#) *Ralf-Udo Ehlers*, CAU-Kiel, Germany

### Presentations on risks

[Fungal metabolites](#) *Claudio Altomare*, ISPA Bari, Italy  
[Risks of bacterial MBCAs](#) *Gabriele Berg*, TU-Graz, Austria  
[Risks of using virus](#) *Jürg Huber*, BBA Darmstadt, Germany  
[Human risks of Pantoea](#) *Joel Vanneste*, HortResearch Ltd., Australia

### Comparison of indicated risks, suggested assessment strategies and current registration requirements

[Current regulating system and data requirements within the EU](#) *Anita Fjelsted*, Danish EPA, Denmark  
[Current regulating system and data requirements in non EU countries](#) *Rüdiger Hauschild*, GAB Consulting GmbH, Germany  
[GENOEG Breed](#) *Tycho Vermeulen*, CLM, Netherlands

## **Annex 3: List of participants of microbial workshops Salzau**

### **Bacteria workshop:**

#### *Academics*

Berg, Gabriele, TU-Graz, Austria  
Ehlers, Ralf-Udo, Christian-Albrechts-University Kiel, Germany  
Mark, Louise, BIOMERIT Research Centre, Ireland  
Möllby, Roland, Karolinska Institute, Department of Microbiology, Sweden  
Strauch, Olaf, Christian-Albrechts-University Kiel, Germany  
Sundh, Ingvar, SLU, Sweden  
Wilcks, Andrea, Danish Institute for Food and Veterinary, Denmark

#### *Industry*

Edgecomb, Don, Agra Quest Inc., France  
Franceschini, Sergio, Intrachem s. r. l., Italy  
Herrero, Maria, Valent Bioscience, Switzerland  
Hökeberg, Margareta, BioAgri AB, Sweden  
Jackson, Trevor, AgResearch, New Zealand  
Junge, Helmut, ABiTEP GmbH, Germany  
Munday, Denise, Valent Bioscience, Switzerland  
Tilcher, Ralf, KWS Saat AG, Germany

#### *Regulation*

Fjelsted, Anita, Danish EPA, Denmark  
Gustafsson, Kersti, KEMI, Sweden  
Pertot, Ilaria, IASMA, SafeCrop Centre, Italy  
Pickl, Christina, Umweltbundesamt, Germany  
Schneider, William, EPA, United States  
Winding, Anne, National Environmental Research Institute, Denmark

### **Fungi workshop**

#### *Academia:*

Altomare, Claudio, ISPA Bari, Italy  
Zachow, Christin, Inst. f. Umweltbiotechnologie, Austria  
Tkaczuk, Cezary, University of Podlasie, Poland  
Kouvelis, Vassili, University Athens, Greece  
Quesada-Moraga, Enrique, University Cordoba, Spain  
Chandler, David, University Warwick, United Kingdom  
Typas, Milton, University Athens, Greece  
Grant, Wyn, University Warwick, United Kingdom  
Jung, Kerstin, BBA Darmstadt, Germany  
Ritchie, Barbara, CAB International, United Kingdom  
Jensen, Birgit, Department of Plant Biology, Denmark  
Pertot, Ilaria, IASMA San Michele, Italy  
Goettel, Mark, Agriculture and Agri-Food CA Lethbrige, Canada  
Grosch, Rita, Institute of Vegetable and Ornamental Crops, Germany

Butt, Tariq, University Swansea, United Kingdom  
Längle, Tobias, Agriculture and Agri-Food CA, Canada  
Kiewnick, Sebastian, Agroscope Changins-Wädenswil, Switzerland  
Strasser, Hermann, University Innsbruck, Austria

*Regulation:*

Buschers, Marloes, CTB, Netherlands  
Scheepmaker, Jacqueline, RIVM, Netherlands  
Dale, John, Pesticide Safety Directory, United Kingdom  
Maritzen, Petra, AGES, Austria  
Jölli, Daniela, AGES, Austria  
Gustafsson, Kersti, Swedish Chemicals Inspectorate Pesticides, Sweden  
Brock, Susanne, Umweltbundesamt, Germany  
Rauch, Martina, Federal Institute for Risk Assessment, Germany

*Industry:*

Ravensberg, Willem, Koppert, Netherlands  
Sterk, Guido, Biobest N.V., Belgium  
Donat, Christina, Bio-ferm, Austria  
Kron-Morelli, Roberto, Agrifutur, Italy  
Niemi, Marina, Vedera Oy, Finland  
Witthaker, Mark, JSC International, United Kingdom  
Lüth, Peter, Prophyta, Germany  
Peters, Arne, E-nema, Germany

*Consultant:*

Luyten, Agnieszka, Redebel, Belgium  
Gwynn, Roma, Rationale Biopesticide Consultants, United Kingdom  
Knauf, Werner, Liederbach, Germany

**Virus Workshop**

*Academia*

Jürg Huber, BBA Darmstadt, Germany  
Johannes Jehle, DLR Rheinpfalz, Neustadt, Germany

*Regulation*

Susanne Guske, BVL, Germany  
Richard Davis, PSD, United Kingdom  
JeroenMeeussen, CTB, The Netherlands  
Heli Nommsalu, PPI, Estland

*Industry*

Philip Kessler, Andermatt BiocontrolAG, Switzerland  
Antoine Bonhomme, NPP, France  
Claudia Mochen, Sipcam, Italy  
Rüdiger Hauschild, GAB Consulting, Germany

## Annex 4: List of presentations Salzau

All presentations are available on the REBECA webpage ([www.rebeca-net.de](http://www.rebeca-net.de)).

### Potential of Microbial Control Agents:

Virus *Martin Andermatt*, Andermatt Biocontrol AG, Switzerland

Bacteria *Trevor Jackson*, AgResearch, New Zealand

Fungi *Sebastian Kiewnick*, Agroscope, Switzerland

Comparison of Registration Requirements in Different Countries

*Rüdiger Hauschild*, GAB Consulting GmbH, Germany

### Summary of the Results of the Innsbruck Workshop (11.-13.04.2006)

Virus *Jürg Huber* (BBA Darmstadt, Germany)

Fungi: Consequences of the EU Project RAFBCA on the Regulation of Fungi

*Tariq Butt*, University Wales, United Kingdom

Bacteria/Fungi: Ranking of Risks and Suggested Waivers

*Hermann Strasser*, University Innsbruck, Austria