

Deliverable 27:

Proposals on how to accelerate regulation and reduction of fees

REBECA

Regulation of Biological Control Agents

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Document History

The document is based on the recommendations and discussions, expressed by the participants of (i) the Innsbruck workshop on microbials April 2006, (ii) the Brussels workshop on botanicals and semiochemicals June 2006, (iii) The Salzau workshop in September 2006 and (iv) the stakeholder meetings industry and regulation Salzau 2006 and (v) a questionnaire on 'main obstacles and proposals'. Draft versions of this document were circulated between regulators, industry and scientists for comments for at least six month. Since there was the demand on further discussion on that topic from the regulator and industry side the final version of this document will be delivered in the final report of the action.

This document reflects the outcome of the REBECA project and contains a number of REBECA recommendations. However it cannot be assumed that all project partners or even all experts who participated in the REBECA workshops fully agreed with all the recommendations/conclusion.

Document Abstract

The document delivers a compendium on proposals how the current regulation system for biological control agents can be improved. The thematic areas are fees, communication, generic approaches, timelines, centralised regulation, legislative framework and efficacy evaluation.

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Preface

The aim of the REBECA project is to propose improvements in the registration process of biological control agents, plant extracts and semiochemicals (here collectively called 'BCAs'). Several documents are under preparation which contains proposals for specific groups, e.g. baculoviruses, botanicals and semiochemicals. However, the present document contains a number of proposals which relate to more general aspects of the regulation and registration of BCAs. The proposals have been discussed and/or elaborated in the REBECA project. The document is based on a questionnaire which was prepared in spring 2007, discussed in two workshops and circulated for comments, inviting stakeholders to highlight advantages and disadvantages of each proposal.

Many stakeholders have expressed advantages and disadvantages of the proposals, and some of them are regarded as controversial. Therefore, both advantages and disadvantages are described here. Special emphasis is placed on two aspects which have emerged in all discussions:

- Implementation. Whether or not a proposal can be implemented in the short term. Short-term implementation is likely for proposals which are not controversial and require no changes of legislation.
- Potential impact. Here, we have tried to take into account expected impact on both the speed of the evaluation process as well as the impact on the costs of registration (for the applicant).

This document provides an inventory of possible measures to change the regulation and registration process of BCAs. We hope that a comprehensive summary of the main advantages and disadvantages of possible measures will stimulate the further discussions. In order to allow a thorough decision-making, this inventory includes measures which we consider advantageous together with measures which we consider less suitable, disadvantageous or unlikely to be implemented. The position of the REBECA project is explained in the 'REBECA conclusions' at the end of each thematic area (marked with the REBECA logo). It cannot be assumed that all project partners, or even all experts who participated in the REBECA workshops, fully agree with all conclusions.

Thematic area 1: Fees / financial support

Introduction: Microbials, botanicals and semiochemicals are still mostly products for niche markets. In addition, most of these products have very low risk profiles and are therefore particularly in line with relevant EU Policies. This justifies indirect subsidies in the form of reduced registration fees, as is already the case e.g. in Canada, USA and many EU member states, or other means of support/subsidies. Registration fees can make up a significant proportion of the total costs for product development. Fee structure varies greatly among EU member states. It is not under the authority of the EU Commission. In some member states, there are no fees for products for minor use, or for products containing new active substances, and some have reduced fees for biopesticides. In Denmark no fees are requested for national authorisations of plant protection products. Instead there is a tax system, with 3 % tax on microbials; 25 % on chemical herbicides and fungicides and 35 % on chemical insecticides.

A survey on fees required by member states has been carried out in 2006 prior to the Regulator stakeholder meeting taking place in September that year. The information that was gathered during the survey is presented in the two tables below. The first table contains information about the fees that were requested by rapporteur member states for the evaluation of new active micro-organisms. The second table shows the amount requested by rapporteur member states for the micro-organisms on the 4th list (existing active substances).

It is evident from the tables that the fees are not harmonized. Regulators acknowledge that this may be a problem for notifiers. However, they also believe that harmonization is not possible. It is up to each member state to decide on the size of the fee. Several regulators mentioned that the fees that had been requested for new active substances had only covered a small part of the actual expenses for the evaluation process, whereas most regulators expect the fees which have been requested for the evaluation of the 4th list micro-organisms to cover all expenses. However, in most member states these fees are still much lower than the fees requested for the evaluation of chemical active substances. E.g. in Denmark the fees for the evaluation of existing chemical active substances are twice as high as for the 4th list microbials (220.000 € versus 110.000 €). In the UK the fee for microbials is 22,500 £ for national authorisation plus 7,500 £ for being rapporteur for Annex I inclusion. The fee for chemicals is 110,000 £.

Table 1. Fees requested for the evaluation of the new active microorganisms

Type of micro-organism	Species	Rapporteur member state	Requested Fee (Euro)
Fungi	<i>Paecilomyces fumoserosus</i> (1)	Belgium	10,000
	<i>Coniothyrium minitans</i>	Germany	0 ¹
	<i>Gliocladium catenulatum</i>	Finland	840 ²
	<i>Ampelomyces quisqualis</i>	France	?
	<i>Paecilomyces lilacinus</i>	Belgium	10,000 ³
	<i>Pseudozyma flocculosa</i>	The Netherlands	5,000
	<i>Paecilomyces fumoserosus</i> (2)	Belgium	10,000
Bacteria	<i>Pseudomonas chlororaphis</i>	Sweden	0 ⁴
	<i>Bacillus subtilis</i>	Germany	0 ⁽¹⁾
Virus	<i>Spodoptera exigua NPV</i>	The Netherlands	5,000
	Zucchini Yellow Mosaic Virus	UK	42,000
	<i>Adoxophyes orana GV</i>	Germany	0 ⁽¹⁾

Table 2. Fees requested for the 4th list microorganisms.

Italy	?
Denmark	110 000 €
Germany	86 000 – 143 400 €
Netherlands	Cost-recovery basis
Estonia	11 610
Sweden	Maximum 215 000 €
France	?

In the US-EPA the fees for microbials is up to 20,000 € and in Canada no fees are requested for microbials.

¹ Not specific to micro-organisms; all new active substances were exempted from fees for the RMS work. Such applications were only accepted in conjunction with a national product application

² In 1998 RMS's national application fee was 5000 FIM (corresponds to 840 euros). RMS's national legislation has been updated since then

³ The importance of the fees is not related "mathematically" to the work that has to be done. The importance of the fee for micro-organisms and substances of the 4th list is also linked to the fact that the market for these products is small. It is also a sort of incentive for organic farming.

⁴ By the time Sweden got the application, 1997, there were no fees established for inclusion in Annex I of Directive 91/414/EEC.

Proposal 1.A

Description: National registration fees as well as fees for Annex I inclusion to be lowered substantially for microbials and semiochemicals.

Advantages: Lower fees will make it easier for companies to register new BCAs. They would also demonstrate that authorities encourage submission of applications for authorization.

Disadvantages/ Problems: Today, many evaluating agencies are under financial pressure. Reduction of fees is only possible for them, if the government carries the losses incurred thereby. In addition, this proposal would cause an unequal treatment of BCAs compared to 'chemicals'. Some chemicals might have similarly low risk profiles, and it would be difficult to justify why they are not given the same, favourable treatment.

Implementation: Likelihood and degree of implementation varies greatly between member states.

Potential impact: This proposal will lower the costs of product development. However, its potential impact is limited, because registration fees make up only one part of the total development costs.

Proposal 1.B

Description: SMEs applying for registration of new microbials, botanicals or semiochemicals should be financially supported by specific programmes and should be given detailed guidance by the regulatory authority. Funding could come from various sources, such as rural development actions, IPM and organic action plans, promotion of SMEs or taxes on pesticides. In The Netherlands, the project GENOEG has used such an approach with success. In the UK the Biopesticide scheme provides guidance to applicants.

Advantages: This proposal is more flexible than 1.A. Such programmes could provide support for production of studies or dossiers, or for covering registration fees. Support is only given to SMEs, and it might be adjusted to the degree of need by the growers.

Disadvantages/ Problems: Such programmes need money. It must be clear which products can be subsidized, and why. Some people see this proposal as not being in line with a free-market economy.

Implementation: Likelihood and degree of implementation varies greatly between member states.

Potential impact: This proposal will lower the costs of product development and speed up the registration process. Its potential impact is higher than in proposal 1.A, because it is not limited to registration fees.



REBECA conclusions concerning fees / financial support

REBECA recommends low fees and support programmes for BCAs, as described in proposals 1.A and 1.B.

Thematic area 2: Improved communication between regulators and applicants

Introduction: In order to shorten the evaluation process and in order for the industry not to submit unnecessary data, there is a need for further communication between regulators and applicants. This can happen e.g. by arranging pre-submission meetings. In these, applicants and evaluators gain a better understanding of the substance and of the procedures relevant for its evaluation, and clarify which data are likely to be required during the evaluation. Many countries have established pre-submission meetings as a routine. This is for instance the case within the UK PSD and their experiences are positive throughout. Applicants avoid producing unnecessary data, and regulators save time, because dossiers better address those points which the regulators consider important. However, also further increase in the communication is needed later on in the evaluation process, e.g. during expert meetings.

Regulators report that some companies have not been interested in taking up the offer for a pre-submission meeting. Some regulators report that completeness check meetings also provide immediate feedback for applicants and improve quality of future dossiers.

Proposal 2.A

Description: Pre-submission meetings shall be established as a routine in all EU Member States.

Advantages: Applicants get better understanding of how to prepare data waivers and how to best address identified data requirements, and avoid producing unnecessary data. Applicants would find it easier to approach the regulators with questions while preparing the data package, if contact had already been established. Better understanding of the regulation process, data requirements etc. by industry will likely lead to submission of better dossiers. Regulators gain better understanding of company's product and intended market. Both will speed up the evaluation/authorization process.

Disadvantages/ Problems: This proposal will consume some time of the regulators. Much of this could be saved if the applicant engages a qualified consultant. Regulators may lack resources for such meetings. Not all problems/data requirements can be foreseen at a pre-submission meeting. RMS's advice during pre-submission meeting may not be accepted by other MSs and EFSA during peer review.

Implementation: This proposal can be implemented easily.

Potential impact: This proposal saves the applicant the costs of producing studies which will not be required. It improves dossier quality and thereby speeds up the evaluation process.

Proposal 2.B Pre-submission information package

Description: The pre-submission information package provides additional guidance for the pre-submission meeting. This proposal can be considered as a further elaboration of proposal 2.A.

Applicants are encouraged to contact the RMS at an early stage of the product development and before preparing a dossier. Applicants that have no experience with the EU regulatory system are encouraged to contact the RMS at a very early stage to get further guidance. Each MS appoints a contact person (a «BCA champion»). A pre-submission meeting should be held at an early stage. The main objectives of pre-submission meetings is to determine the appropriate test substances, study protocols and data that are required for the dossier of

a particular active substance and plant protection product, as well as the information required to support a justification for non-submission of data (waiver). Before consulting the RMS, the applicant should familiarize himself with the data requirements.

When an applicant has asked the RMS for a pre-submission consultation meeting, the RMS will ask the applicant to send a pre-submission information package. A pre-submission meeting will take place no later than 90 days after the submission of the information package. The information package should contain the following:

- A cover letter requesting a pre-submission meeting (for which a template could be made available).
- A proposed agenda of the issues to be discussed (a template should be made available).
- Completeness check tables (document O) containing information about a) which information is included in the pre-submission information package, b) which studies have already been carried out (if any) c) for which data requirements a justification for non-submission of data is submitted in the package.
- Proposed use pattern (Table of Good Agricultural Practise), proposed label, international regulatory status.
- Characterization of the active substance (for microbials also information on mode of action).
- Short summaries of available information regarding manufacturing processes, product specifications, safety to the environment and human health.
- Scientific justifications for non-submission of data (waivers).
- Proposed study protocols (if available).

After the pre-submission meeting, the completeness check table will be updated by the RMS. The table contains information about which data requirements have to be fulfilled with a study on the active substance and product in question, and where a justification for non-submission of data is likely to be accepted. A copy of the completeness check table must be enclosed in the dossier. The applicant will be reminded that depending on the outcome of the risk assessment, additional data/information may be required. Since most studies are unlikely to be available at the pre-submission meeting, the regulators will at this stage not be able to guarantee that no further data will be necessary.

Advantages: This procedure gives guidance to the applicant, which facilitates the preparation of the dossier, avoids that the applicant carries out unnecessary studies and improves the quality of the dossier.

Disadvantages/ Problems: see proposal 2.A.

Implementation: see proposal 2.A

Potential impact: see proposal 2.A

Proposal 2.C

Description: When appropriate, the applicants could be given the opportunity of attending part time at the evaluation/expert meetings during discussions of their specific product. It must be clear that they are only invited for clarification of questions, and neither for introducing new data nor for lobbying. The applicants should not attend throughout the discussions, so that regulators may have additional discussions in the absence of the applicants.

Advantages: Minor issues/mistakes can be solved much faster. The applicant will have a better understanding of the procedure and the comments /reasoning made by other MS.

Disadvantages/ Problems: In the presence of applicants, it is not possible to refer to previous discussions on other compounds due to confidentiality. Some regulators feel that the presence of applicants would compromise the independence of the expert meetings. Some regulators also fear unwanted pressure/lobbying from applicants, or criticisms of the RMS and MS experts. Finally, this system would cause additional costs for the applicant, particularly if there are many evaluation/expert meetings.

Implementation: This proposal can be implemented quite easily.

Potential impact: This proposal will help to clarify certain questions and misunderstandings rapidly, which speeds up the registration process.



REBECA conclusions concerning communication between regulators and applicants

REBECA supports proposals 2.A, 2.B and 2.C.

Thematic area 3: A more generic approach in risk assessment (Precautionary principle vs. QPS approach)

Introduction: The 'precautionary principle' is a fundamental element of Directive 91/414. Its assumption is that all potential risks have to be excluded, before a substance can be included into Annex I of the directive. A practical consequence in the registration of microorganisms is that most data are required at the strain level, and not at the species level. In areas other than plant protection, other strategies of risk management are discussed. For microorganisms entering the food chain, EFSA considers the «QPS» (Qualified Presumption of Safety) concept. QPS is based on scientific evidence and experience. Wherever possible, a more generic approach is taken instead of a full case-by-case assessment. It allows the generic listing of microorganisms, provided that certain criteria are met, e.g. absence of acquired antibiotic resistance factors. QPS should be similar in concept and purpose to the GRAS (Generally Recognised As Safe) concept used in the USA, but is not identical to GRAS.

Experience gained during the EU evaluation of the microorganisms in the 4th stage of re-evaluation may be taken as a basis to determine in which cases a generic approach is justified.

Note 1: the current EFSA opinion specifically excludes including organisms known to produce toxins that require specific human health risk assessments (e.g. *Bacillus cereus* sensu lato group that includes Bt) and it excludes the large group of filamentous fungi as well, to which many fungi used for biological control belong to.

Note 2: The EFSA potential QPS approach did not consider wider environmental issues extensively. In the assessment documents on which consultation has just finished, only safety concerns to humans and livestock have been considered to date. For the evaluation of plant protection products, the concept may also be useful, but the generic assessment would need to be extended and the criteria need to be adapted.

Proposal 3

Description: Establish risk management strategies taking a generic approach wherever possible, and restricting case-by-case evaluations to those cases where this is necessary and justified. I.e. evaluate microorganisms at species level whenever possible and evaluate other substances as groups as well (e.g. certain botanicals and semiochemicals). However, this approach can only be followed if there is enough experience/scientific evidence about a certain group.

Advantages: Saves costs for producing studies, and speeds up the registration process. Provides incentive to use microbial strain which is best suited for a purpose (while currently a registered strain is often preferred to a non-registered strain, even if the non-registered strain is more efficient).

Disadvantages/ Problems: Data protection must be ensured for those applicants who have provided data on which regulatory experience is based. This approach cannot be followed if there is not enough experience/scientific evidence about a certain group, but only unsubstantiated claims.

Implementation: Such an approach is now being taken for baculoviruses and maybe for another couple of groups of substances in the 4th list evaluation. However, in order to expand this proposal to further groups, this proposal will require considerable discussion.

Potential impact: This proposal will greatly reduce the costs for dossier preparation, and speed up the registration process.



REBECA conclusions concerning precautionary principle vs. QPS approach

REBECA considers a more generic approach as promising. Experience from the 4th stage should be used to determine groups which are amenable to such an approach (e.g. baculoviruses, straight chained lepidopteran pheromones (SCLPs) and certain microbial species).

Thematic area 4: Guidance documents based on experience from the 4th stage evaluation

Introduction: A large number of microbials, semiochemicals and botanicals are currently under EU review in the so called 4th stage. When this process has been finalized, the EU regulators will have obtained more experience in assessing these kinds of substances. In a number of reports/draft guidance documents on “lessons learned from the 4th stage” regulators could summarize their experiences with these substances. Of course, data protection has to be respected. For microorganisms the production of such documents has already been discussed. The lessons learned documents could be used for various purposes, as suggested in proposal A and B below.

Proposal 4.A

Description: The «lessons learned documents» should be used by applicants and regulators in general and in particular during future pre-submission meetings to determine data requirements/waivers for new substances in analogy to substances evaluated during the 4th

stage. In the pre-submission meeting, it must be clarified in which way the applicant has to address the data requirements.

Advantages: This approach will result in better/more focused dossiers. It improves consistency across member states, reduces data requirements, lowers the costs for applicants and it results in a faster procedure.

Disadvantages/ Problems: Data protection may be a problem when writing the lessons learned guidance documents. The lessons learned documents would have an uncertain legal status, It must be clear that new uses /other kinds of exposure of similar substances may trigger many more data requirements.

Implementation: As soon as such documents has been prepared this proposal can be implemented easily by those member states which are open to this approach.

Potential impact: This proposal may reduce the costs for dossier preparation, and speed up the registration process.

Proposal 4.B

Description: The «lessons learned documents» could be used to justify a generic approach, and as a basis for determining generic safety profiles..

Advantages: see proposal 3.

Disadvantages/ Problems: see proposal 3.

Implementation: see proposal 3.

Potential impact: see proposal 3.



REBECA conclusions concerning guidance documents based on experience from the 4th stage approach

The 4th stage of re-evaluation has imposed enormous work and costs both on applicants and on evaluators. The preparation of «lessons learned guidance documents» is a way to utilize the experience gained through these efforts. The REBECA project recommends the preparation of such documents. However, data protection must be respected.

The «lessons learned guidance documents» will be particularly useful to determine data requirements/waivers (see proposal 4.A) and they may also be useful for developing a more generic approach (see proposal 4.B).

Thematic area 5: Timelines

Introduction: Most applicants of BCAs are SMEs and only have resources to apply for national provisional authorisation of their products in very few (1-2) member states during the process of Annex I inclusion of their BCA. However, due to the large investments in the preparation of the dossier etc., it is crucial for the industry to reach the market as soon as possible, either by provisional authorisations, or by obtaining authorisations right after the Annex I inclusion. It is thus important for the applicants that the Annex I inclusion is obtained as fast as possible.

In the past, Annex I inclusion of microorganisms has taken several years. This is a hurdle for the industry compared with the authorisation system in the USA, where the products often reach a large part of the US market within 1-2 years after the application is submitted, because authorization by the US EPA is quite fast and most states do not require any further evaluation and authorisation. In the USA and Canada, strict timelines are in place for the registration of BCAs, and the industry reports good experience with this.

Proposal 5

Description: Strict and short timelines for the EU risk assessment as well as for national registrations should be included in the EU regulation. The timelines should be as short as is practicable to enable the appropriate risk assessments to be checked, and to ensure they have been supported by robust information.

Advantages: Gives the applicant the opportunity for more adequate planning, since strict timelines would provide better predictability on the length of the evaluation/registration process.

Disadvantages/ Problems: There are already strict deadlines, but member states have problems to respect them. What sanctions should be applied if the deadlines are not met? Lack of resources within member states. If additional information or clarifications are needed, these may have to be provided within a very short time; otherwise the application must be rejected. In such a case, a «clock-stopping» mechanism may be more useful than a strict and short timeline. Strict and short timelines could however also be combined with the possibility of obtaining Annex I inclusion with the requirement of submitting e.g. one or two confirmatory studies within a short timeframe.

Implementation: This proposal will require considerable discussions concerning procedural issues, before it can be implemented. Lack of resources within member states and EFSA may have to be taken into account.

Potential impact: This proposal will help to ensure short duration of the registration process, and in particular increase security about its duration.



REBECA conclusions concerning timelines

REBECA considers strict and short timelines to be useful. However, exact deadlines and procedures need to be developed.

Thematic area 6: Improved communication among regulators of BCAs

Introduction: When BCAs are on the agenda in evaluation/expert meetings these meetings should be attended by experts within this particular field, thus special meetings for BCAs needs to be organised. However, when only e.g. a few microorganisms are in the EU regulatory process and are being discussed at expert or evaluation meetings specifically for microorganisms, there is the risk that discussions are put on hold until there are an adequate number of microorganisms on the agenda to justify a meeting. The BCA industry (mainly SMEs) is very vulnerable to these long evaluation periods. Various possibilities to shorten and facilitate the regulatory process should be sought. Innovative companies developing environmentally friendly technologies should not suffer from the small size of the industry, therefore the extra costs are justified.

Proposal 6.A

Description: Further and more regular expert/ evaluation meetings should be arranged, and thus further resources allocated to such meetings. The meetings should be arranged without requiring a certain number of active substances on the agenda.

Advantages: This will speed up procedures. Regular meetings also contribute to building a network among member states, and improve expertise and harmonization between member states.

Disadvantages/ Problems: Depending on the issue, it might be difficult and in particular expensive to organize such specialized meetings.

Implementation: This proposal can be implemented fast, if the Commission and/or the member states are willing to cover the additional costs.

Potential impact: This proposal will help to speed up the registration process.

Proposal 6.B

Description: The member states that are appointed as lead Rapporteurs for BCAs in the 4th list review process should also after the finalisation of the review of these substances have a function as a kind of lead Rapporteurs for new active BCAs (microbials, semiochemicals, botanicals), and thereby contribute to the harmonization and consistency in the evaluation process. The aim should be to facilitate communication and close cooperation among regulators as well as between regulators, experts, EFSA and the Commission.

Advantages: This approach would increase the communication, harmonization and consistency between member states, and would facilitate and speed up procedures. It is a simple way to make use of the experiences gained in the 4th stage.

Disadvantages/ Problems: This approach places an additional burden on a few member states. Some stakeholders expressed fears that the involvement of the «lead rapporteurs» could make the process more complicated than necessary (although it is meant to achieve the opposite).

Implementation: This proposal can be implemented easily, if the RMSs concerned are willing to take over this task.

Potential impact: The guidance and harmonization resulting from this proposal will in the long term reduce the costs for dossier preparation, and speed up the registration process.

Proposal 6.C: Establishment of expert groups for BCAs

Description: One expert group is established for each of the following types of active substances: microbials, botanicals and semiochemicals. For each expert group, one member state is appointed as chair. The chair facilitates a high level of information exchange and is responsible for the coordination of two annual meetings. The groups comprise a representative from the Commission, an EFSA expert, national regulatory authorities and national experts with experience in evaluating the particular type of active substances (ideally 10-15 experts in total). The expert meetings should be hosted by the Commission, EFSA or by a MS. Travel expenses should be covered by the Commission. The minutes of the meetings should be made available to all MS (reported at meetings of the WG legislation).

The groups will discuss various issues (ecotox/fate/human health, etc.) in plenum, without splitting into subgroups. The purpose of the expert groups is to give guidance to the RMSs,

other MS and applicants. The group can e.g. discuss issues raised during pre-submission meetings with applicants. RMSs may ask the expert groups for an opinion regarding specific issues. Such questions may be raised at the meetings or throughout the year by a written communication between the members of the group. The groups should discuss both risk assessment and risk management issues. Discussions in these groups will facilitate the peer-review process. The groups will also develop draft guidance documents, which are subsequently discussed and finally agreed upon by all MS. To reduce travel expenses, the expert groups should try to organize their meetings jointly with other meetings. Conference calls /video conferences and e-mail discussions may also be useful tools.

Advantages: Increases the communication, harmonization and consistency in the risk assessment and risk management throughout the EU. Better guidance to the applicant facilitates preparation of the dossier, and increases its quality. Better guidance to the RMS facilitates preparation of the Draft Assessment Report (DAR) and the subsequent peer-review process.

Disadvantages/ Problems: Lack of time among regulators/experts to attend these meetings. With regular meetings, there may not be enough issues to discuss, or the timing of the meetings may not fit into the schedule of the evaluation process. High cost to cover expenses for these meetings.

Implementation: This proposal can be implemented relatively fast. The workload can be adjusted to the needs, which facilitates its initiation and its acceptability.

Potential impact: The guidance and harmonization resulting from this proposal will in the long term reduce the costs for dossier preparation, and speed up the registration process.



REBECA conclusions concerning communication between regulators of BCAs

REBECA supports all initiatives which improve communication between regulators of BCAs. Of the three proposals, proposal 6.C will probably have the highest impact and is particularly supported by REBECA.

Thematic area 7: Centralized registration authority

Introduction: Microbials, semiochemicals and botanicals make up only a small fraction of all plant protection products registered in the EU. Consequently, many regulators have relatively little experience with the evaluation of these substances. At the same time, these kinds of substances may have different environmental and human health risk profiles, and the evaluation requires specialized expertise. If there was a centralized and specialized authority for the evaluation of such substances, it could build up more expertise; it would speed up the evaluation process, reduce the costs and potentially improve the quality and consistency of risk assessments DARs. Within the US EPA, a separate unit has specialized in the evaluation of such products, and the industry reports good experience with this.

Some stakeholders point out that during the evaluation of the substances on the 4th list, national evaluators will become more experienced with these kinds of substances. Thus, the need for a centralized agency will be less pronounced.

Proposal 7

Description: Establishment of a new and centralized authority (similar to U.S. EPA) for the evaluation of the active substances: microbials, botanicals and semiochemicals (and potentially also macrobials).

Advantages: Many applicants consider a centralized authority to be the most effective means to speed up procedures and secure consistency in risk assessments.

Disadvantages/ Problems: Politically, it will be difficult to give up national evaluation of BCAs and hand it over to a centralized organization. As a result of this proposal, member states will gain less experience with these specific groups. This lack of experience will cause problems when MS have to decide on national authorisation of the BCA-product. It is not evident that such a centralized authority would require less studies/accept further waivers than in the present system. The resources needed to create and run such a new authority will be relatively high compared to the small number of active substances to be dealt with. What will this authority do, if only few applications are submitted, or if applications are submitted at irregular intervals?

Implementation: This proposal conflicts with the sovereignty of member states and seems to meet strong opposition from this side. This proposal would require long discussions, before it could be implemented (if it would ever be implemented).

Potential impact: The impact of this proposal is difficult to estimate. The industry claims that a centralized registration authority would greatly reduce their costs for dossier preparation, and might speed up the Annex I listing process. On the other hand, this might be offset by a lack of expertise in the member states, which could affect national registration of products.



REBECA conclusions concerning a centralized registration authority

In the opinion of the REBECA project, the evaluation of BCAs should be harmonized as much as possible, and the evaluators should have as much expertise as possible. This may be achieved through further communication among regulators (in particular by implementing proposal 6.C (Establishment of expert groups)). REBECA does not support the establishment of a centralized authority, mainly because this is regarded as politically unachievable.

Thematic area 8: Optimal Legislative framework - Specific data requirements for BCA

Introduction: Some stakeholders believe that even though it has been attempted, the Directive 91/414 it is still not adequately adapted to the special properties of microbial biocontrol agents and semiochemicals, which have completely different modes of action than the conventional pesticides, as well as completely different modes of production, methods for characterization and environmental and human health risk profiles. Proper evaluation of microbials and semiochemicals requires a different approach with different data. However, microbials and semiochemicals also differ greatly from each other. For these reasons, separate legislation for these two groups of substances seems relevant. Chemical as well as microbial biocides are regulated according to Directive 98/8/EC. The data requirements and

format for submission of biocide dossiers are different from those for plant protection products.

Proposal 8.A

Description: Microbial biocontrol agents and semiochemicals to be taken out of Dir. 91/414, and regulated by a separate directive (or regulation) for each group.

Advantages: More 'tailored' regulation/requirements.

Disadvantages/ Problems: It will be a long and time consuming process to prepare and agree on a separate Regulation/directive. Separate regulations may then fall under the responsibility of different (national) authorities which have otherwise no experience with regulating plant protection products. They may also fall under different General Directorates of the Commission.

Implementation: This proposal will require long discussions, before it can be implemented.

Potential impact: This proposal will have great influence on the registration process. It may change procedures and data requirements considerably, and speed up the registration process. However, there are also great uncertainties involved in this proposal, particularly if a new set of agencies becomes involved.

Proposal 8.B

Description: Keep microbials and semiochemicals in Directive 91/414, but specify separate data requirements for semiochemicals in a new Annex, and revise the Annex with the data requirements for microbials.

Advantages: Some stakeholders stated that it would be an advantage to keep the regulation of all kinds of plant protection products within one EU legislation.

Disadvantages/ Problems: The preparation of separate data requirements as an Annex to a regulation is a long, time-consuming process (although certainly less than proposal 8.A). If the data requirements are too prescriptive, there may be a loss in flexibility that the current system allows.

Implementation: This proposal will require long discussions, before it can be implemented (although probably less than proposal 8.A).

Potential impact: This proposal may change data requirements considerably. It may increase predictability of the process.

Proposal 8.C

Description: Keep microbials and semiochemicals in Directive 91/414, but specify separate data requirements for semiochemicals with guidance documents.

Advantages: Some stakeholders stated that it would be an advantage to keep the regulation of all kinds of plant protection products within one EU legislation. The approach with guidance documents is faster and more flexible than changing legislation.

Disadvantages/ Problems: Guidance documents are not legally binding.

Implementation: This proposal can be implemented quite easily, and changes are possible thereafter.

Potential impact: This proposal may change data requirements considerably, increases predictability of the process and facilitates preparation of the dossier.

Proposal 8.D

Description: Harmonization in the regulation of plant protection products and biocides based on BCAs as well as increased communication among national authorities of the two product types. Comment: Harmonization has already started. Some stakeholders stated that there is now a high level of harmonization in data requirements and uniform principles for microbial biocides and pesticides. Other stakeholders stated that there is an urgent need to harmonize the data requirements and the structure of dossiers. It is clear that it is more difficult to obtain harmonization in situations where products have different fields of use.

Advantages: Saves costs in the preparation of dossiers.

Disadvantages/ Problems: It may be a time consuming process to harmonize between different DGs within the Commission.

Implementation: Given the involvement of two DGs within the Commission, this proposal would probably require long discussions before it could be implemented.

Potential impact: This proposal is expected to have a great influence on the registration process. If the data requirements for biocides are adapted to those for plant protection products, this will result in considerable improvements. Harmonization in dossier format will facilitate dossier preparation for those active substances which are used both as plant protection products and as biocides.



REBECA conclusions concerning the optimal legislative framework

REBECA considers separate data requirements for BCAs to be adequate. This goal can be achieved fastest with guidance documents (proposal 8.C). REBECA also recommends harmonizing dossier format and data requirements for BCAs which are used both as plant protection products and as biocides (proposal 8.D).

Thematic area 9: Efficacy evaluation

Introduction: Compared with conventional chemical substances, many BCAs have a lower efficacy. There is some uncertainty as to what levels of efficacy are required for BCAs. In addition, many BCAs have a different mode of action as conventional chemical substances, which may make it necessary to adapt trial protocols. This is particularly the case for semiochemicals, where it is often impossible to use replicated trial designs.

It should be noted that efficacy is currently only an issue at member state level, not in the EU review system for Annex I listing. However, efficacy may become an EU issue with the revision of 91/414.

Proposal 9.A

Description: Authorities should accept modified trial protocols, provided that the applicant can justify the modification. Rationale: Efficacy testing of BCAs may involve specialized techniques, which require modification of trial protocols (e.g. plot size, replicates, parameters for assessment). BCAs may be more variable in their performance than conventional chemical pesticides, but provided a demonstrable and consistent benefit is achieved, approval should still be acceptable. The product label should accurately reflect the levels of performance that may be expected, as well as provide guidance on how to achieve these. PSD efficacy draft guideline 220 on mating disruption products provides an example of such a flexible approach.

Advantages: Efficacy testing and evaluation can be tailored to the specific properties of each BCA.

Disadvantages/ Problems: no serious disadvantages obvious.

Implementation: This proposal can be implemented easily.

Potential impact: This proposal will simplify the preparation of efficacy data.

Proposal 9.B

Description: If efficacy evaluation will be a part of the EU evaluation in the future, it needs to be accompanied by appropriate guidance on evaluation criteria.

Advantages: Leads to clarification among regulators and applicants. May also lead to harmonization in national evaluations.

Disadvantages/ Problems: Development of such guidance requires resources.

Implementation: This proposal will require some discussions, before it can be implemented. However, no serious obstacles to implementation are obvious.

Potential impact: This proposal will have some influence on the registration process. It will lead to harmonization of efficacy evaluation. This may also help applicants to produce adequate data and dossiers.

Proposal 9.C

Description: Even products with only minor beneficial effects should be acceptable, provided that the effect is shown to be reproducible and the label accurately reflects the likely benefits.

Advantages: This proposal facilitates the registration of products with minor beneficial effects. Such products may be particularly useful for organic farming and as components of IPM programmes or resistance management strategies. It would facilitate the registration of BCAs for use on a wider range of crops (e.g. minor uses), on which they have only a partial efficacy.

Disadvantages/ Problems: no major disadvantages or problems are obvious.

Implementation: For most member states, it is not a question *whether* this proposal can be implemented, but *to what extent* it should be implemented.

Potential impact: This proposal would facilitate the registration of BCAs considerably, and result in a wider use of BCAs.

Proposal 9.D

Description: The applicant can choose the option that the authorities do not evaluate efficacy during registration, In this case, there must be a disclaimer on the product label saying that efficacy has not been evaluated. It must be ensured that regulators are not liable for failures in efficacy of the products.

Advantages: This proposal makes registration faster, cheaper and more flexible, and delegates the responsibility for selecting efficient products to the market.

Disadvantages/ Problems: End users who do not carefully read the label might have wrong expectations concerning efficacy. This option might also be used for marketing products/ uses which do not work, which is not in public interest. The BCA industry fears that this might compromise the reputation of BCAs.

Implementation: It is not clear under which circumstances this proposal is consistent with the requirements of Dir. 91/414 (Art. 4 requires that substances must be «sufficiently effective»). It is also not clear whether the BCA industry would support this proposal, because of fears for their reputation.

Potential impact: This proposal would considerably reduce the applicants efforts needed for product registration. It is likely to increase the use of BCAs considerably, including possibly some products/uses which have little or no effect.

Proposal 9.E

Description: The same proposal as 9.D, but limited to a period of five years. After five years, efficacy data would need to be submitted, otherwise the authorisation of the plant protection product would be revoked. This option would therefore only be available for a transitory phase. This might be useful under the following circumstances:

- To register a BCA against an emerging pest, or for minor uses;
- In cases where there are some, but not sufficient data supporting the efficacy claims, e.g. trials carried out under unfavourable field conditions, or by institutions which are not officially recognized;
- To facilitate product development and market entry of SMEs with very limited research funds.

Advantages: This proposal facilitates market entry of all BCAs, but limits the possibilities for misuse and market entry of ineffective BCAs.

Disadvantages/ Problems: During the period of five years, products with low or no efficacy might be on the market, and might compromise the reputation of BCAs to some extent.

Implementation: See proposal 9.D.

Potential impact: This proposal would facilitate market entry of BCAs.



REBECA conclusions concerning efficacy evaluation

REBECA supports proposals 9.A – 9.C.

REBECA regards 9. E as an interesting potential approach, but does not support 9. D.

Summary evaluation of the proposals. For each proposal, the table gives an estimate of the timespan/difficulties for implementation, and of the potential impact on the duration of the registration process and on the costs for the applicants. Proposals which require a change in EU legislation or which conflict with the sovereignty of MSs are scored * for implementation. All other scores are based on expert judgement. With respect to proposals 7.A, 8.A and 8.B, experts from industry and from authorities expressed very different views concerning the potential impact. For details, see text.

Implementation

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

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)

Thematic area / Proposal	Implementa tion	Impact on duration	Impact on costs
1. Fees / financial support			
I.A Lower fees	**	-	**
I.B Financial support and guidance	**	-	**
2. Improved communication between regulators and applicants			
2.A Pre-submission meetings	***	***	***
2.B Applicants to attend expert/ evaluation meetings.	**	**	*
2.C Pre-submission information package	**	***	***
3. Precautionary principle vs. QPS approach			
3. Generic approach as often as possible	*	***	***
4. «Lessons learned from the 4th stage» approach			
4.A Lessons learned – data requirements	**	**	**
4.B Lessons learned – justify generic approach	*	**	**
5. Timelines			
5. Strict and short timelines	*	**	**
6. Further communication among regulators of BCAs			
6.A Further expert/evaluation meetings	*	**	***
6.B Lead rapporteurs also after 4th list evaluation – chairing meetings/increase communication between regulators.	*	***	**
6.C Establishment of expert groups for BCAs	**	***	**
7. Centralized registration authority			
7.A Centralized registration authority	*	*/***	*/***
8. Optimal Legislative framework			
8.A Separate directive for microbials and semiochemicals	*	*/***	*/***
8.B Specific and revised data requirements for microbials and semiochemicals in Annexes of Dir 91/414	**	**	**
8.C Specific data requirements for microbials and semiochemicals in guidance documents	***	**	**
8.D Harmonization in the regulation of PPP and biocides	*	*/***	*/***
9. Efficacy evaluation			
9.A.Flexible trial protocols.	**	**	*

9.B Guidance for efficacy evaluation	**	*	*
9.C Minor beneficial effects	**	**	*
9.D No efficacy evaluation	*	***	***
9.E No efficacy evaluation, limited to five years	*	***	***

Overview

The aim of the REBECA project is to propose procedural improvements which result in easier market access of BCAs, while ensuring their safety. The present proposals focus mainly on the EU review, and to a lesser extent also on the national registration processes, but the implementation of these proposals is not in the hands of the REBECA project. The following discussion sheds a brief light on the priorities with which these proposals should be followed up.

Some proposals were rated as being easy (***) or relatively easy (**) to implement. It can be expected that a number of these proposals will be implemented within the next few years. Several of these proposals can be implemented at member state level, and therefore require consensus only within one member state. Some of these have already been implemented in certain member states or are likely to be implemented soon. However, the REBECA project would welcome *all* member states to implement at least some of these proposals.

REBECA proposals which are relatively easy to implement at member state level:

1. Pre-submission meetings
2. Pre-submission information package
3. Use of lessons learned guidance documents from the 4th stage in pre-submission meetings
4. Flexible efficacy trial protocols
5. Acceptance of products with minor beneficial effects

REBECA proposal which are more difficult to implement at member state level:

1. Reduced registration fees
2. Financial support and guidance to applicants
3. Strict and short timelines for national authorisation

Other proposals require action at EU level. These require willingness of the member states and the Commission (DG SANCO) to go in this direction.

REBECA proposals which are relatively easy to implement at EU level:

1. Applicants to attend evaluation/expert meetings
2. Establishment of expert groups of BCAs (a microbial expert group already exists) as well as further and more regular expert-/evaluation meetings on BCAs
3. EU Efficacy evaluation criteria

REBECA proposals which are more difficult to implement at EU level:

1. New specific data requirements for microbials and semiochemicals
2. Generic approach in risk assessment
3. Strict and short timelines for EU risk assessment
4. No efficacy evaluation prior to a 5 year registration period

REBECA proposals which are very difficult to implement at EU level:

1. Centralized registration authority
2. No efficacy evaluation prior to registration

Annex I: Questionnaire on main obstacles and proposals

Workshop on Current Risk Assessment and Regulation Practice, September 18-22, 2006, Germany

Input from participants

I. REGULATORS

Name	Agency/Institute	State
Richard Davis/Sonia Barker/Sue Mattock/John Dale	PSD	UK

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Lack of knowledge/expertise in the Regulatory Authorities in highly specialised areas.	Development of expert panels (EFSA?). Further development both at EU (Expert and OECD level) of guidance documents. Training.	Regulators/Comm/OECD/Industry	0-2 years
2. Lack of industry expertise on regulation and appreciation as to why it is necessary.	Further development both at EU (Expert and OECD level) of guidance documents. Training.	Industry/Regulators	0-2 years
3. Lack of Guidance, both for notifiers & regulators.	Further development both at EU (Expert and OECD level)	Regulators/Comm/OECD/Industry	0-2 years
4. Tendency for regulators to consider biopesticides in the same way as conventional chemicals.	Development of an expert panel (EFSA?). Further development both at EU (Expert and OECD level) of guidance documents. Training.	Regulators/Comm/OECD/ Industry/EFSA	0-2 years
5. Lack of commercial returns from market/Limited market (niche products).	Subsides. Better use of mutual recognition (MR). Improvements to MR	National Governments/Com MSs/Com	3-5 years
6. Poor dossiers.	More considered input from industry and willingness to	Regulators. Industry.	3-5 years

	address the regulators concerns. RMS providing pre-submission meetings and training.		
7. Notifiers making pre-assumption of knowledge in dossiers and including too many unsubstantiated claims. Notifiers also failing to use all the relevant (e.g. public domain data) information that is available to them.	More considered input from industry and willingness to address the regulators concerns. RMS providing pre-submission meetings and training, but also industry educating regulators. Where there is available guidance such as OECD, applicants should still make an effort to relate to their particular product/use rather than just referencing it and letting the regulator make the case. Notifiers to make better use of available information.	Regulators. Industry.	0-2 years
8. Fear! Applicants being afraid to talk to Regulators.	Better communication both ways.	Regulators/Notifiers	0-2 years
9. Regulators not willing to discuss issues with applicants	Better communication both ways. Improved MS access. More workshops.	Notifiers/Regulators	0-2 years
10. Cost/Fees (of compiling the dossier and regulatory fees)	Subsidies. Development of efficient systems. Streamlined requirements.	Governments/Com/ Regulators	3-5 years
11. Limited access to Researchers for Regulators (e.g. hence some studies are not suitable for regulatory purposes)	Better communication between research bodies and regulators	Science/Industry/ Regulators	0-2 years
12. Poor transfer of research to market place	Subsidies. Better communication between research bodies and regulators. Needs analysis of	Science/Industry/ Regulators	3-5 years
13. Unwillingness of some MSs to accept data from other countries.	Increased flexibility of MSs. Need for attitude change and for MSs to at least consider all available data.	Regulators/Com/EFSA	0-2 years
14. Lack of quality systems (GLP, GEP and Official Recognition (OR))	Develop of generic EU systems & guidance	Regulators/Com/OECD	3-5 years

Name	Agency/Institute	State
Kersti Gustafsson	Swedish Chemicals Inspectorate	Sweden

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Poor quality of the dossiers. They have improved since the first organisms, however there is more to do. They also diverge in quality.	Improved knowledge about risk assessment and careful compilation of the dossiers.	Notifier/Industry/IBMA	3-5 years
2. Lack of common understanding of the data requirements.	Discussions and seminars. Improvements, simplifications and clarifications in Annex IIB and IIIB.	Industry/Notifiers/IBMA European Commission/MS	0-2 years
3. Lack of discussions on interpretation of risk assessment.	Seminars and discussions on risk assessment with representatives for Industry, Authorities and OECD. Communication on risk assessment.	Industry/IBMA/European Commission/OECD	0-2 years
4. Lack of scientific research in the area of biological control and risk assessment. Lack of theories.	Expressing the need to scientists and research funding organisations. Industry to support research on risk assessment.	Industry/IBMA/OECD	3-5 years
5. Lack of general experience in the field.	As always when there is lack of experience - time and lots of work and learning.	MS/National regulators Industry/Notifiers European Commission OECD Science ... etc.	3-5 years
6. Too few test methods and models.		Industry/Notifiers European Commission OECD Science ... etc.	3-5 years
7. Too few guidance documents.		Industry/Notifiers European Commission OECD Science ... etc.	3-5 years

Name	Agency/Institute	State
Anja Bartels	AGES	Austria

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. notifiers not providing data required for evaluation	clearer rules what is required; more understanding of notifiers that also for low risk products some data requirements exist	notifiers	0-2 y
2. work load of regulators with EU review of chemicals (not with BCA`s)	??, more staff is not a solution, because work load might be temporary	regulatory bodies	?
3. lack of information exchange between different MS on their experience and authorisations	creation of an internet platform / forum	?	0-2 y
4. lack of information exchange between regulators and science	creation of a web page with regularly updated informations	science	0-2 y
5. lack of experience of regulators in many MS (e.g. new MS)	training, workshops creation of a positive list, help of more experienced regulators	?	1-2 y
6. lack of guidance on data requirements	develop guidance documents	e.g. EFSA, OECD, EC, science, MS	1-3 y
7. no legislation on BCA`s authorisation in some MS	implement legislation	national governmental bodies	1-3 y
8. low financial capacity of small biocontrol companies	international data sharing, new studies paid by many companies, financial support of governments, lower authorisation cost for low risk products	industry, governments	

Name	Agency/Institute	State
Daniela Jölli (Dep. for Environmental Behaviour & Ecotoxicology) Petra Maritzen (Dep. for Toxicology)	Austrian Agency for Food Safety and Health / Institute for Plant Protection Products Evaluation & Authorization	Austria

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Lack of time, capacity (staff) and of experience in evaluation and authorization of bio-pesticides	Employment of (specialised) staff (microbiologists, molecular biologists,...), professional training	National regulators	0-2 years
2. No general procedure for evaluation and risk assessment, no guidance document	Implementation of a guidance document	National regulators, European Commission, industry/notifier, science	3-5 years
3. Communication between national regulator and industry/notifier	Process of preparing a dossier (EU or national authorization) should be interactive to ensure that the dossier is complete to assess the risk. Possibility to discuss the requirement of case-specific information or the possibility to use waivers.	National regulators, industry/notifier	0-2 years
4. Dossier not complete, studies are missing which are needed for risk assessment	see point 3	Industry/notifier, national regulators	0-2 years

Name	Agency/Institute	State
Jeroen Meeussen	CTB	The Netherlands

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. applicants/notifiers are not familiar with the legislation, registration process	Pre-consultation meetings initiated by RMS are necessary.	National regulators	0-2 years
2. extensive list of data requirements	Make a set of core data requirements	EC, OECD	3-5 years
3. agents and products are often evaluated by persons with a chemical background	More specialists need to be involved	Science, EFSA	0-2 years
4. fees are often too high	Governments need to take their responsibilities	Political people	?

Name	Agency/Institute/Company	State
Jacqueline Scheepmaker	RIVM	Netherlands

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Too many data requirements	a: Several sets of data requirements depending on the tonnage. Thus, a small data set when the product is used in a small crop. Look at the legislation of 'new substances' where this principle is used. When the tonnage increases the applicant has to provide		

	<p>new studies.</p> <p>b: studies for exposure are not necessary in the first tier. Only when risks are defined with NTOs ,additional information can be asked on exposure.</p> <p>c: should mode of action be a data requirement? Sometimes several modes of action coexist and not all modes of action may be discovered.</p>		
2. Registration has the same template as the chemicals. This is limiting the freedom of an overall look at the problem	<p>a: Only the preparation of a dossier for identity and characterisation. Then risk assessors identify possible risks. These risk will be monitored in the field. In the meantime the product is on the market for the time being. If post monitoring does not show the risks than the product is legally allowed. The post monitoring has to be paid by the applicant as he saved money and starts to earn money in an early stage.</p> <p>b: stepwise filling of dossier. After completion of identity and characterisation, regulators and risk assessors determine the studies that need to be done.</p>	RIVM starts a project in 2007 for development of a post-monitoring system for GMOs and BCAs. (decision on funding has not been taken yet)	3-5 years.
2b.	Comparison with chemicals in legislation.	RIVM starts a project in 2007 for the comparison of soil health when using BCAs or chemicals. (decision on funding has not been taken yet)	3-5 years
3. Dossier quality is inconsistent	<p>a: Good instruction by registrators.</p> <p>b: Risk assessors can do the literature search when the applicant does not have the tools and the experience.</p>		
4. preparation of monograph is only a smaller percentage of the total of 8 years.	EU/EFSA meetings on inclusion in Annex 1 not only one or twice year but as soon as possible in a telephone conference independent of other agenda points.		0-2 years
5. uniform principles not	some toxicity to NTOs should	risk assessors,	0-2 years

decisive and too vague	be allowed, like it is with chemicals. We need to think about the risk criteria and use those of chemicals as an example.	regulators	
6. Expertise most risk assessors is still limited. They have to use their limited expert judgement as guidance documents are still missing. Potential danger is that extra, maybe unnecessary data are asked for.	a: identification of gaps b: working groups for preparing guidance documents. c: more connections with experts d: funding for specific extra research	a: risk assessors. b: OECD c: risk assessors and scientist. network development d: registrators	3-5 years
7. data requirements on for example persistence ask for expensive studies (if data from the literature are not available already: then studies are not necessary).	preparation of review articles or generic statements where possible that make these studies unnecessary	risk assessors together with scientists	0-2 years

Name	Agency/Institute	State
Susanne Brock Christina Pickl	UBA (Federal Environmental Agency)	Germany

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. A lack of knowledge about the detailed modes of action (molecularbiological) which might exclude effects on non-target organisms	Guidance documents being applicable for specific, agent-depending test strategies. Data are needed to characterise the mode of action, to define groups with same characters and to deduce recommendations for a tiered test strategy.	Industry/Notifier together with scientific community	Have to be answered by the responsible players
2. Microorganisms: Host specificity is often used as the main argument for low risk to non-target organisms	Where high host specificity is claimed, it has to be proven e.g. by cross-transmission tests.	Industry/Notifier together with scientific community	Have to be answered by the responsible players

without providing appropriate evidence.			
<p>3. Botanicals: Extracts not only differ in content of ingredients but also in the concentration of the active substances.</p> <p>The appointment of only one lead active substance is not applicable for testing the eco-/toxicity of an extract/product.</p> <p>The absence of comparability of studies conducted with different extracts does not allow a risk assessment based on lead substances and single concentrations.</p>			

Name	Agency/Institute/Company	State
Susanne Guske Herbert Köpp	BVL	Germany

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Missing / unsuitable test guidelines for microbial plant protection products (e.g. for sensitisation for classification and labelling) classification and labelling: of sensitising properties	New test guidelines	National regulators Industry OECD/BPSG has already started European Commission Science EFSA	
2. Batch analysis of microbial active substances /products-	New Guidance documents or regulations	National regulators OECD/BPSG has already started	

Testing for contaminant micro-organisms: Which indicator organisms have to be checked? What are the limits? When is a Mouse IP injection assay necessary? No detailed EU requirements are available.		European Commission Science EFSA	
3. Fees		Industry/Notifiers Governments	
4. Metabolites (Identification, evaluation)	New test guidelines, criteria	National regulators OECD/BPSG has already started European Commission Science EFSA	
5. High costs for dossier compilation and data generation (including literature data)	Joint generation of data which are not strain specific	Industry/Notifiers	

Name	Agency/Institute	State
Heli Nõmmsalu	Estonian Plant Production Inspectorate	Estonia

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Guidance documents for evaluation and authorisation of biological control agents are missing	To work out guidance documents	European Commission OECD Science	0-2 years
2. Simplified procedure for evaluation and decision making of biological control agents is missing	To develop a simplified and short procedure	European Commission National regulators	0-2 years
3. Marketing obstacle:		Industry	0-2 years

products are expensive			
4. Different and high evaluation fees in Member States for biological control agents	To reduce the evaluation fees for biological control agents and to harmonise the fees in different Member States	National regulators European Commission	0-2 years
5. The common standpoint and scheme for authorisation of macrobials at EU level is missing, there are still different approaches in different MS-s	To make a decision at EU level about the authorisation of macrobials	European Commission Science	3-5 years

Name	Agency/Institute/Company	State
Hommel, Martin	BBA/Institute for Plant Protection in Horticulture	Germany

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. High costs for studies	Reduce number of studies to a minimum	National regulators; EU, OECD	3-5 years
2. High fees for registration	Reduced or no fees for low risk products	National regulators; EU	0-2 years
3. High data requirements for the different areas, like human tox or eco tox	QPS-concept, waivers for the different groups of substances for special data requirements were possible	National regulators; EU, OECD	3-5 year
4. High efforts for registration at all	Financial support by national and EU-programmes	National government and EU	0-2 years

Name	Agency/Institute/Company	State
Antoon Loomans	Plant Protection Service, 6700 HC Wageningen	The Netherlands

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators, Industry / Notifiers, European Commission, OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Dossier: Information	Harmonization Information	All stakeholders	1-2 years

Requirements between countries very diverse	Requirements (see Bigler et al., 2005)		
2. Procedures very diverse	International standardized procedure for implementation	EC, NPPOs	> 3-5 years
3. Evaluation criteria unclear / different	Hierarchical information and evaluation system (see Van Lenteren et al., 2006)	Science, Comp Nat Authority/ NPPO, Industry	1-2 years
4. Costs	Include administrative costs only	Comp Nat Authority/ NPPO	0-2 years
5. Latency time (application > permit)	Maximum time period for administrative and risk evaluation	Comp Nat Authority/ NPPO	0-2 years
6. Additional research / generated information needed (costs)	Focus on European native BCAs, or on exotics with low establishment potential and no broad (NT) host range > low risk species list	Science, Industry; NPPOs	> 3-5 years

Name	Agency/Institute	State
Franz STREISSL	EFSA	EU

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Risk assessment for biocontrol agents is not conducted on a regular basis as for chemical plant protection products. The guidance for the risk assessment of biocontrol agents is much less elaborated as for chemicals.	2. Organization of workshops to develop guidance or to work out the existing guidance on risk assessment for different biocontrol agents including provision of worked out examples.	All stakeholders mentioned above	?

Name	Agency/Institute	State
Libby Harrison	Environmental Risk Management Authority	New Zealand

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers	0-2 years

		European Commission OECD Science ... etc.	3-5 years > 5 years
1. Cost	More government subsidy; or encourage industry to work collaboratively	Government & Industry	
2. Uncertainty of outcome	Uncertainty is an intrinsic part of a regulatory system. Regulators need to be clear about what they are protecting and why, and the criteria for protection. Better understanding of the science of biological control; risks, costs and benefits.	Regulators, Scientists, researchers.	
3. Information requirements	Regulators provide clear directions on what they need to carry out a risk assessment. Links to number 2 above. Understanding impacts on ecosystems and how to predict what will happen	Regulators, scientists, researchers	
4. Regulators keep increasing the height of the regulatory (bio-protection) hurdle	May need to reduce hurdles or know when to stop increasing them	Regulators	

II. INDUSTRY

Name	Agency/Institute/Company	State
Marina Niemi	Verdera Oy	Finland

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
1. High cost for generating a full data package for a complete dossier on a MPCA/MPCP (often for a niche market)	More waivers accepted, based on information on the origin and characteristics of the MPCA and its intended use	Industry/EC/national regulators	0-2 years
2. Lack of test methods suitable for MPCAs	Development of methods for testing of MPCAs	Science	> 5 years
3. Unclear definition of 'relevant metabolites' and extent of testing/analysis of metabolites that is needed	Decision that no metabolite studies are requested unless there are clear indications from literature and/or basic toxicology tests that there is cause for concern for toxic metabolites	EC	0-2 years
4. Demand for GLP status of efficacy trials	Acceptance of 'Principles of good research practice' instead of GLP	EC/OECD	0-2 years
5. Extent of efficacy data package that is needed is not known	Zoning and mutual recognition, plus defined minimum data package = only representative trial data in support of intended uses	EC/OECD/national regulators	0-2 years
6. Lack of definition of and evaluation process for low risk active substances	Agreed definition and specific guidance document for evaluation of low risk actives (including MPCAs)	EC/OECD	0-2 years
7. Mutual recognition of	Implementation of mutual	EC	0-2 years

authorisations not accepted by all MSs	recognition throughout EU		
8. Lack of experience and expertise in microbiology among regulators/evaluators	Recruitment of microbiologists/biologists/ecologists to EFSA/Competent Authorities in MSs or Centralised evaluation of dossiers for MPCAs by a few MSs with necessary experience and expertise.	EC/National regulators	3-5 years
9. Lack of data sharing between RMS's	Establishment of a centralised data bank for toxicological, ecotoxicological, Efatel data etc., which RMSs can use as reference when accepting waivers	EC/OECD	3-5 years
10. Lack of standard/equal evaluation fee in all MSs, since/if notifiers cannot choose RMS for their dossiers	Introduction of a standard fee throughout EU, possibly covered (at least partly) by the EU	EC	0-2 years
11. Extent of data required for national authorisation after Annex 1-inclusion unclear	Acceptance of submitted Annex II and III data as such (and assessment made based on that), possibly supplemented with data of particular relevance to the conditions in the MS (zone) where national approval is sought.	National regulators	0-2 years
12. Slow registration process, during which sales with provisional authorisation not possible in many countries	Provisional authorisation throughout EU when the DAR is ready (and RMS proposes inclusion on Annex 1).	EC	0-2 years
13. Annex III in dossier submitted for Annex I-inclusion is prepared for a 'representative formulation', which may be further developed during the slow registration process -> unclear how much data on the new formulation and how much bridging data between formulations is needed for national authorisations	Agreed definition of a minimum data package for a new formulation (including data on the new formulants) plus necessary bridging data; otherwise originally submitted Annex II and III data should be accepted in the evaluation of the new formulation.	National regulators	0-2 years

Name	Agency/Institute/Company	State
W. Ravensberg	Koppert Biological Systems	Netherlands

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Costs of registration dossier	Reduce requirements for dossier; ask only relevant matters (example like solution in organic solvents of a salt: leave out); use literature; reduce efficacy data to a minimum and use extrapolation to other crops; leave out phytotox (producers responsibility); reduce ecotox, fate questions of natural compounds and organisms. Create dossier requirements appropriate to each groups of a.s. (do not follow chemical requirement list)	EC, OECD, national regulators	3-5
2. Administrative costs (fees)	Develop EU wide system of equal and fair fees, each country should asks the same fee, an EU administrative bureau should collect fees and redistribute to MS's. Each dossier (or category) should have the same costs, not depending on RMS. Create a low or no fee system based on turnover of synthetic chemical pesticides (like EPA) to stimulate alternatives to chemicals.	EC (Politic issue, fair treatment)	0-2
2. Procedure is too complicated and takes much too long	A two way system: a.s. and product registration is only acceptable if the a.s. is registered within a short period, like 18 -24 months. Why do other countries need to do the work of the RMS again (DAR) , develop a system of trusts and perhaps RMS 's with special expertise.	EC, EFSA, national governments	3-5

	<p>This will lead to shorter evaluations. And products can be registered in 1 year and in all countries (provided that GAP table is comparable) by mutual recognition. Three years waiting for a possibility to get any return of investment is already very long for small companies. Dossier generation is about 2 years, so five years investments or more and no income !!!!</p>		
3. registration is needed in 25 countries, while a.s. has been evaluated	Develop a simple procedure for mutual recognition or even obligatory registrations	EC	3-5
4. No separate approach and evaluation line for low risk substances	Develop one agency who can handle these a.s. centrally in EU (like EPA)	EC, EFSA	3-5
5. no real experts	Appoint experts in central agency and keep them there; use some experts in case needed, but avoid long procedures	EC, EFSA	3-5
6. Take non-registered "snake oils" from the market; including regulations that allow this	Country's responsibility, Inspection service/police; gives biocontrol a bad image	All countries, EC	0-2
7. Create a positive list of substances and organisms that are effective and safe, so registration is not needed.		EC, countries	0-2

Name	Agency/Institute/Company	State
Franceschini Sergio	Intrachem Bio Italia Spa	Italy

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
1.Lacking of competent experts for the	create an "experts" task force	E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
		European Commission OECD	0-2 year

evaluation procedure			
2. Requirements for efficacy on national level as high as for chemicals	reduced trials number	European Commission	3-5 years
3. Consistency and level of efficacy influenced by many environmental factors	determine the level of acceptability	European Commission	
4. Available scientific data	database with open literature	Science - EC Project	0-2 years
5. Registration cost for Annex III preparation	adopt more simple and harmonise procedure at National level	European Commission	3 - 5 years
6. Provisional authorization	Maintain 3 years provisional authorization	European Commission	0-2 years
7. Lack of competent on the preparation of the dossier small medium company	Preparation of Company experts	Industry/Notifiers OECD Science	3-5 years
8. More harmonised approach on the dossier evaluation between member states	Centralised evaluation system	European Commission	0-2 years
9. Reduction and harmonization of the fees	Centralised evaluation system	European Commission	0-2 years
10. Data requirements	Develop specific methods for BcA	OECD Science	3 – 5 years

Name	Agency/Institute/Company	State	
Giuseppe Manzaroli	Bioplanet	Italy	
Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	Possible timeframe for implementation of changes 0-2 years 3-5 years > 5 years
1. Lack of harmonization in the approach and procedure between the different national	Create a network between national regulators and a common database. Have a real distinction between	Political Level with the contribution of stakeholders, in primis science and	?

regulatory authorities. Different dossier costs. Absence of data exchange	traditional chemical active ingredients and IBCAs or plant extracts and plant strengtheners	plant protection authorities.	
2. Lack of flexibility and 'chemical' scheme of 91/914	Re-definition of the concept of what is a PPP and reduce sharply the role of efficacy tests focusing on safety.	same	?
3. Lack of experts in biological agents and common evaluation criteria.	Create a permanent expert panel or committee (another....) able to give to national regulators support and quick answers when needed.	same	?
4. Absence of clear EU policy of promoting biological product and alternative methods of pest control. Actions for removing obstacles to a widespread use of the low toxic methods and lack of clear effort to reduce the use of chemicals as stated in EU intentions.	Establish a clear principle that IPM or Bio (Eco) Label cannot be accepted without the routinely use of IBCAs and strong reduction of chemicals.	same	?

Name	Agency/Institute/Company	State
Maria Pilar Herrero	Valent BioSciences Corp.	

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
Large amount of efficacy data required for the EU. Large matrix of crops/insects, etc., under multiple systems, in every country. Huge cost for possibly very small, niche markets.	Proof of concept. Require efficacy to show that the product does work but allow bridging to other crops and across environmental zones.	E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years

Name	Agency/Institute/Company	State
Philip Kessler	Andermatt BIOCONTROL AG	Switzerland

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
Dossier requirements			
The cost for the expensive studies, particularly for human and ecotoxicology are too high for SMEs	If the active ingredient/product has already been generally assessed to be safe for human and/or environment, no studies on human or eco-toxicology has to be submitted. Assessment will be based on consensus documents Position papers and consensus documents for evaluation are necessary	EC, national regulators Science, OECD	0-2
Extra costs due to registration experts in the company to handle the dossiers and to deal with registration	Reduce requirements for the dossiers	EC, national regulators	0-2
Cost for external experts (consulting persons) to compile registration dossiers and to deal with registration	Reduce requirements for the dossiers	EC, national regulators	0-2
Registration fees			
High registration fees are <u>unbearable for SMEs!</u>	No registration fees for biological control agents in order to facilitate the market introduction for BCAs	EC, national regulators	0-2
Long evaluation times			
Insufficient knowledge at the registration authorities	Experts for biological control agents in regulation authorities	EC, national regulators	3-5

how biological control agents and their risks should be assessed	needed Guidelines for facilitating the evaluation of biological control agents. Positive list.		0-2
No short track registration for low risk products	Short track system to facilitate the market introduction of low risk products		0-2
National registrations in 25 MS. After Annex 1 inclusion, the product has to be registered in each MS separately, which leads to further costs and time before product can be approved for the national markets	Mutual recognition Provisional national approvals should be directly given after DAR publication and recommendation by RMS	EC, national regulators	0-2
Efficacy trials of 2-3 years	No efficacy trials needed (cf. EPA). Market will decide on good products Provisional national approvals should be directly given after DAR publication and recommendation by RMS	EC, national regulators	0-2

Name	Agency/Institute/Company	State
R. P. Sheppard	IBMA	International

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products For Semiochemicals	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
1. Lack of acceptability of OECD Registration Guide-lines. (Because 91/414 “overrides” any non-EU requirements?) Situation is worse for Biocides	Immediate acceptance and introduction of guideline already agreed between industry and the regulators, i.e. OECD 12. Include as an amendment to the proposed PPP Regulation dealing with the introduction of a simplified procedure for low risk	E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
		Some MS regulatory authorities. However, it will need the EU Commission to provide an enforceable remedy for this problem.	0 – 2 years

	substances and products. (COM(2006) 388 final 2006/0136 (COD).		
2. Lack of knowledge and expertise in some regulatory authorities	Formation and operation of an independent expert group who can advise regulatory authorities as appropriate. (Network of Excellence?)	EU Commission	0 – 2 years
3. Inflexibility in interpreting defined waivers	As 1. & 2. above	EU Commission	0 – 2 years
4. Likely delay in implementing latest EPA relaxations within the EU.	Request that the BPSG (Biopesticides Steering Group) of the OECD undertake a review of OECD 12 in the light of the EPA proposed relaxations.	EU & OECD	0 – 2 years

III. SCIENTIFIC RESEARCHERS

Name	Agency/Institute/Company	State
Margareta Hökeberg	MASE laboratories AB	Sweden

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Lack of relevant knowledge (e.g. in microbiology) BUT a strong chemical tradition for notifiers to argue against.	Recruitment of personnel competent in the biological control area, alternatively extended use of external expertise. Education of regulatory authority toxicologists etc.	Regulatory authorities National regulators	0-2 years
2. Relevant Study guidelines are lacking; notifiers have to develop new methods, get authorities/rapporteur's consent for the method, then do the actual testing. Time consuming and expensive.	Make resources available for experts (toxicologists, microbiologists, ecologists etc) to develop such guidelines	European Commission, Science	3-5 years
3. Relevant models for exposure evaluation are lacking	Make resources available for experts to develop such guidelines	European Commission, Industry, Science	3-5 years
4. Agendas and time tables are not kept. Member state representatives could be ill prepared and not updated on the latest submissions on Circa. Biocontrol questions not prioritised in regulatory meeting scheduling, are	Better structure for updating and preparations for meetings (more resources?). Put biocontrol items first on the meeting agenda. This will give a clear signal that the European Union and MS put priority in biocontrol products.	National governments, National authorities, National regulators, European Commission 0-2 years	0-2 years

often last item on the agenda.			
5. Different expert opinions on details are abundant during the registration process but the ability to have a view on the overall state of the art for a specific application is often lacking.	Put more emphasis on, and clearer guidelines for the role of the rapporteur to communicate the overall picture and the regulatory history of an a.i.	European Commission	0-2 years
6. Uniform principles for efficacy assessment are lacking, all fight for their national principles	Create uniform principles for efficacy testing, or better, use a centralised efficacy testing in conjunction with the a.i. evaluation (see 7. below)	European Commission Science	3-5 years
7. The double evaluation system (active ingredient – EU level, product – national level). Mutual recognition not implemented.	Change to one system – like for e.g. feed additives. Let the market decide if a product is interesting on different national markets. OR, second best, quick implementation of mutual recognition within the three zone system.	European Commission (National governments)	0-2 years
8. Poor regulatory affairs resources at biocontrol companies, sometimes resulting in ill-prepared dossiers	Creation of “generic” helper dossiers for different organism groups and applications.	Industry Science Regulatory authorities	0-2 years
9. Unwillingness to accept waivers	Ability to trust expertise.	National regulators	0-2 years
10. There is no “fast track” possibility – not adjusted to niche products and SME:s	Define low risk products and create a fast track process for these.	European Commission, Science, Industry	0-2 years
11. High application fees	Reduction of fees, or no fees – if governments and EU want to encourage these products	National governments, European Commission	0-2 years

Name	Agency/Institute/Company	State
Ingvar Sundh	Dept of Microbiology, Swedish University of Agricultural Sciences	Sweden

Main obstacle for quick evaluation/authorisation	Proposal that can facilitate the obstacles and accelerate	Responsible player	Possible timeframe for
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and market introduction of biocontrol agents and products	the evaluation and market introduction of biocontrol agents and products	E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	implementation of changes 0-2 years 3-5 years > 5 years
1. Very bureaucratic evaluation procedures within the EU, making the time needed to come to a decision far too long.	Perhaps a more “centralised” process: Less possibilities for country authorities/regulators to raise questions? One rapporteur member state for microorganisms? Central recognition of both active agent and product?	European commission. National regulators. Politicians.	> 5 years
2. The financial resources (and time) needed to compile an application dossier, pay the fee, and wait for a decision are too big. The companies are often small and have limited resources.	Reduced fees for BCA:s. Either because society (politicians) actually want more of these products , and/or that we can establish criteria to define BCA:s (at least some) as low risk products.	Politicians. National regulators. Industry. EU. Academia.	0-3 years?
3. Uninsufficient expertise with regulators and/or authorities doing the evaluations. Special and broad competence is needed for the safety evaluation of microorganisms, e.g. within microbial ecology, clinical microbiology, human microbial ecology and everyday exposure to microorganisms, occupational microbiology etc. etc.	Ensure that necessary expertise is available. If not in person at the actual authorities, good and rapid/efficient contacts must be established. More money may be needed.	National regulatory authorities. Academia.	0-3 years
4. Scientific knowledge is lacking in some areas, e.g.: methods to determine pathogenicity and production of toxic metabolites in microorganisms; biogeographies of microorganisms; incremental human exposure to BCA(:s) <i>in relation to the everyday exposure</i> .	More research funded with <i>public resources</i> is necessary. Many of the companies are very small and lack such resources.	Politicians. National and EU authorities and funding agencies. Academia.	3-5 years/> 5 years

5. Some of the data requirements for microorganisms are almost impossible to fulfil or poorly applicable: e.g. <i>strain-specific</i> info on geographical distribution; info on the spread and dissemination of the organism <i>and its metabolites</i> in the environment; genetic stability in the environment; toxicological endpoints (ADI) for microorganisms.	New regulation better adapted for microorganisms.		> 5 years
6. Low level of harmonization and cooperation regarding authorization of microorganisms for use in other applications, e.g. as feed additives, in new food products, or for biodegradation or bioremediation of polluted soils.	Better communications between the various players doing the evaluations of the different kinds of products with microorganisms. Possible to establish a common player? What will be EFSA:s role in the future?	Responsible national authorities. EFSA? OECD?	

Name	Agency/Institute/Company	State
Pertot Ilaria	SafeCrop Centre, IASMA	Italy
Yigal Elad	Safecrop Centre, ARO	Israel

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Mixture of two or more microorganisms have to be evaluated for each single active ingredient	If the mixture is going to be used only as mixture, the evaluation process could be done for the entire mixture (toxicology, ecotoxicology, efficacy).	EC	0-2 years

2. If the microbial BCA strain secret a mixture of compounds, each of the components of the mixture have to be identified and characterised and toxicology should be run separately	Consider the toxicology of all the metabolites together produced in a standard medium (model). Identify (HPLC) only known relevant antibiotics or toxins.	Standard model to be developed by scientists	3-5 years
3. Efficacy trials have to be performed for each pathogen/crop	Provide only in one system (two times repeated). Indicate on the label only the system on which it was tested. If active in additional systems and environments it should be demonstrate by the market.	Industries, science	0-2 years
4. Ecotoxicology	If the microbial BCA strain is not toxic for humans, avoid ecotoxicology on animals. In particular it is not necessary: 8. Effects on non-target organisms*	Industries, science	0-2 years
5. Ecotoxicology	If the microbial BCA strain is not surviving more then a certain period (i.e. 1-2 week) in the environment, avoid all ecotoxicology. In particular it is not necessary: 8. Effects on non-target organisms	Industries, science	0-2 years
6. Toxicology and ecotoxicology	If the microbial BCAs is already used in food industry, then Avoid toxicology and ecotoxicology. In particular 7.1. Persistence and multiplication	EC, science	0-2 years
7. Ecotoxicology	If the microbial BCAs is already as additive in fertilisers or composter: then Avoid ecotoxicology. In particular 7.1. Persistence and multiplication	EC, science	0-2 years
8. Toxicology	If the microbial BCA strain is inactivated by low pH and/or digestion enzymes and it is not producing toxins: Then avoid human toxicology (still to be discussed by scientist and regulator agencies)	EC, science	0-2 years
9. Information has to be obtained in GLP	To accept in the dossier also peer reviewed publications	EC	0-2 years
10. Each member state has to register the commercial product	After the registration of the active ingredient at EU level, it has to be accepted in all member states.	EC, National regulators	0-2 years

	Opponent have to discuss their concerns during a.i. registration		
11. (2.9. Antibiotics and other anti-microbial agents) Information on the micro-organism's resistance or sensitivity to antibiotics or other anti-microbial agents must be provided, in particular the stability of the genes coding for antibiotic resistance, unless it can be justified that the micro-organism has no harmful effects on human or animal health, or that it can not transfer its resistance to antibiotics or other anti-microbial agents.	If the microorganism does not survive in the environment for more than -2 weeks, it is not necessary.	EC, science	0-2 years
12. (3.5. Information on the occurrence or possible occurrence of the development of resistance of the target organism(s)) Available information on the possible occurrence of the development of resistance or cross-resistance of the target organism(s) must be provided. Where possible, appropriate management strategies should be described	Not relevant	EC, science	0-2 years
13. (3.6. Methods to prevent loss of virulence of seed stock of the micro-organism) Methods to prevent loss of virulence of starting cultures are to be provided. In addition, any method, if available, that could prevent the micro-organism from losing its effects on the target species must be described.	Not relevant	science	0-2 years

*Numbers refer to the directive on microbials registration

Name	Agency/Institute/Company	State
Anna-Carin Bäckman	Inst. Agr. S. Michele a/A, Italy Swedish Univ. of Agr. Sci.	Sweden

Main obstacle for quick evaluation/authorisation and market	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol	Responsible player E.g. National regulators	Possible timeframe for implementation of changes
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introduction of biocontrol agents and products	agents and products	Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1.Future biocontrol products based on non-pheromonal semiochemicals will probably need adaption to region and crop.	To facilitate the use of combinations/recombinations of registered semiochemicals.	Scientific researcher	?

Name	Agency/Institute/Company	State
Kerstin Jung	BBA, Institute for Biological Control	Germany

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. number and costs of studies that are required	Focus on the indication for which the product will be used and avoid unnecessary additional data	National regulators/European Commission	0-2 years
2. different requirements in different memberstates of the EU	Adapt and accept registration procedures based on a minimum standard	National regulators, European Commission, OECD	> 5 years
3. Taxonomic confusion/re-classifications of e.g. microorganisms	Enable research on basic <u>and</u> applied aspects. Taxonomists are an endangered species!	Industry, European Commission, OECD, Science	> 5 years

Name	Agency/Institute/Company	State
Wyn Grant	University of Warwick	UK

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Internal organisation of	Dedicated biopesticides	National regulator	0-2

PSD	division on EPA model		
2. SMEs lack of knowledge of help available from PSD	Enhanced outreach programme	National regulator	0-2
3. Mutual recognition	Implementation of eco-zones	European Commission	3-5
4. Lack of species concepts	Further research	Scientists	3-5
5. Efficacy requirements	Relaxation of requirements	European Commission/national regulator	3-5

Name	Agency/Institute/Company	State
Dr. G. Louise Mark-Byrne	Biomerit Research Centre University College Cork	Ireland

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Cost of registration of microbial BCAs as PPPs	At present the costs are the same as that of registering chemical based pesticides. The cost should be lower. The cost is lower in the USA and encourages companies to develop (in collaboration with scientific community) microbial inoculants that produce antimicrobials as biopesticides.	National regulators in Ireland (DAFRD, EPA, PCS) EU Commission OECD	0-2 years
2. Extensive data requirements	To provide more comprehensive focus data requirements for dossier preparation Increased funding to carry out extensive risk assessment required for microbial BCAs	National regulators in Ireland (DAFRD, EPA, PCS) Scientific community EU Commission	3-5 years
3. Specific action and efficacy of microbial BCA products	Increased funding opportunities for the development of microbial BCAs with enhanced efficacy in a variety of situations/ environments	National regulators in Ireland (DAFRD, EPA, PCS) EU Commission OCED	0-2 years
4. Biosafety concerns	Education of public sector, stakeholders and policy makers	Scientific community OCED National regulators	3-5 years

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Name	Agency/Institute/Company	State
Tobias Laengle	Pest Management Centre, Biopesticides Initiative Agriculture and Agri-Food Canada	Canada

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Cost for submission	Waive submission fee for biologicals (like in Canada) or tie to projected sales (US)	National, EU	0 – 2 years
2. Evaluators approach data review with “chemical pesticides mindset”	Biologists need to be in charge of reviewing biologicals.	National, EU	3-5 years
3. Review timeframe is too long and not consistent	Canadian model could work: guaranteed review timeframe on the condition that data requirements are met	EU, national	3-5 years
4. Workload for regulators is significant and experience with biologicals often limited	Better co-ordination and worksharing on OECD level. Final regulatory decisions may remain the authority of the respective jurisdiction, but scientific reviews of data must be shared (compare EPA-PMRA workshare).	OECD	3-5 years ??
5. “Playing field” for biologicals and chemicals is not level	Allow for comparative risk assessment in decision making, i.e. take into account the risk of alternatives to the proposed biological solution (see new Canadian legislation).	All levels	3- 5 years
6. Acceptance of data waivers not consistent	Encourage registrants to take pre-submission consultation. Discuss at pre-submission consultation the arguments for waiver rationals and agree where these will be accepted.	EU guidance for national regulators required	3- 5 years
7. Metabolite data for microbials is extremely expensive to generate and often irrelevant	Only require data on metabolite toxicity if there is a toxic mode of action, or if an organism or closely related organism is known to produce toxins, and only if there is a	All levels	0 – 2 years

	possibility of exposure. Sound judgement is required in this context.		
8. Registrants of biologicals are often inexperienced in working with regulators	Provide guidance in the form regulatory support to registrants through an independent/mediating institution	National, EU	0 – 2 years
9. Efficacy data	Provide clear information on what level of control is acceptable for BCAs, what other terms (such as suppression) could be used for lower levels of control/long-term downregulation.	National, EU	0 -2 years

Name	Agency/Institute/Company	State
Mark Goettel	Agriculture & Agri-Food Canada	Alberta, Canada

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Lack of commercial product availability for commercial evaluation and integration into IPM.	Tiered approach to registration. Provisional registrations be granted after primarily only user safety considered. This would allow limited quantities into the marketplace for evaluation. Full registration can follow later. Full efficacy and best use practices can only be determined after years of commercial/practical use	National regulators primarily, but of course all other players must play a role.	0-2 years
2. Small market size	Facilitate regulations to make registration faster and cheaper. Do indigenous organisms need full regulatory oversight?	National regulators primarily, but of course all other players must play a role.	0-2 years
3. Bad reputation on efficacy	Tiered approach to registration. Provisional registrations be granted after user safety considered. This would allow limited quantities into the marketplace for	National regulators primarily, but of course all other players must play a role.	0-2 years

	evaluation. Full registration can follow later.		
4. Insecticidal approach bias	Not all biocontrols need to be used inundatively. Actually, recent studies have demonstrated that resistance to microbials used inundatively has occurred for viruses and bacteria. Regulators must have a cheap, fast tracking option for products that could be used augmentatively or inoculatively (non-inundative, insecticidal approach)	All involved. More public good research for non-inundative IPM approaches. Relaxed regulations for instances where more "natural" means of biocontrol use are to be considered. (does inoculative approach of an indigenous microorganism need much regulatory oversight?)	0 – 2 years
5. Lack of on-site demonstrations	Provisional registrations would allow producers to see for themselves the value of upcoming new microbials. Eventual higher acceptance and uptake by producers would make products more viable.	Public good institutions, National regulators	0 – 2 years
6. Lack of public investment	Many products are not commercially viable however would have great public good benefits (address environmental contamination by pesticides, public nuisance pests etc). Public good institutions must be supported and play key role here.	Governments, NGO's	>5 years

Name	Agency/Institute/Company	State
Jeff Bale	Univ of Birmingham	UK

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
MACROBIALS		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Variation in ERA systems between	Harmonisation of ERA systems across EU	Probably EU, but they may not wish to	3-5 years

different EU states		do it	
2. Insufficient or inadequate scientific information for compilation of ERA	No obvious solution – see point 3 below	Industry and scientists	
3. Low returns for companies to justify finance necessary for research for realistic ERAs	Would seem to require EU or national government support for ERAs i.e. biocontrol preferable to pesticides	EU or National Authorities	3-5 years
4. Understandable reluctance of industry to share ERA information to protect 'IPR' investment via R&D costs (apparently very variable between companies)	Very difficult to resolve		
5. Failure to recognise different viewpoints in ERA debate	Better communication, and acknowledgment that no-one is 'right'. ERA is not going to 'go away'. So, agree on a sensible, harmonised ERA, and then seek ways to fund it. Industry will not be able to afford it, and what they can afford will be not be sufficient	All parties	

Name	Agency/Institute/Company	State
Cezary Tkaczuk	University of Podlasie	Poland

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. not clear regulatory system	<ul style="list-style-type: none"> - To establish new documents (guidance) for regulation system - To propose alternative regulation procedures and strategies for BCAs - Agreement about criteria for inclusion of microbial BCAs 	<p>EU, National regulators</p> <p>Science, National regulators, Industry</p> <p>EU, National</p>	<p>0-2</p> <p>0-2</p> <p>3-5</p>

	<ul style="list-style-type: none"> - on "Positive list" - Agreement on guidelines across countries - the guidelines must be dynamic and can be changed with the advent of new knowledge 	EU, National reg.	0-2
2. to long and to expensive process of registration	<ul style="list-style-type: none"> - appropriate research methodology (risk assessment, production and application) - independent analysis free from biased judgement influenced by current regulatory situation - reduced registration requirements for native and established BCAs - creation of scientific experts groups - less bureaucracy 	Science, Industry Science National reg, Science EU, science EU, National reg.	3-5 0-2 0-2 0-2 3-5
3. Still fragmentary and not sufficient knowledge about BCAs among farmers and community	<ul style="list-style-type: none"> - education of farmers - special programs at school 	Science, advisors	3-5

Name	Agency/Institute/Company	State
ENRIQUE QUESADA-MORAGA	UNIVERSITY OF CORDOBA	CORDOBA (SPAIN)

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1.LONG-term field experiments for each target pest to be registered	Registration with a "model" pest and further pest to be included without needing long-term field experiments		
2.In the case of entomopathogenic fungi: secretion in vivo of toxic metabolites	It has been demonstrated by the RAFBCA project that this aspect is not as important as actually considered		
3.why to repeat risk	Minimize risk assessment		

assessment studies for each strain of a same fungal species to be registered in Europe?.	studies of strains belonging to previously registered species (and particularly fungal species).		
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Name	Agency/Institute/Company	State
Dionyssios Perdikis	Agricultural University of Athens	Greece

General ideas

1. The application should be directed confidentially to a new EU bureau with very few servants (i.e. 1-2) that will be paid normally by EU. They will be connected with contact people in each state. These people will receive the applications. The evaluation of the already available information, the determination and the generation of additional required data before the release of a BCA is permitted should be undertaken by an expert group of the most related scientists. The expert committee should be met to evaluate the situation and give the permission or ask for additional data on certain aspects of the bioecology of the BCA.
2. The generation of new data is the main obstacle for the regulation process because it costs in money and time. The cost could be covered partly by the interested company and the EU.
3. Possibly could be established a permanent scientific committee of a few highly experienced experts in both science and regulation that will contact the most related experts with the BCA in question. These people could preferably already related to the regulation.
4. Ideally the committee of the related experts to the certain BCA in question, should consist of few experts, but both the southern and the northern EU should be represented in the panel since there could be different problems that the BCA could create in different habitats, regions etc. In the selection of the experts the use of BCA should be considered (i.e. if it is a BCA of citrus pest scientists should be mostly from the south).
5. The acceptance should be given if positive written opinions exist from the majority of the experts (i.e. 2/3), so as to have a higher degree of safety, to be more conservative to avoid future failures, the impact of which will be much greater if permission has been given for the natural enemy release.
6. There will be a cost for the company that should be kept as low as possible. The possibility to provide the company with a protection of the product against the use of other companies could be given for a period of time (i.e. 1 year).
7. If further studies are needed to collect additional data, these ideally should be conducted in EU Universities-Research Institutions under the supervision of experienced - related scientists. The information should be kept confidential. Probably an obstacle could be the direct assignment of a project. In this case there could be something like a "call of proposals", the subject of which will be kept general to keep confidence (i.e. studying host range and dispersal of a parasitoid on vegetables).
8. The cost of the research could be covered partly by the interested company and by the EU (possibly 40:60). The cost should be related to the actual cost of the research needed according to the experts' estimation. The EU funds can be originated from

sources related to the protection and conservation of the environment and biodiversity in agriculture. That is well justified if considering that BCAs regulation aims to the protection of biodiversity, biological control has a high return rate, it is friendly for the grower, it is a main component towards the production of high quality food etc. The possibility to provide the company with a protection of the product against the use of other companies could be given for a period of time (i.e. 2 years instead of 1 year in the previous case since the company has paid more money and more delay).

Problem	Solution proposed
Bureaucracy, time requirements	Central manipulation of the applications with contact persons in each state and experienced servants could help to avoid high delays. All necessary forms to be filled in from the applicant, should be assessable to the companies.
Cost for the permission	The fee should be covered by the company. It should be kept as low as possible so that small companies to be able to ask for new products. The company will give the right to exclusively use the product for 1 year.
Additional research cost	It will be covered by the company and the EU. If additional data is required, i.e. higher cost for the company, it will have the right to exclusively use the product for 2 years. If other companies wish to use it then they could apply and pay a fee 1 year after the permission.
Selection of the experts for the evaluation	They should be selected based on their scientific relationship to the BCA under question. Probably they could be contacted from a permanent committee.
Selection of the Institutes where the additional research has to be conducted	The scientific related committee could propose some related Institutions to an EU council or an open call for proposals should be undertaken.
Decision on the permission	It is preferable to be a little conservative

IV. CONSULTANTS

Name	Agency/Institute/Company	State
Ulf HEILIG	Consultant – Intervention SA	France

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player E.g. National regulators Industry/Notifiers European Commission OECD Science ... etc.	Possible timeframe for implementation of changes 0-2 years 3-5 years > 5 years
1. Discrepancy between high evaluation and administration fees and company size (frequently SMEs) and market size (frequently target specific or small range of activity)	Reduce evaluation costs if possible down to zero for biocontrol products of interest or create funding system to cover harmonised fees with central fee collection	EC and Nat Regulators	0-2 years
2. Lack of expertise with regard to the high specificity of many BCAs at EC level and in many Member States	Create EU expert panel or improve work sharing between MS and mutual recognition	EC (EFSA ?) and Nat Regulators	0-2 years
3. Inappropriate application of standard data requirements by authorities to BCAs	Develop an appropriate well defined and evolving waiver system for groups of active substances (some microbials at family or species level, semiochemicals by chemical class etc). Mode of application and formulation type (e.g. in discrete dispensers) should also be considered	Could be based on OECD guidance where available. OECD create additional guidance docs. EU Expert Panel for BCAs (to be created) could establish waiver system or even positive list for low risk act subst, in the mean time EC in coll with Nat Regul and Industry representatives Accept justification of waivers from other OECD MS (in particular EPA)	3-5 years

4.Complexity of regulations and of data requirements	Establish right of systematic pre-submission meetings with Competent Authorities; CA appoint a “pilot” or “project champion” who gives “personalised” guidance to (pre)applicants	Define principle in EU regulation but support to applicant to be given either at EC level if centralised evaluation by expert group or at MS level	0-2 years
5. Duration of procedures and evaluation until final approval	Give priority to BCAs in evaluation, re-establish provisional approval (especially for non residual act substances), and in the meantime, respect regulatory time frame (penalties ?)	EC and Nat Regul	0-2 years
6.Cost of generation of dossier	Explore and set up system of support or funding/subsidies Create research projects with EC/public funding to generate data of principle/general interest. Facilitate bridging and extrapolation between related active substances	EC, MS and industry in common Science to conduct studies EC/Expert Panel/Project Champion (see item 4) to give guidance for bridging	0-2 years to launch funding
7.Difficulty to characterise botanicals and similar natural products down to 0.1% level It is virtually impossible to quantify with precision natural substances without corresponding analytical standards who often do not exist	After identification of compounds in botanical e.g. by mass spec: accept estimated order (large range of concentration) for substances typically present in vegetables/food plants or known to be uncritical. Values can often be extrapolated by analogy in mass spec etc without precise quantification. Create positive list (progressively) of uncritical = low risk compound in plant extracts	EC and MS amend regulation correspondingly.	0-2 years for amendment ; positive lists progressively
8. Exaggerated data requirements for natural elicitors (stimulating natural defences)	Maintain and generalise reduced requirement approach equivalent to German “Plant Resistance Improvers” (Pflanzenstärkungsmittel) approach	EC and MS	Immediate (maintain) to 4 years (introduction in all MS)

Name	Agency/Institute/Company	State
Rüdiger Hauschild	GAB Consulting	Germany

Main obstacle for quick evaluation/authorisation and market introduction of biocontrol agents and products	Proposal that can facilitate the obstacles and accelerate the evaluation and market introduction of biocontrol agents and products	Responsible player	Possible timeframe for implementation of changes
		E.g. National regulators	

		Industry/Notifiers European Commission OECD Science ... etc.	0-2 years 3-5 years > 5 years
1. Long evaluation procedure	Definition of binding time frames for applicants and authorities; Formation of European expert groups instead of consultation of all MS	European Commission	0-2 years
2. Demands for additional studies during evaluation	a: Pre-submission meetings between applicants and authorities b: More precise definition of data requirements	Notifiers and RMS regulators	a: 0-2 years b: 3-5 years
3. High fees and differences between MS	Reduction and harmonization of fees	European Commission	0-2 years
4. Efficacy data are not comparable to chemicals	Efficacy data and risk evaluation have to be compared for biologicals and chemicals. Consistency of efficacy has to be determined	National regulators	0-2 years