

**COMMENT**

**on the**

**Proposal for a**

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**Concerning the placing of plant protection products on the market**

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**IMPACT ON THE REGULATION OF BIOLOGICAL CONTROL PRODUCTS**

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## Objectives of the REBECA Action

The REBECA Action is reviewing regulation practice for biological control agents (BCAs) in the EU with the objective to propose modifications of existing regulation procedures in order to facilitate a quicker market introduction of such products and make the registration process more cost-effective without compromising the level of safety for human health and the environment. BCAs need a distinct approach for risk assessment to establish reasonable regulation procedures.

The objective of the Action REBECA is to elaborate proposals which can accelerate the regulation process for BCAs. More information on the Action is available at [www.rebeca-net.de](http://www.rebeca-net.de).

## Positive effects of NEW REGULATION for BCA registration

The Draft presents several improvements for the regulation of BCAs. The following comments on these improvements and makes proposals on further definitions and improvements:

### 1. Mutual recognition in Zones

The new regulation proposes compulsory mutual recognition of PPP if authorisation has been granted in a MS belonging to the same zone as defined in Annex 1 of the regulation. **REBECA supports mutual recognition within climatic zones.**

A major hurdle for BCAs is high costs related with the registration process. Regulatory requirements and associated fees are considered inhibitory to market development of BCAs. Biological agents are usually very specific in their mode of action. Consequently the potential market size is limited and often does not justify high registration costs. A mutual recognition would reduce registration effort in MS after the listing on Annex 1, as registration in three zones would be enough to cover the complete EU. Effort and time can be avoided by registration in just one MS in each zone. Unnecessary duplication of work and bureaucratic efforts are avoided. The speed of market introduction can be increased.

A mutual recognition is not on the cost of the safety for consumers, users and the environment as all major risks are assessed during Annex I inclusion at the EU level. It is also not on the cost of member state influence on the authorisation process, as MS can participate in the decision making at the EU level.

### 2. Low risk substances and basic substances

**REBECA welcomes the specific measures for low risk and basic substances.** The draft for the new regulation opens the possibility to group PPP according to their potential risks and classify some of them as "low risk substances". The identification of a PPP as "low risk substance" can only be made after a comprehensive risk assessment. The current draft, however, does not clearly define what a "low risk product" is. Should this tool be used to reduce administrative burden and costs, clear guidelines must be available to define what "low risk products" are and lists should be made available, which identify certain agents as "low risk substances" so no authorisation or a less stringent authorisation would be possible. It would enable applicants to refer to these guidelines and lists in order to discuss with regulation authorities about reduced data requirements prior to submission.



REBECA is not able to provide comprehensive information on criteria and definition of "low risk substances". A follow up activity beyond the REBECA Action might be able to gather such information and discuss the results with SANCO, MS regulatory authorities and other stakeholders. Much information and experience is available on "low risk substances". Once gathered in studies they can be discussed with the experts and decisions can be made whether the substances have the potential to be listed as "low risk substances" or whether additional data on selected risks are necessary prior to a decision on the status of a substance or agent.

The same exercise should be made for basic substances. It would save much work and costs if formulation compounds would be qualified as safe and published on lists of safe basic compounds, so that companies could adjust and improve formulation of BCAs after authorisation without the necessity to apply for an additional permit again.

### **3. Approval Time**

**REBECA welcomes clear deadlines.** In the past, regulation of some BCAs was a long lasting process. Strict deadlines will certainly accelerate the authorisation process. The availability of the DAR within 12 months of the date of notification of the completeness check, 3 months for submission of comments and six months after receiving the conclusions from the authority a "review report" by the Commission is a challenging task and will significantly improve the time-frame for regulation. A decision by the MS within 90 days after application is also most welcomed.

However, it must be considered that applicants of BCAs are in most cases SMEs with limited financial and intellectual resources and often with no or little experience in how to handle the application and communication with the authorities. REBECA therefore strongly recommends support from authorities to SMEs applying for registration, in particular and whenever appropriate, the authority shall organise pre-submission meetings to decide on data requirements at an early stage.

To meet the deadlines will be a challenge for EU authorities and MS. As BCAs are particularly diverse in all major characters and novelties are more frequent than in chemical PPP, authorities will have a difficult task to gather knowledge for a fair assessment. REBECA therefore recommends the authorities to contact relevant experts whenever possible during the risk assessment, preferably even prior to the receipt of the application, e.g. in connection with pre-submission meetings.

### **4. New regulation makes reference to the Precautionary Principle**

**REBECA welcomes the reference to the Precautionary Principle in the New Regulation.** The commission has published a comprehensive communication on Precautionary Principle (COM2000/1): "Where the levels of uncertainty are high, where potential impacts are very large, and/or where those impacts may be irreversible, there are grounds for adopting a precautionary approach until such time as we have sufficient scientific knowledge to make a risk-based decision".

The communication also mentions that the Precautionary Principle is relevant only in the event of a potential risk. Before invoked, scientific data relevant to the risks must first be evaluated. However, one factor logically and chronologically precedes this evaluation, namely identification of the potentially negative effects of a phenomenon. Scientific evaluation of the potential adverse



effects should be undertaken based on the available data when considering whether measures are necessary. These general principles include proportionality, examination of the benefits and costs of action or lack of action and examination of scientific developments (COM2000/1).

The Precautionary Principle is thus demanding prior analysis of potential risks including an examination of benefits and costs of the regulation action based on scientific knowledge. For the introduction of biological control in agriculture and forestry the consideration of these principles is of major importance. Scientific data give evidence that risks related to BCAs are of minor concern; however, requirements for risk assessment are comprehensive and often inadequate. In several cases data requirements have not been based on a sound analysis of potential hazards prior to introduction of the rules. The consideration of the Precautionary Principle opens room for a continuous discussion and improvement of regulation requirements between stakeholders to base the regulation and data requirements on available scientific evidence of potential risks. As more and more results are published on the aspects of BCAs, the consideration of the Precautionary Principle will ensure that progress will be considered for the assessment of risks and be included in future modifications of regulation rules.

The REBECA Action introduced a dialogue between all stakeholders on all aspects of risks and risk assessment of BCAs and will make proposals on how the data requirements can be reduced or adjusted. The results provide potential for modification of existing rules and practice.

Other than for synthetic chemical PPP, regulation of BCAs has not evolved from a gradual evolution and dialogue between industry and authorities. Biocontrol industry was never well represented, lack mechanisms of lobbying and until recently have not even been organised and represented. Regulation of BCAs was thus not based on scientific reports of damages, like occurred in synthetic chemicals. The evolution of regulation rules involving all stakeholders has only started with the REBECA Action. The future must develop more adapted and more balanced approaches.

## 5. Transparency

**REBECA welcomes the publication of DARs of BCAs.** A major progress in the proposal of a new regulation is the proposal of introducing transparency on the assessment data by publication of the DAR. It should be extended also to the provision of more information on the decision process. In the USA the EPA even publishes correspondence with applicants. The EU system is now making a significant step forward on the development and improvement of the dialogue with all stakeholders including consumers and users of PPPs. Coordination by electronic means in cooperation with MS will accelerate the regulation procedures as well and promote harmonisation of the regulation process.

## What is missing in the New Regulation?

In addition to what was already suggested, the REBECA Action has identified other aspects for improvement of the guideline. In particular, it was noticed that the new regulation has not considered the specific situation of BCAs. The draft for a New Regulation contains no proposals for reviewing and adjusting data requirements to the need of BCAs. **REBECA asks that the data requirements for BCAs are adjusted.**

It was certainly difficult to include the aspects of biocontrol as the proposal has been made mainly on the experience of regulation of synthetic PPP. Only few BCAs have been authorised



until today under the Dir. 91/414. With the assessment of even more BCAs within the 4<sup>th</sup> stage re-evaluation, additional experience will be available. REBECA has been a valuable platform for information exchange and discussion during this process. It would be favourable for biocontrol and all stakeholders if this dialogue can be continued with the objective to make further proposals on how the existing rules can be adapted. **REBECA asks that this dialogue is continued.**

One major drawback of existing regulation structures is that experience with BCAs and consideration of biological and ecological principles is not easily introduced into the regulation process. The REBECA Action reviewed the possibilities to introduce the principle of Qualified Presumption of Safe Use (QPS), an assessment, which allows the consideration of long term experience of use without major negative effects. It should be realized that due to the nature of biological control, science will never have a complete picture of the complex interactions in biological systems. Consequently, science will not be able to answer all possible questions on potential risks. But we also should accept, that biological control is taking place in natural and agricultural environments also without any anthropogenic impact including regulation and without measurable negative effects for consumers of agriculture products. Agricultural production would be impossible in the absence of biological regulation systems based on insect pathogens, parasites and predators. The experience and knowledge gathered on the natural distribution of BCAs and ecological function of these organisms should be considered to assess the risks. Exploitation of this knowledge and future scientific contributions to the understanding of biocontrol mechanisms and impacts should continuously be implemented to develop more flexible regulation procedures. Directives and rules can only be developed for risks, which have been identified. BCAs, however, challenge regulators and authorities with new, sometimes undescribed modes of action. A more flexible system could possibly make better use of scientific information, which could be used during pre-submission meetings to exclude less or irrelevant data requirements. **REBECA asks for flexible solutions in the entire process of regulation of BCAs at EU and at national level.**

More detailed proposals for improvements of regulation practice will be reported at the end of the REBECA Action.