

# Evaluation and registration of plant protection inputs for organic farming

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**Abstract** – Organic farmers may only use those plant protection products which are listed in Annex II B of the 'Organic Regulation' 2092/91 and also registered for use at national level. At present, new compounds may only be listed in Reg. 2092/91, if they do not come into direct contact with the crop (although in perennial crops, contact outside the growing season of the edible parts is possible), which is a major obstacle for progress. The EU-funded ORGANIC INPUTS EVALUATION project aims at making Reg. 2092/91 more flexible with regard to new products, while safeguarding the principles of organic farming. Registration under the 'Pesticide Directive' 91/414 represents a considerable financial hurdle. The REBECA project will propose registration requirements which are better adapted for biological control agents, plant extracts and other low-risk products. The aim is to accelerate registration and make it more cost-effective, without compromises to the level of safety.<sup>1</sup>

## INTRODUCTION

In organic farming, prevention of damage caused by pests and diseases relies primarily on management practices such as the choice of varieties, crop rotation and cultivation techniques. In some cases, however, the use of plant protection products (thereafter abbreviated 'PPP') is necessary to avert immediate threat to a crop. The range of available PPP strongly affects quantitative yield, yield security, quality of produce and profitability of crops. It may also affect the environment and have an impact on public perception. Therefore, PPP are strictly regulated in organic farming. In the EU, organic farmers may only use those PPP for which the following two conditions are met:

- The active ingredient must be listed in Annex II B of Council Regulation 2092/91.
- The product must be registered for use at national level.

## LISTING IN REGULATION 2092/91

All substances which may be used as PPP in organic farming are listed in Annex II B of Reg. 2092/91. It contains the following sections: (i) substances of crop or animal origin, (ii) microorganisms, (iii) substances to be used in traps and/or dispensers, (iv) preparations to be surface-spread between plants, (v) other substances from traditional use. It also contains *specifications* concerning compositional requirements, conditions for use etc.

## Changing of Annex II B

Organic farming is an evolving system. This may necessitate changes in Annex II B such as (i) inclusion of a new product, (ii) removal of a listed product or (iii) changing the specifications for a listed product.

Article 7 of Reg. 2092/91 contains the rules for evaluation of new products. Unfortunately, these are very rudimentary and provide little guidance. As a consequence, requests for amendments of Annex II B are often discussed for prolonged periods before a decision is taken.

Also, it contains a so-called 'non-contact clause' which specifies that new products may only be listed if the conditions for their use preclude any direct contact with the crop (although in perennial crops, contact outside the growing season of the edible parts is possible). This is a major obstacle for progress.

## A new system

The ORGANIC INPUTS EVALUATION project (for details see [www.organicinputs.org](http://www.organicinputs.org)) has developed proposals for a new system for inputs evaluation (Speiser et al., 2005). The main points are:

- To replace the current evaluation criteria (Article 7) by a more complete set of criteria covering all aspects relevant for organic farming, and to restrict the 'non-contact clause' to synthetic products.
- To provide detailed guidance to applicants and evaluators. For this purpose, the project has elaborated a 'criteria' matrix with specific questions, and illustrated its use with two case studies.
- To use an evaluation procedure with strong involvement of Member States and support by an independent expert panel.

## Revision of Regulation 2092/91

Reg. 2092/91 is currently under revision. The Commission's proposal from December 2005 contains no criteria for input evaluation; probably, these will be in an Annex. However, the proposals for the revised Annexes have not yet been published and it is uncertain to what extent the above described proposals will be taken up.

## REGISTRATION

Registration is compulsory for all PPP, regardless whether they are used in organic or conventional farming, and the organic sector has very little influence over this process. Registration procedures were developed for synthetic pesticides, which make up the vast majority of all compounds, and are not well adapted for the PPP used in organic farming. Presence or lack of registration is one of the most important factors influencing the availability of PPP in different EU Member States (Speiser and Schmid, 2004).

### *Registration of new products*

The registration procedure for new products is as follows: In a first step, the active substance has to be registered at EU level according to Council Directive 91/414. Registered substances are listed in Annex 1 of Dir. 91/414. Then, commercial products can be registered at national level relatively simply.

### *Re-evaluation of old substances*

Before Dir. 91/414 was in force, PPP registration was exclusively under national authority. In the transitional period, all 'old substances' are therefore re-evaluated under Dir. 91/414. Re-evaluation proceeds in four stages. The 4<sup>th</sup> stage is most relevant for organic farming.

### *4<sup>th</sup> stage of re-evaluation*

The 4<sup>th</sup> stage of re-evaluation covers substances such as 'substances used in human foodstuffs / animal feeding', 'plant extracts', 'animal derived products', 'commodity substances', 'pheromones & other semiochemicals' and 'micro-organisms including viruses'. These substances make up a *large proportion of all PPP allowed for organic farming*.

The deadline for product notification was October 2003, and the deadline for dossier submission was June/October 2005. The 4<sup>th</sup> stage is scheduled to be completed in 2008. Products which have not been notified, or for which no dossier was submitted, have to be withdrawn from the market. Withdrawal can be postponed by four years, if Member States declare 'essential use' for a substance.

*Opportunities and threats for organic farming:* Substances which have successfully completed re-evaluation are likely to be more homogeneously available across the EU than under the present system of national registration. On the other hand, the costs of dossier preparation and the registration fees represent considerable financial hurdles. At the same time, organic farming is a small market and most products are too old to be protected by patents. There are doubts whether the industry will sufficiently invest in re-evaluation. If not, many PPP important for organic farming might be impossible to use in the future. To address this problem, a joint working group of DG AGRI and DG SANCO has been set up.

### *Requirements for low-risk compounds*

The REBECA project (for details see [www.rebeca-net.de](http://www.rebeca-net.de)) will develop proposals for improving the registration process for biological control agents (BCAs) and related products. The aim is to accel-

erate the process and make it more cost-effective without compromises to the level of safety. The Action will review current legislation at EU and Member State level and compare them with countries where the market introduction of BCAs was more successful. REBECA is concerned with three groups of compounds:

- '*Macrobials*': Beneficial arthropods and nematodes. This group is not subject to registration under Dir. 91/414 and is very successful in Europe. However, the industry is concerned that nematodes might be subordinated to this directive in the future.
- '*Microbials*': Microbial agents for biological control, such as *Bacillus thuringiensis*.
- '*Botanicals and semiochemicals*': Various PPP with a reduced risk, such as plant extracts (e.g. lecitine, neem oil), microbial extracts (e.g. spinosad), commodity substances (e.g. potassium bicarbonate = baking powder) and semiochemicals (sex pheromones, used e.g. for mating disruption; applied in traps or dispensers).

## CONCLUSIONS

Two EU-funded projects address improvements of legislation. (i) The ORGANIC INPUTS EVALUATION project aims at making the 'Organic Regulation' 2092/91 more flexible with regard to new products, while safeguarding the principles of organic farming. (ii) The REBECA project aims at accelerating registration under the 'Pesticide Directive' 91/414 and making it more cost-effective, without compromises to the level of safety. For this, it will propose registration requirements which are better adapted for biological control agents, plant extracts and other low-risk products. Progress in these two areas has a crucial effect on the future of plant protection in organic farming.

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