

Constraints to providing biopesticides for the farmer

IBMA notes that the Sustainable Use Directive (SUD; Dir. 2009/128/EC) strongly promotes a targeted use of integrated control of pests and diseases where non-chemical measures are preferred, including the use of plant protection products (PPPs) based on low-risk substances and basic substances.

Background: To deliver an effective toolbox for farmers and growers, many measures must be taken by EU Member States as described in their National Action Plans. IBMA endorses the importance of these measures.

Governments expect the industry to develop innovative crop protection products and the promotion of their use. Our members have many new biocontrol agents in research, development and on the market which can help achieve this objective. However experiences to date have included non-tailored inappropriate dossier requirements and preparation for biopesticide substances and products, long-term and non-transparent submission procedures, and the high cost for the SMEs that develop these products. IBMA anticipates that a large number of products based on micro-organisms, semio-chemicals and plant extracts to be classified as low-risk products. Basic substances also fit perfectly in sustainable crop protection, but shall not be placed on the market according to 1107/2009 as a product. However, IBMA notes that despite motivation and activities from the European Commission, insufficient progress with a number of issues related to submission and approval has been made:

- 1. Low-risk substances.**
- 2. Basic substances.**
- 3. Appropriate dossier requirements.**
- 4. Rapid and timely registration procedures.**

1. About four years after the implementation date of the EC Regulation 1107/2009, there are still no positive criteria for low-risk (LR) substances identified, nor a different procedure for their evaluation. Existing negative LR criteria have been developed for (synthetic) chemical substances and prove to be ill-adapted for biopesticides. An EU Working Group with appropriate scientific expertise has been established, but timelines need to be agreed to get these active substances and products on to the market as soon as possible. There are also many previously authorized biopesticides in the EU which are likely to be classified as low-risk substances. According to 1107/2009 the evaluation of low-risk criteria can only take place at the time of re-registration following a reassessment of the whole dossier. This means for many currently approved substances a delay of up to ten years is possible until they can be classified as low-risk. **This is a missed opportunity.**

IBMA encourages the EC to engage in direct assessment of LR criteria of already authorised biopesticides so that these will be available immediately following establishment of the criteria. In this way LR products become available for farmers and growers and, as such, can support the policy goals of the Sustainable Use Directive: a more sustainable agriculture.

2. Similarly with basic substances (BS) four years after 1107/2009 came into force there is a lack of understanding as to what a basic substance could be and how it will be evaluated. Moreover, the industry is faced with a number of uncertainties on the use of basic substances, for example if a company wants to use a BS as a co-formulant, or wants to register it as a Plant Protection Product (PPP). A Guidance Document and answers to these questions are needed for developers of products that satisfy LR criteria. Further, this guidance is also required so that BSs can be approved for use by farmers and growers.

3. Data requirements for non-chemical substances and products are derived from synthetic chemicals. A risk assessment of biopesticides should be based on scientific evidence appropriate for the substance and actual risks, and should not merely follow rules developed for synthetic chemicals. An adaptation of the dossier requirements tailored to the nature of the various categories used in biopesticide active substances and products is therefore required. Currently, authorities often “over-ask” on the number of studies because the requirements are not appropriate to the type of active substance, for instance, for a microbial agent, pheromone or plant extract. More appropriate data requirements and guidance documents are being developed but are needed as soon as possible in order to aid industry in dossier preparation and risk assessors in performing risk assessments and approving new products.

4. Submission procedures are lengthy and unpredictable, both at EU and Member State levels. For the biocontrol industry, mostly SMEs, this is the most pressing problem. Survival and profitability consequently are placed under intense pressure. Faster procedures and enforcement of time limits set under 1107/2009 are vital. If new products can come to market quickly, they generate income, and with this, further research and development can take place. We propose an accelerated procedure for LR substances. We suggest checking the completeness of a LR substance dossier, based on minimum data requirements as decided at a pre-submission meeting, and, at the same time, evaluating whether it complies with the LR criteria. If positive, product registration should be granted as a provisional authorisation at national/zonal level. In this way products become available to the end-user for sustainable crop protection.

IBMA calls on the European Commission and Member States to expedite the following solutions:

- Finalise criteria for low-risk substances;
- Finalise criteria for basic substances;
- Implement an accelerated approval process for low-risk products by means of a pre-screening procedure, leading to fast provisional authorisations that allows products to be marketed, followed by a full assessment, with possibly more dossier requirements and possibly due to a withdrawal of low-risk classification to a normal substance. This encourages the industry to develop such products;

- An adaptation of the dossier requirements tailored to the nature of the various categories of active substances used in low-risk products. Where necessary further Guidance Documents need to be developed with all stakeholders involved;
- A separate status for LR products. These are often of natural origin, innovative, selective, effective, and sustainable. LR criteria for biopesticides should be different than those for (synthetic) chemical substances. Derived from nature, many biopesticides pose a low and acceptable risk to humans, animals and the environment.
- Due to their inherent nature, they often do not pose issues associated with water quality, biodiversity, food safety and exposure to workers and residents. LR products could also be approved for safe and sustainable use outside agriculture. In sports and recreation areas, pavements, and for non-professional use biopesticides offer an effective and reduced-risk alternative.

If the process issues can be resolved quickly, the implementation of the sustainable crop protection policy could be adopted faster and more effectively. The biocontrol industry has many solutions, and if the EC improves the efficiency of the frameworks, these solutions can play a significant role in achieving sustainable crop protection in the very near future.

An innovative and sustainable crop protection requires an innovative and effective regulation. IBMA is offering their continued help in achieving the policy goals through an improved and more tailored registration process.