

## **IBMA proposed approach to revise procedures via amendment or adaption of Regulation (EC) 1107/2009 for the EU approval of Low-risk Active Substances and authorisation and placing Low-risk Products on the market in EU Member States**

**IBMA requests the EU Commission to address the observed shortcomings of the existing regulation on bringing biocontrol solutions as examples of low-risk substances and products to the market**

**Background: The intention of 1107/2009 when approved by EU Council and EU Parliament was to reduce the reliance of EU agriculture on traditional chemistry-based plant protection products (PPPs). This was seen as a two point approach, with one objective to restrict the use of those products that pose the most risk to human health and the environment and the second objective to facilitate the authorisation, bringing to the market and use of lower risk active substances and products. To date whilst the 1<sup>st</sup> objective is being effectively addressed, the 2<sup>nd</sup> objective has proved elusive.**

Various issues related to authorisation of biocontrol agents, including review prioritisation, resourcing, level of expertise, lack of guidance documents, timelines to registration, costs of registration, etc. has resulted in the biocontrol industry taking decisions to abandon or delay submission of innovative products in the EU. Following submission biocontrol active substances have suffered disproportionately through resourcing issues and severe delays to registrations and review conclusions.

### **Proposals:**

#### **1. Active substances (a.s.)**

- A revised procedure should be enabled where active substances proposed as low-risk are submitted with a full dossier according to the data requirements will be subject to a revised completeness check, including an assessment of low-risk status. Dossiers satisfying the requirements of this **revised completeness check** will lead to a provisional approval of the active substance. This would be followed by the full assessment, with possibly additional dossier/ information requirements, and possibly due to a withdrawal of low-risk classification to a normal substance classification, should the substance be re-classified during the approval process.
- Low-risk active substances proposed at the pre-submission meeting and confirmed in the revised completeness check as satisfying the criteria of low-risk should be given priority for evaluation by the rapporteur member state and EFSA.
- The low-risk active substance approval, currently 15 years, shall not be time-limited and subject to automatic re-evaluation. Re-assessment should only be required if sufficient concern of

additional risk to human health or the environment is reported with scientific evidence post the initial evaluation of the active substance.

- Substances that are already approved today and anticipated to meet low-risk criteria are reviewed for low-risk status with priority before July 2016 by their rapporteur member state. This could simply be done through a retrospective low-risk evaluation of those active substances proposed by an applicant and co-ordinated by IBMA, and should result in granting the same status and incentives as applicable to any future new substance evaluations and approvals. These active substances should not merely wait for a review or renewal to be conducted. To do otherwise would discriminate against these substances in the marketplace.
- Appropriate guidance for the revised completeness check for Member States, EFSA and applicants should be prepared.

**Proposed modification of 1107/2009 for the existing low-risk category of active substances:**

- IBMA believe that these changes could be given effect by introducing an appropriate implementation act or straightforward amendments to Articles 22, 30 and 47 and Annex ii (5) and would be happy to offer drafting suggestions and participate with the EU Commission to deliver these proposals in due course.

**2. Products**

- Product applications only containing low-risk substances shall be given an automatic accelerated (fast-track) approval process for low-risk products. If an a.s. or a.s.'s satisfy low-risk criteria, products shall be marketed after notification to a zonal rapporteur or member state, provided that the product fits any conditions established for the low-risk listing(s) of the substance(s) and conditions for low-risk PPPs established in Reg. (EC) No 1107/2009 Art.47(1), (2) & (4).
- No authorisation expiration date and hence no time-related re-evaluation should be seen as the standard practice for products approved as meeting low-risk criteria. Re-assessment should only be required if sufficient concern of additional risk to human health or the environment is reported with scientific evidence post the initial evaluation of the PPP.

**Proposed modification of 1107/2009 for the existing low-risk category of plant protection products:**

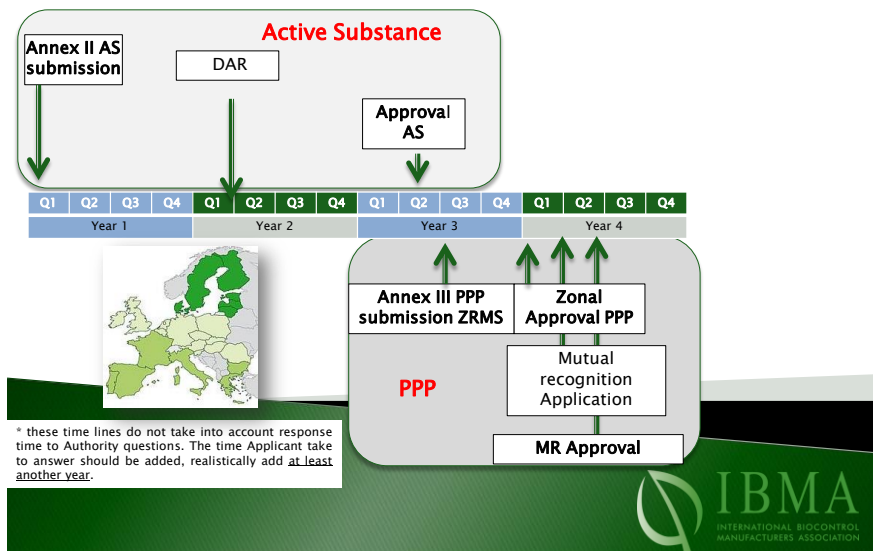
- IBMA believe that these changes could be given effect by introducing an appropriate implementation act or straightforward amendments to Articles 30, 47 and 66 and would be happy to offer drafting suggestions and participate with the EU Commission to deliver these proposals in due course.

**Envisaged Outcome:**

The revised procedures will deliver an increase in low-risk products available to the farmer/grower as per the intentions of EU policymakers, and reduce the burden upon an SME rich young developing biocontrol industry. It further encourages investment in the industry to discover and develop new technology as a significant burden is removed as an obstacle for the expansion of the biocontrol industry and its investors. These proposed modifications would lead to increased scientific progress as return on investment periods would be significantly reduced.

It further ensures that farmers have access to a wide range of low-risk plant protection products tested and labelled with true accurate and substantiated claims in just over 1 year after submission as opposed to the current situation of between four and five years.

**Timelines 1107/2009  
(best-case example with no request for additional information\*)**



**Timelines 1107/2009  
(typical example with request for additional information\*)**

