Unlock the potential of Biocontrol:
IBMA calls on Europe's regulatory authorities for urgent action.

1. Overview of status and goals

In December 2019, the EU Commission has launched the "European Green Deal" and the subsequent "Farm to Fork" strategy in May 2020, promoting the growth of a healthy crop with no or reduced use of conventional chemical pesticides and encouraging the use of non-chemical methods. Biocontrol holds the greatest potential to achieve these targets, yet the EU's implementation of Regulation (EC) No 1107/2009 applicable to microbials, natural substances and semiochemicals[1] results in multiple obstacles and consequently delays in getting biocontrol products into the hands of European farmer. The EU's current snail-paced regulatory process is taking up to 10 years for biocontrol product authorisations.

IBMA calls for immediate action to solve this. Europe's response to the COVID pandemic has shown that Europe is capable of rapid and coordinated action without compromising safety. IBMA now calls on the European Union and Member State authorities to show the same sense of urgency to combat the climate and biodiversity crisis.

More than 10 years to bring a new product to the EU farmer. The EU's snail-paced obstacle race to register a biocontrol product dissected.

A new biocontrol active substance has been identified! A 'waiting period' of 1-3 years prior to submission is typically required to get a time slot with almost any Member State's competent authority before the evaluation of the application can start.

The approval procedure for an active substance according to timelines defined in Regulation (EC) No 1107/2009 should be between 30 months and 44 months. In reality, the timelines are much longer - 52 months on average.

Once the active substance is approved, authorisation of an actual formulated product is an additional 1-2 years, assuming availability of an evaluation slot. All together it is taking more than 10 years from start to finish. The rest of the world take no more than 2-3 years.

IBMA advocates a **three-step action plan**.

1. Biocontrol Definition
2. Proper implementation of Regulation (EC) No 1107/2009 and possible small modifications
3. Longer term - develop a new appropriate legislative framework for biocontrol

[1] Invertebrate biocontrol agents are the one product category not covered under Regulation (EC) No 1107/2009 therefore they are not within the scope of the current document.

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As a first step, biocontrol needs an EU wide definition, confirmed in EU legislation. This can be achieved quickly, as the "SUD" directive on sustainable use of pesticides where this definition belongs, is now under revision to become a "SUR" regulation. Biocontrol includes 4 product categories: invertebrate biocontrol agents, microbials, semiochemicals and natural substances. A biocontrol definition enables specific action in support of biocontrol through existing legislation, for example through incentives under Common Agricultural Policy (CAP)-eco-schemes[2]. By increasing the uptake of biocontrol use, as a mandatory part of Integrated Pest Management (IPM), the CAP can be better aligned with the Farm-to-Fork strategy and with the Sustainable Development Goals (SDGs) outlined by the United Nations.

An EU definition of biocontrol will also help create a platform for further legislative initiatives as outlined under steps 2 and 3 below. The main aim of this document is to provide further detail on what IBMA believes can and should happen in step 2.

Step two, to implement Regulation (EC) No. 1107/2009 properly, in the way it was intended. This will drastically shorten the time to market for biocontrol. The EU Commission has scope to take initiatives in implementation of this regulation. Member States eager to lead the path for sustainable agriculture can also make a huge difference. This is urgent and essential and it is undoubtedly possible, to compress timelines to bring a biocontrol innovation to the farmer – without compromising safety standards - from what now typically takes 10 years to approximately 4 years. This will make a serious difference but remains insufficient to make the EU competitive in terms of time and cost to market for a biocontrol product introduction with other advanced agricultural economies where time to market is typically 2 years[3].

Step three: the development of a new and dedicated legislation for biocontrol products. The regulatory process should be fundamentally reshaped to be appropriate to biocontrol technologies and reduce time to market to 2 years. The "Green Deal" means that by 2030 most PPPs will be biological. A dedicated biological legislative framework that does not compromise safety yet cuts out all unnecessary bureaucratic obstacles and delays, will therefore be essential: it cannot be achieved without this.

The body of this document is focused on step two and lists a number of specific and realistic policy asks that the EU institutions and member states can take to speed up market access for biological products.

[2] Eco-schemes are a new instrument designed to reward farmers that choose to go one step further in terms of environmental care and climate action.

[3] It is noteworthy that application of minimal evaluation timelines rather than maximum timelines could also deliver a biocontrol authorisation within 2 years.

Finally we also provide some initial considerations with regard to a long term system change.

2. How do we get from 10 years to 4 years: an overview of specific IBMA policy asks

This section looks at **who can do what at EU and MS levels** to make the application of Regulation (EC) No 1107/2009 less cumbersome for biocontrol products, all without compromising safety. Both the **EU Commission** and Member States can take various initiatives compatible with current regulation but leading to better implementation.

2.1 Better Implementation of Regulation (EC) No 1107/2009

A. Prioritise and streamline evaluation process

EU Commission can take action to encourage a **streamlined approach** in the evaluation and approval process including ensuring **prioritisation** of biocontrol active substances to ensure legal timelines are met. **Member States** can also prioritise **applications** for authorisations of biocontrol products. Commercially it should be noted that most crop protection companies are now developing biocontrol as well as chemistry, so most companies will benefit from such a measure.

B. Deploy dedicated biocontrol experts

Regulation (EC) No 1107/2009 provides for a science-based review with expert input. Leaving the evaluation of biocontrol products to MS evaluators and EU Standing Committees largely composed of experts trained in the evaluation of chemical compounds. This does not allow for a proper science based review of PPPs derived from biology. The EU Commission should advocate and drive the establishment of an EU wide **group of biocontrol experts** from across Member States that, in close cooperation with EU Commission, will be responsible for all evaluations and assessments of biocontrol active substances and products submitted in the EU. A similar network of biocontrol experts is needed in EFSA. This would guarantee a consistent and scientifically sound approach that would considerably speed up procedures.

C. Advocate wider use of zonal system and mutual recognition

A lot of resources are often required to obtain product authorisations in different Member States. The zonal system and mutual recognition (Guidance: SANCO/13169/2010 Rev. 11) was developed to facilitate this process but Member States have a lot of latitude to refuse a zonal authorisation and /or mutual recognition and invariably reopen a dossier already evaluated in another Member State. The EU Commission can strongly encourage Member States to only reopen dossiers if absolutely necessary and to stimulate better cooperation between Member States, particularly within the same zone. For example the “zones” should be encouraged to extend their Guidance Documents on Work-sharing (as exist in the Northern and Southern zone) to biocontrol to ensure consistency and so provide confidence between MS on the approach to evaluation in other MS

D. Issue additional guidance documents for tiered approach to evaluating biocontrol actives

In line with Article 77 of Regulation (EC) No 1107/2009 the EU Commission can issue tailored **guidance documents** to ensure a consistent and harmonized assessment of biocontrol actives by all Member States and highlighting, for example, data requirements relevant to chemical pesticides – such chemical only relevant data requirements do not need to be studied and could hence be subject to a "waiver". A guidance document is available on botanicals but should be prepared for additional groups of natural substance and other mixtures. IBMA itself has worked on decision trees that can provide valuable input for this type of guidance documents. EU Commission can promote that the guidance documents developed are legally binding and that evaluators should accept them.

E. Position and resource the national competent authority to act as a biocontrol "role model"

Companies are free to select a competent authority for the evaluation of a new active. Member States can attract applicants by strengthening their evaluation body ("competent authority evaluations") with a dedicated biocontrol team with strong science-based expertise and, very importantly, sufficient staff and resources to deal with applications for biocontrol PPPs rapidly and effectively. These Member State's experts will in turn contribute to strengthen the EU wide expert groups.

By way of example, good steps in this direction have been taken by the Netherlands with a special 'biocontrol' contact point ('helpdesk') and/or specific biocontrol related information on websites (The Netherlands).

F. Reduce or cancel national fees for biocontrol product applications.

National fees due for product registration can add substantial cost when registering a biocontrol product across the EU. Biocontrol products most often target specific pests or diseases and hence this investment needs to be recovered from sales in a market that is often narrower than in the case of chemical pesticides.

By way of example, France, through their national biocontrol strategy has allowed multiple biocontrol uses to be applied for under one registration fee, incentivising applicants to apply for all possible uses of a biocontrol product at the initial registration, so providing farmers with more options immediately when a product is authorised.

G. Allow product application process to start prior to completion of active substance approval

The EU review process separates the process for active substance approval and product authorisation, this is an important element contributing to long timelines from "innovation to farmer".

Promote the use of **Article 37(3)** of Regulation (EC) No 1107/2009 for biocontrol products. This Article indicates that Member States should start the evaluation of a product application as soon as it has received the draft assessment report with regard to the relevant active substance. However, this provision with the potential to shorten timelines considerably, is almost never used, due to fear that endpoints may change during the second part of the evaluation process with EFSA and Member States would have to redo their work. Expert evaluators in Member States and EFSA would address this fear and allow Article 37(3) to be effectively implemented.

H. Maximise the field of use in terms of crops when authorising a biocontrol product

Extending (extrapolation of) an authorisation for a given crop to another crop depends on considerations with regard to safety and efficacy. In many cases, biocontrol products will not be subject to MRL's and application in other crops will not raise additional safety concerns.

Member States have certain latitude in allowing extrapolation to other crops and IBMA advocates that this scope should be used more proactively. Extrapolation of efficacy data from one crop to another one should be encouraged. Extrapolation tables for minor uses have been developed and are available on the EPPO website. These extrapolation tables may also be used for major and/or minor uses of low-risk products. Approving **low-risk active substances for all crops m**ay be the next step.

For example in Ireland when there is an application for a certain crop, an authorisation is granted for all crops belonging to that crop group.

I. Use National action plans as required under SUD to achieve wider use of biocontrol

An EU wide definition of biocontrol allows clarity of reference to biocontrol within the National Action Plans and so specific actions relating to biocontrol. Such actions may include setting targets, incentives to farmers, advisers and other value chain players, training and stimulation of research activities. A definition of biocontrol in particular allows inclusion in CAP strategic plans as a specific IPM enabling tool.

With the French definition of biocontrol and the development of a national plan for biocontrol, France now has the highest market share in Europe of biocontrol at 12% of PPP use. J. Effective implementation of low-risk provisions

Current implementation of provisions in Regulation (EC) No 1107/2009 meant to facilitate the regulatory path for low-risk[4] has had very limited impact. For example, low-risk status applies only post-evaluation, hence the time benefit of faster first approval is not realised.

An **ex-ante presumption of low-risk status should apply to new biocontrol active substances.** The process and timelines for low-risk should be applied from the start of the evaluation process (pre-submission and admissibility stages) for all potential low-risk PPPs. If specific risks are identified during the evaluation process, the provisional low-risk categorisation can cease to apply.

This will automatically lead to more frequent use of low-risk status for biocontrol based PPPs, reducing registration resources for EU COM, MS, EFSA and applicants.

K. Advocate smart use of derogations under article 53 (temporary "emergency" authorisations).

The EU Commission can advocate better use of this derogation procedure available to Member States for phytosanitary problems for which no alternatives are available. While this procedure is now often used to allow the continued use of old chemistry already withdrawn for safety reasons, it should be more often used to allow accelerated use of biocontrol alternatives, always subject to a check of available safety data. Under the SUD, biocontrol products with a strong safety record, should not be subject to the hazard score penalty that applies to products authorised via this procedure.

[4] COMMISSION NOTICE concerning a list of potentially low-risk active substances approved for use in plant protection (2018/C 265/02).

2.2 Small Modifications of Regulation (EC) No 1107/2009

The **following** initiatives require small modifications to Regulation (EC) N0 1107/2009 but will have a major impact on availability of biocontrol products for EU farmers. Re-instate provisional authorisation (Article 30)

Re-instate the option of the **provisional authorisation** (Article 30 of Regulation (EC) No 1107/2009) to facilitate the placing on the market of PPPs containing new biological active substances that have been evaluated and assessed by the RMS and concluded that the substance can be approved.

II. Smart allocation of resources for re-registration

Renewals for low-risk substances can be extended to a longer period than 15 years saving valuable evaluation expertise without compromising safety. Removal of the requirement for renewal could be made for low-risk substances.

III. Justified exemptions to be extended to additional data points

Data requirements in Regulation (EC) No 1107/2009 are developed for chemicals. Today the option for "**justified exemptions** can be made" or "a **different approach** may be taken if adequately justified" exists for some data points for natural substances and semiochemicals. This option should be extended to all data points. The IBMA decision trees can provide valuable input to prepare these justifications and provide input in what different approaches to follow. Ultimately, this should lead to the creation of a **new set of data requirements** for natural substances and semiochemicals.

3. Long-term system change – new and dedicated legislation for biocontrol products

Develops a new appropriate legislative framework for biocontrol products and streamlined provisions with a dedicated centralized regulatory body, presumption of safe use (GRAS), tiered assessment and tailored data requirements.

Such a new legislative framework should have:

- EU wide group of biocontrol experts to ensure evaluations are provided by experts with the proper field of expertise and relevant scientific knowhow;
- Dedicated efficacy evaluator team at zonal level for product authorization;
- System with clear and proportional fees;
- Close liaison between applicants and authorities from early stage presubmission to final decision;
- Authorisation extension possible for either target pest or crop;
- Low-risk substances should be approved for an unlimited time period unless evidence of adverse effects;
- Simplified procedures, as currently applied to SCLP's (Lepidopteran pheromones) and to baculoviruses, for biocontrol substances that belong to groups with specific properties;
- Uniform Principles that are adapted for the various biocontrol technologies;
- A presumption of 'safe use' and of MRL exemption unless there is strong evidence for a residue of concern;
- Harmonize approaches within the EU with international bodies as OECD and FAO.