The International Biocontrol Manufacturers Association (IBMA)'s feedback to the open public consultation on the EU Single market Strategy for 2025

IBMA welcomes the European Commission's upcoming Communication on a Single Market Strategy for 2025 to fully exploit the potentials of the single market and boost Europe's productivity.

European Commission's President Ursula von der Leyen's political guidelines highlight the need to "make business easier and deepen our Single Market to help innovative companies grow" while Mario Draghi states in his recent report that "innovative companies that want to scale up in Europe are hindered at every stage by inconsistent and restrictive regulations".

Creating a truly integrated single market is **therefore critical for European competitiveness**.

Biocontrol is the most rapidly growing segment of the global crop-protection industry. Biocontrol plant protection products (PPPs) are nature-based solutions and part of farmers' plant protection toolbox. They have the potential to help accelerate EU's transition to sustainable and resilient agriculture systems. In Europe, the **biocontrol market in Europe provides more than 6,500 green industry jobs** and is **worth over €1.6 billion, representing about 10% of the European crop protection market**.

However, these companies are facing challenges and there is an urgent need for regulatory improvements that reduce time-to-market constraints and enhances the attractiveness of the EU for the industry.

Context

Currently, biocontrol is regulated under **Regulation No 1107/2009** - regulating the placing of plant protection products – PPPs – on the EU market -, together with chemical PPPs. This regulatory framework **is one of the most complex frameworks with the longest authorisation timelines – up to 10 years from submission to market compared to 2-3 years in other global jurisdictions**.

A better implementation of Regulation No 1107/2009 through the principle of mutual recognition

The EC Regulation (No) 1107/2009, has the facility for Member States to mutually recognise authorisations products authorisations of an EU approved active substance, that have been authorised in another Member State in the EU. This is within the principles of the single market. However, many Member States are reluctant to implement such practices due to national requirements. Proper implementation of the mutual recognition of authorisations is necessary to ensure a single market for biocontrol.

EU Regulation (No) 1107/2009 is built on a zonal system according to climatic regions within Europe. With changing climate and consequent crop growing and pest and disease profiles, these zones and their associated differing regulatory requirements are no longer fit for purpose and should be removed from the regulatory system for registration of biocontrol.

Implementation of mutual recognition and the removal of zones would reduce evaluation resources required in Member States and help alleviate the huge workload and backlog at MS level.

Mutual recognition can only help existing approvals – it cannot speed up the approval of new substances nor can it alleviate the delays caused by re-registration or limitations of label extension.

More is needed immediately **to unblock** the new approvals and the label expansions of current biocontrol products approved in the EU Single Market to reduce the administrative burden faced by Member States' competent authorities and biocontrol companies :

A harmonized EU definition of biocontrol
First and foremost, there needs to be an EU-wide definition of biocontrol

This definition was also a clear ask in the Agrifish meeting of 09-10 December 2024 where a group of Member States made a joint call for a harmonised terminology of biocontrol that would enable a common understanding and assessment of the biological substance across Member States, with a view to speeding up their availability

This harmonized definition should go together with measures to amend the treatment of this defined group of PPPs within Regulation (EC) No 1107/2009.In particular the following amendments can be made:

- Re-instatement of Article 30 to allow Provisional Authorisation of biocontrol PPPs
- Waive the renewal process for biocontrol PPPs unless there is a scientific need
- Facilitate label expansion for biocontrol PPPs

These corrective measures to deal with the most serious bottlenecks in the current system have already been extensively discussed in the European institutions.

As to the three main measures outlined above :

- **Re-instate Article 30 to allow the provisional authorisation of biocontrol**
  Biocontrol PPPs are nature-based solutions. The process of provisional authorisation follows the initial evaluation procedure to ensure a robust safety evaluation has been made and can be reinstated for biocontrol PPPs allowing their immediate availability.
- **Waive the renewal process for biocontrol unless there is a scientific need**
  The current re-registration procedure for biocontrol, which is set between 10-13 years is bureaucratic and wasteful of competent Member States' authorities and industry resources for no gain in safety evaluation. This time could be spent evaluating new biocontrol solutions currently held up in the backlog of evaluations.
- **Facilitate label expansion for biocontrol**
  Biocontrol PPPs are frequently first authorised in fruit and vegetable crops where the demand for sustainably grown produce is strongest. There is now an urgent need to extend these authorisations to arable crops and facilitation of label expansion of biocontrol PPPs can increase their availability in arable crops.

These amendments can be implemented in the **short term in any suitable legislative vehicle such as the upcoming Biotech Act.**

It is essential that these targeted changes are made. Without them we will have to wait another 5-10 years for change and a new regulation. While not perfect this interim solution means that pioneering biocontrol producers selling and developing for today's market are able to deliver the products into the hands of EU farmers now.

A Mid Term Solution: A New Regulatory Framework for Biocontrol

While failing to achieve quick wins will only deepen the problems faced by EU farmers and further affect the competitiveness of the EU biocontrol industry, a sustained position of competitiveness and resilience in the global agricultural and crop-protection markets needs a fundamental rework of the regulation for biocontrol PPPs. This will contribute to food security, ensure a continuous stream of innovative and sustainable crop protection solutions to farmers, and stimulate investments and innovation in future-proof crop protection technologies.

Therefore, to deepen the Single Market even further, **a new fit for purpose regulatory framework is required for biocontrol**. The new regulation should consolidate a future-proof regulatory environment and well-tune to the market needs for biocontrol. It should result in a one-step procedure of 1.5-2 years in the EU for the authorisation of biocontrol products based on new active substances, and a shorter procedure for biocontrol PPPs based on active substances already on the EU market.

This new Regulation should therefore establish an EU group of biocontrol experts that would deal with the applications (incl. pre-submission meetings) and assessments for the placement of biocontrol in the EU market in a centralised and efficient way. **These experts should be hosted by a European Biocontrol Agency. This agency should be an independent entity and could be part of an existing authority (such as EFSA)** with a specific and independent mandate.

A new **regulatory framework would result in efficiency gains by unifying EU resources and expertise**; **produce high(er) quality and consistency of evaluations and assessments in line with the Single Market**; be **better equipped and more agile to deal with innovation**; having one single contact point for international players and applicants and **improve consistency and predictability.**