

Position Paper

Accelerate biocontrol to ensure farmers' livelihoods and Europe's competitive edge

Biocontrol must be enabled now to provide European farmers with much needed solutions and to maintain a future-proof European crop protection industry.

The EU President's political guidelines¹ highlight the need to **“make business easier and deepen our Single Market to help innovative companies grow”** while Draghi² states that “innovative companies that want to scale up in Europe are hindered at every stage by inconsistent and restrictive regulations”. Globally, biocontrol is the most rapidly growing segment of the global crop-protection industry but Europe's biocontrol industry is **severely hindered by inconsistent and restrictive regulation**. This is the primary reason European farmers have fewer biocontrol solutions available than farmers in other leading agricultural nations such as the USA and Brazil. It is also holding back an innovative sector of the European crop-protection industry with leading companies increasingly deciding to invest elsewhere. How do we give European farmers more tools to produce food with nature-based solutions

and ensure a future-proof crop protection industry in Europe?

The Strategic Dialogue³ report calls on the European Commission to **‘enable a robust legislative framework for biocontrol products and approaches’ by 2025, which among others should “prioritise fast track authorisation processes for biological control.”** Mission letters for both Commissioners for Health and Agriculture and Food **call for accelerating the authorisation and use of biocontrol**. Farmers need biocontrol solutions as soon as possible both to continue their transition to sustainable resilient agriculture, to remain productive and so ensure food security. Biocontrol has been shown to maintain and enhance biodiversity and provide on farm climate mitigation solutions⁴ thereby contributing to Europe's sustainability leadership ambitions.

IMMEDIATE SIMPLIFICATION

1 EU-wide Legal Biocontrol Definition and Corrective Measures

A harmonised legal definition of biocontrol PPPs is immediately needed together with measures to amend the treatment of this defined group of PPPs within Regulation (EC) No 1107/2009.

In particular, the following amendments are imperative to make biocontrol solutions available to farmers now:

- **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, identified by the European Commission and elaborated in the form of a set of relatively simple amendments to Regulation (EC) No 1107/2009 all in connection with the proposal for a Sustainable Use Regulation. While

the overall Sustainable Use Regulation was heavily debated and ultimately withdrawn by the European Commission, these corrective measures for biocontrol PPPs received broad political support. The upcoming ‘Vision for Agriculture and Food’ should refer to the **direct implementation of these measures via any pertinent immediate Commission legislative initiative such as the Biotech Act or legislative proposals related to the announced simplification (omnibus) packages**. The immediate implementation of these measures will bring quick-wins on the table within the timeline expressed in the report on the Strategic Dialogue.

As to the three main measures outlined above:

- 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 immediate access for farmers. ,
- The current re-registration procedure for biocontrol PPPs which is set between 10-13 years is bureaucratic and wasteful of competent authorities and industry resources for no gain in safety evaluation. This time could be spent evaluating new biocontrol PPPs currently held up in the backlog of evaluations.
- 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.



Biocontrol plant protection products (microbials, semiochemicals and natural substances) are regulated under the EU Plant Protection Products (PPPs) Regulation (EC) No 1107/2009, together with chemical pesticides. This **regulatory framework** has been designed for chemical pesticides and is not well adapted to biological PPPs, leading to unnecessary delays in the evaluations and to a waste of valuable resources by evaluators and applicants. As a result, the EU probably has **the most complex framework in the world with the longest authorisation timelines** for biocontrol products - up to 10 years from submission to market - compared to 2 - 3 years in other global jurisdictions. An IBMA study shows that there is a consolidated pipeline of biocontrol - 129 biocontrol substances, of which 75 are new biocontrol substances - for EU submission between 2023-28, but if the current regulatory framework does not

change, these submissions will not reach the market until 2033-2038. In the meantime, EU farmers are losing active substances and have fewer products available to control pests and diseases.

We therefore need immediate solutions to address the most serious bottlenecks in the current system and in the longer term a fundamental rethink of the regulatory system for biocontrol to ensure that Europe can reclaim a position of global leadership combining a thorough safety review with an effective process that is fit for purpose.

2 LONG TERM SOLUTION

A New Regulatory Framework for Biocontrol

In the longer term, a fundamental rework of the regulation for biocontrol PPPs is needed to maintain the competitiveness and resilience of the agricultural and crop protection markets in Europe.

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. Europe has the ambition to be a global leader in sustainability and should have the ambition to develop and produce most biocontrol products used in Europe and to maintain a leading role in the global crop protection industry as it makes the transition to biocontrol.

To deepen the European Single Market, 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 will require a Single Agency for biocontrol active substances and products.

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 using harmonized procedures. 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**. Furthermore, it should be staffed by experts from EU Member States selected based on their **good understanding of biocontrol, biology and/or ecology and relevant scientific know-how**, and should not represent a specific Member State. Finally, this agency should be financed by a combination of general funds and fees that are related to the handling of applications.

Other key features include: (i) moving away from the current zonal system established under Regulation (EC) No 1107/2009 so that there would be instead **one single zone for biocontrol products ('one market, one assessment')** and (ii) a risk assessment procedure adapted for biocontrol products. Practically, the applicant would submit an application to the Agency and indicate in which Member State they are looking for an authorisation.

The establishment of a fit-for-purpose EU Biocontrol Agency 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.

In conclusion, only by rapidly introducing a legal EU-wide definition for biocontrol PPPs and ensuring targeted amendments to EU Regulation (No) 1107/2009 for these biocontrol PPPs -via any immediate legislative initiative- will the EU address the urgent needs of European farmers through an immediate acceleration of biocontrol authorisations. In the longer term, elaborating a new fit-for-purpose regulation for biocontrol will address the urgent needs of European farmers with an immediate acceleration of biocontrol authorisations and lay the foundations for sustaining our food security, a resilient agricultural sector and further development of the EU biocontrol industry as a dynamic force in shaping the future of crop protection.

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Footnotes

¹ Political guidelines for the next European Commission 2024-2029 - (https://commission.europa.eu/document/download/e6cd4328-673c-4e7a-8683-f63ffb2cf648_en?filename=Political%20Guidelines%202024-2029_EN.pdf)

² The future of European competitiveness: Report by Mario Draghi (EU competitiveness: Looking ahead - European Commission (europa.eu))

³ Strategic Dialog on the future of EU Agriculture (Main initiatives: Strategic Dialogue on the future of EU agriculture - European Commission (europa.eu))

⁴ The agricultural transition: Building a sustainable future | McKinsey June 2023

Date: 05.02.2025

Join us to accelerate the uptake of biocontrol.

To make this happen we need a European wide biocontrol definition that enables us to:

✓ Speed-up authorization processes for biocontrol

✓ Focus on short term measures for improved implementation of and targeted changes to 1107

✓ Work on a new regulatory framework.