17 December 2024

Enabling biocontrol now provides European farmers with much needed solutions and is essential to maintain a future-proof European crop protection industry.

The EU President's political guidelines[1] highlight the need to **"make business easier and deepen our Single Market to help innovative companies grow"** while Draghi[2] 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 Dialogue[3] 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 solutions[4] thereby contributing to Europe's sustainability leadership ambitions.

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 a combination of immediate solutions to address the most serious bottlenecks in the current system as well as a fundamental rethink of the regulatory system for biocontrol to ensure

[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

that Europe can reclaim a position of global leadership combining a thorough safety review with an effective process that is fit for purpose.

I. Immediate solution - The Biotech Act

A harmonised definition of biocontrol PPPs must be included in the Biotech Act[5] 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, 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 measure for biocontrol PPPs received broad political support. The preparatory documents in connection with the Biotech Act set the ambition to accelerate market access for biocontrol PPPs and the Biotech Act now under preparation and due in 2025 provides the best if not unique opportunity to ensure these quick-wins are brought 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.

II. 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

[5] Commission Communication, "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU" March 2024.

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 the approach consisting of (i) rapidly introducing an EU wide definition for biocontrol PPPs as well as targeted amendments to EU Regulation (No) 1107/2009 for these biocontrol PPPs via the Biotech Act, and (ii) 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.