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IBMA's written feedback to the consultation on Commission's Communication "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU"

IBMA, the association representing biological control manufacturers in Europe and globally, welcomes the Commission's Communication on boosting biotechnology and biomanufacturing in the EU. Specifically, we fully support the recognition of the role of innovation to help reduce the overall environmental footprint of agri-food production systems by making them more resilient and supportive to reach the EU's climate neutrality goal. New solutions, such as biocontrol ones in the pipeline, are needed to drive the green transition and to solve the combination of challenges facing this sector; global competition, climate change and biodiversity loss, and. This is where, in line with this Communication, we believe that biocontrol plant protection products (PPPs) have a role to play. They are proven alternatives to chemical pesticides to control pests and diseases effectively through natural and nature identical means (when synthetized). They can also contribute to a better protection of health and the environment by, for example, reducing crop losses and enabling a more efficient and reduced use of natural resources and input materials (such as chemical pesticides). The biological control industry is currently estimated to be **worth €1.6 billion in Europe** and €6 billion worldwide.

But to fully unleash the potential of biocontrol, there is a need for an EU regulatory framework that reduces time-to-market constraints and enhances the attractiveness of the EU when it comes to R&D, production, and post-production activities. The return on investment for biocontrol in the EU market is the lowest of the 4 largest regions in the world due to the slow market entry relative to the rest of the world. Global companies are deprioritising Europe for biocontrol PPP investment.

The reality is that biocontrol companies are facing a situation in which **the path to market in other leading agricultural markets is much shorter and easier than in the EU**; e.g. the **approval and authorisation process on average takes 7 to 8 years in the EU, compared to 1 to 3 years or less in other major markets**. This leads to a **lack of competitiveness** of the European food production and an excessive dependency on import from other regions, while putting additional pressure on European farmers. If the status quo remains**, the European biocontrol industry is predicted to grow at only 5% in the next 5 years compared to 12 % in the rest of the world.**

In **the Annex of the document**, you will find relevant case studies which showcase the hurdles faced by several biocontrol companies in Europe due to the current slow approval process in place and the direct impact on farmers who are deprived of these much-needed alternatives.

We therefore **welcome the Commission's plan, as part of this Initiative, to launch a study** to explore how the broader framework for the approval of innovation can be better streamlined. We believe this study should **consider first a better implementation of existing** Regulation No 1107/2009 (regulating the **placing of plant protection products on the market) at Member State level, which includes: the set-up of a green priority lane for biocontrol products**; a better use of the mutual recognition process; accepting label expansions during the renewal process of biocontrol products, provision of expert evaluators with biocontrol understanding and if emergency authorisation is necessary a prioritisation of biocontrol products within this procedure. **. These different points do not require any regulatory changes and can readily be implemented at Member State level**.
Another route to consider is the **implementation of targeted and limited changes to** EU Reg (No) 1107/2009 focusing on allowing provisional authorisation for biocontrol; removing the periodic re-registration process for biocontrol and facilitating the label extension of biocontrol products**.**

These quick targeted and easy-to-implement changes can ensure that market approval for biological PPPs is simpler without safety being compromised. They also have the **potential to shorten the**

payback time for investments by a factor of 2 or 3 and **trigger considerable green growth employment opportunities in Member States**, with start-ups and SMEs more confident to build biocontrol businesses, attract investment and place the EU as a leader of innovation.

Next to these targeted changes, the Commission should assess **other building blocks that are needed to support the increased uptake of biocontrol**, such as an EU-wide **definition of biological control** and the establishment of a dedicated Biocontrol Agency that would deal exclusively with the assessment of biocontrol and formulated products in a centralized way using harmonized procedures and supporting a single European market.

Annex **– Case studies**

- **Agriodor –** *Biocontrol category*: kairomones (pest-repelling fragrance) in arables – France
  Kairomones are scented molecules that have a repellent effect on aphids and can reduce infestation levels, thereby delaying the need for insecticide treatments. Agriodor product -which is under testing in several countries - could offer farmers an alternative to bee-killing neonicotinoids, banned in the EU since 2018. However, although semiochemicals – such as pheromones from animals and kairomones from plants - have no lethal effect on pests, are generally effective at low doses, and quickly dissipate or degrade in the environment, they must go through the
  same authorisation procedure that applies to chemical plant protection products in Europe. This process is lengthy and costly. The approval takes about 8 years (compared to 18 months in Brazil and 24 to 36 months in the USA)
  and costs on average 3 million EUR, which sometimes amounts to more than twice the cost of developing the technical solution. Start up investors, as the ones investing in Agriodor, cannot wait that long to have a return on investment. As a direct consequence, EU frontrunners are often forced to move to other countries with a more favourable regulatory environment seeking economic viability.

- **DCM** – *Biocontrol category:* bacteriophage (new technology) in orchards – Belgium
  DCM has developed the award-winning bacteriophage-based product PEA-02® against fireblight in apples and pears. Fireblight is a bacterial disease for which no curative treatments are available.
  Compiling the registration dossier in IUCLID for the new active substance was perceived as a difficult process, as the data requirements in IUCLID were not fully aligned with the data requirements for registration of microorganisms, such as bacteriophages, as biocontrol active substance in the EU. Additionally, aside from the timely preparation of the IUCLID dossier, it was understood that most Rapporteur Member States still

require a Word version of the registration dossier, as it is considered more user-friendly for assessment.

Regarding the admissibility check of the registration dossier for this new innovative biocontrol active substance, we must note that the 45-day period prescribed in EU Regulation 1107/2009 is significantly exceeded. It appears that the admissibility check has become a complex procedure which requires a substantial amount of administrative work from the Rapporteur Member State. The EU needs to adapt the procedures and/or requirements to accommodate new applications, so that they are more user friendly and imply less administrative burden for both applicants and competent authorities. More efficient procedures would lead to a quicker access of European farmers and growers to innovative biocontrol solutions.