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IBMA VISION ON A NEW REGULATORY FRAMEWORK FOR BIOCONTROL IN THE EUROPEAN UNION

Accelerating the authorisation and use of biocontrol is a key EU political priority for the 2024–2029 mandate, highlighted in the Mission Letters for the Commissioners-designate for Health and Agriculture and Food. The Strategic Dialogue report urges the European Commission to **establish a robust legislative framework for biocontrol products by 2025, including fast-track authorisation processes**. Farmers urgently need these solutions to transition to sustainable, resilient agriculture while maintaining productivity. Biocontrol ensures food security by working with nature to manage pests and diseases effectively.

Currently, biocontrol is regulated under the EU Plant Protection Products Regulation (EC) No 1107/2009, alongside chemical pesticides. This framework—one of the most complex globally—results in authorisation timelines of up to 10 years, compared to 2-3 years in other jurisdictions. **It is ill-suited to biocontrol, lacking the flexibility to handle innovative solutions**. This mismatch delays market availability, discourages investment, and stifles innovation. According to an IBMA study, the current framework risks delaying the introduction to EU farmers of products based on 129 biocontrol substances—75 of them new—until 2033-2038.
A harmonized EU definition of biocontrol is a critical first step. Short term procedural measures within Regulation (EC) No. 1107/2009 can address immediate needs but do not eliminate the necessity for a dedicated regulatory framework.
A **dedicated biocontrol regulation is needed** to provide farmers with timely access to sustainable crop protection solutions, foster innovation and investment in the EU and enhance EU competitiveness and agricultural sustainability. Key elements of this new framework include:

1. **Establishment of a European Biocontrol Agency**:
   - A centralised body staffed by biocontrol experts from EU Member States.
   - Responsible for pre-submission meetings, application processing, and assessments of biocontrol active substances and formulated products.
   - Funded through a combination of general funds, fees and/or monetary assessments.

2. **Single Market Assessment**:
   - Replace the zonal system under Regulation (EC) No 1107/2009 with a unified “one market, one assessment” approach.
   - Optimise expert resources and eliminate duplication of work.

3. **Risk Assessment Tailored to Biocontrol**:
   - Fit-for-purpose product characterization criteria and evaluations of the foreseeable risk that ensure safety for humans, animals, and the environment and tailored risk assessments based on problem formulation.

This proposed structure aims to expedite authorisation processes, enabling products with new active substances to reach the EU market within 1-2 years of submission. By enhancing evaluation efficiency and consistency, providing a single contact point for applicants and international organisations, and fostering agility to embrace innovation, the framework represents a significant advancement.
Ultimately, this regulation will expand the availability of biocontrol solutions across the EU, supporting farmers, driving progress toward the EU's sustainability and clean industry objectives, and enhancing EU competitiveness. It reflects a proactive alignment with EU citizens' expectations for a greener, more sustainable, and resilient agriculture.

TECHNICAL ASPECTS OF THE NEW REGULATORY FRAMEWORK FOR BIOCONTROL

What is considered biocontrol?

Biocontrol has the same intended uses as described in Article 2 of Regulation (EC) No 1107/2009 and as such: (i) it originates from nature and as such uses natural mechanisms and (ii) it can either be sourced from nature or is nature identical if synthetised (iii) it has uses in agriculture, forestry, public spaces and home and garden, and (iv) it contributes to a more sustainable agriculture. The new regulatory framework will cover at least the following categories of biocontrol: micro-organisms, semiochemicals and natural substances. New categories of biocontrol products like bacteriophages, microbiomes and peptides are rapidly developing. Therefore, it is necessary to have regulatory pathways that can be easily adapted to emerging techniques and innovations**. Regarding Biological Control Agents (BCAs; macrobials/invertebrates) IBMA considers existing regulation to be sufficient and so invertebrates remain out of scope of any new framework discussion here.**

Why is a new regulatory framework for biocontrol urgently needed?

The current regulatory framework in the EU for plant protection products is one of the most complex frameworks with the longest timelines, compared to other global jurisdictions. To achieve the transition to a more sustainable agriculture within the foreseeable future, the current time from submission (of a dossier for a product based on a new active substance) to market should be reduced from more than 10 years to 2 years. To make this happen, the current regulatory process for biocontrol should be fundamentally reshaped while keeping the same level of protection for humans, animals and the environment. It should be acknowledged that there is a trend that most submissions for new active substance dossiers in the EU, as well as in the USA, Canada, and Brazil, are currently for biocontrol. Biocontrol developments show that there are more than 100 biocontrol substances, of which 75 are new biocontrol substances, planned for submission by 2028 in the EU. Furthermore, timely authorisation and use in the EU potentially also favours the production of biocontrol in the EU i.e. prevents delocalisation of their production.

A regulatory framework for biocontrol, consisting of a dedicated regulation for biocontrol and the establishment of a separate Biocontrol Agency, that is future proof and fit for purpose is therefore urgently needed. This dedicated regulatory framework should (i) align with ongoing initiatives and developments regarding sustainability, innovation, food security, (ii) build the future with nature, (iii) reduce the dependency of EU agriculture on import of chemicals, (iv) enlarge the IPM (Integrated Pest Management) toolbox for farmers, (v) ensure competitiveness of EU agriculture, (vi) reduce bureaucracy, (vii) use available resources more efficiently and (viii) not compromise the safety for

humans, animals and the environment, (ix) should result in a product authorisation within 1-2 years of submission and (x) stimulate the biocontrol industry to develop and produce in the EU.

How to achieve a more streamlined registration process for biocontrol products?

A harmonized definition of biocontrol at EU level is key for establishing a dedicated regulatory framework for biocontrol. As biocontrol includes a very diverse range of organisms and substances and may consist of very complex mixtures with different modes of action and intrinsic characteristics, an EU wide group of experts with a good understanding of biocontrol, biology and/or ecology and relevant scientific know-how is of utter importance for adequate and consistent assessments.
Additionally, a timely and efficient evaluation procedure requires a thorough organisation, with no room for duplication of work. For this reason, the proposal is to create an EU group of biocontrol experts that will centralise the assessment for placement of biocontrol products in the EU market and that will be hosted by a Biocontrol Agency. The establishment of a Biocontrol Agency would guarantee a coordinated centralized approach for all biocontrol applications (including pre-submission meetings) and assessments. There would be one single contact point for international players and applicants. That is also the model used in many other countries, e.g. USA-EPA Biopesticides Pollution Prevention Division (BPPD) and Canada-PMRA Microbial and Biochemical Evaluation Section. A new Biocontrol Regulation will replace Regulation (EC) No 1107/2009 for biocontrol and a Biocontrol Agency will deal with the assessment of biocontrol active substances and formulated products in a centralized way using harmonized procedures. The registration process should be a streamlined procedure to evaluate and authorize a biocontrol product using noted EU guidance documents, zonal and national scenarios, and options for Risk Mitigation Measures as provided by Member States for the assessments done by the Biocontrol Agency. This should result in a one-step procedure of 1.5-2 years for the authorisation of biocontrol products based on new active substances, and a shorter procedure for biocontrol products based on actives already on the EU market.

The Biocontrol Agency should be staffed by experts from EU Member States who would be selected based on their expertise and should not represent a specific Member State. The Biocontrol Agency should be financed by a combination of general funds and fees that are related to the handling of applications.

The Biocontrol Agency should be an independent entity and could be part of an existing authority under the prerequisite of the repurposing of the chosen authority with a mandate to host this Biocontrol Agency. In this way the administration and accountability would be centralized. Procedural elements of such a system are already operating for other regulations (e.g. animal feed additives or biocides). The Biocontrol Agency would liaise with the EU Biopesticides Working Group and international bodies such as OECD and FAO for the development of harmonized approaches to risk assessment.

What about the zonal system?

Under Regulation (EC) No 1107/2009 the EU is divided into regulatory zones “where agricultural, plant health and environmental (including climatic) conditions are considered comparable”. However, to achieve the transition to a more sustainable agriculture within the foreseeable future and to speed up arrival of biocontrol to the EU market, it is recommended to move away from the current zones in the

new Biocontrol Regulation as the existing zonal system complicates the regulatory process unnecessarily for biocontrol. There would be one single zone for biocontrol products (´one market, one assessment´).
Based on the biology of the product, the intended uses and the mode of action, the relevant environmental conditions (soil temperature, humidity, etc.) for an optimal use and efficacy of the biocontrol product should be determined. The use of a product is also determined by the distribution of the pest, and the occurrence of the pest (´pest pressure´) is determined by environmental conditions. These optimal environmental conditions should be reflected on the label. In this respect it should also be considered that due to climate change today crops are grown in different regions to 10-15 years ago, making historical zonal boundaries obsolete.
This approach would facilitate a wider use of efficacy and residue data generated outside the EU, when scientifically valid and if agronomic and environmental conditions are similar.
An intensified use of (existing) crop grouping systems and the risk envelope approach would greatly facilitate and support the availability of biocontrol products, including for minor crops. In this respect also the extrapolation from similar pest-target combinations to different crops should be considered more widely.

Risk Assessment Approaches
The risk assessment of biocontrol products should follow a different approach compared to the assessment of chemical active substances. In contrast to a ´tick-box´-approach, the risk assessment of most biocontrol products is case-by-case and based on a fit for purpose risk assessment. The following approaches focus on the submission of data that is necessary to do a proper assessment considering naturally present background levels of biocontrol substances in the environment. (i) The ´problem formulation´ phase of risk assessment can be used to tailor the risk assessment to the individual biocontrol product in a structured and transparent way. (ii) As the data required for risk assessment are guided by the proposed use pattern and properties of a product, a weight of evidence approach to risk assessments can be used. (iii) A submitted dossier should contain information which is sufficient to evaluate the foreseeable risks which the biocontrol agent or product may entail as defined during Problem Formulation. Specific data requirements and a tiered approach could be indicated for particular product types providing a clear approach for applicants and evaluators to follow and thus increasing consistency and reducing waste of resources.

How would this work in practice?

The applicant submits the application(s) for the biocontrol products to the Biocontrol Agency and indicates in which Member States he is looking for an authorisation. The assessment of the application by the Biocontrol Agency would result in issuing a ´master label or registration certificate´ for the biocontrol product(s) that is valid in all Member States (open field and under protection) and can be used for translation and to finalise national labels/certificates by adding e.g. a registration number on national labels. No additional assessments based on national specific requirements should be carried out by Member States. In this respect the importance of education and training of farmers in the use of biocontrol should also be highlighted.

What would be the future role of the Member States?

Member States should provide to the Biocontrol Agency the national assessment scenarios and risk mitigation measures that could be applied at national level. Member States will decide individually on ´Emergency Authorisations´ and determine what are minor uses/minor crops. Enforcement and advisory services will also operate at national level.

A cornerstone of the Sustainable Use Directive (SUD) is the promotion of IPM. The National Action Plans (NAPs) describe the policy intentions of individual Member States and actions that have been defined to meet the requirements under the SUD. The use of sustainable biological methods is key in IPM programmes and as such more biocontrol solutions are necessary to meet the sustainable targets in the EU. More recently this has been highlighted in the Strategic Dialogue promoting the application of on-farm biocontrol practices as for Integrated Pest Management Control. This requires Member States action in accelerating the availability of biocontrol solutions. This Member States role is complementary to the single EU Biocontrol Agency´s role of authorising a range of biocontrol solutions for use in the Member States.

What are the potential benefits of a new regulatory framework for biocontrol?

A new regulatory framework for biocontrol would have several advantages: (i) better use of resources, (ii) no duplication of work, (iii) high(er) quality and consistency of evaluations and assessments (iv) improved efficiency, (v) better equipped and more agile to deal with innovation, (vi) faster access of farmers to innovative and sustainable crop protection solutions (vii) increased transparency, (viii) increased predictability and consistency of decisions, (ix) centralized database with an overview of all authorized biocontrol products, and (x) the EU would become more attractive for investments.