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The Food and Feed Safety Omnibus is an important first step on the road to fit-for-purpose regulation for biocontrol solutions

"The amendments to Reg (EC) 1107/2009 proposed by the European Commission in its Food and Feed Safety Simplification Omnibus, are important first steps in adapting EU regulation to give more choice of safe and effective biocontrol products in a timely manner," said Kristen Sukalac, Secretary General of the Biocontrol Coalition. "However, there are still fundamental issues that can only be addressed through a dedicated framework adapted to the characteristics of biocontrol products." (See our gap analysis below.)

Positive developments in the Omnibus

- The Biocontrol Coalition lauds the proposed definition of biocontrol substances, which is future-proof and innovation friendly. We acknowledge the need to refine the definition during interinstitutional negotiations to further strengthen the boundary with conventional plant protection products. In this context, we draw attention to our principles for defining biocontrol, particularly the additional criterion that products must decompose in the environment in a well-established and predictable manner or be environmentally inert to be categorised as biocontrol. Being derived from natural sources alone is not sufficient.
- Recognising that competent authorities have not had the resources to cope with the excessive administration burden and duplication of the existing system for plant protection approvals, we welcome the Commission's efforts to streamline processes by applying a one-zone approach for the authorisation of biocontrol products, improving mutual recognition with strict timelines, and focusing the obligation to undergo systematic renewal to the substances most likely to be of concern.
- Bearing in mind that commercialising and using biocontrol products are business decisions that require a positive return on investment for manufacturers and farmers, we applaud how the proposed measures, including provisional authorisation, will improve the economic dynamics of bringing biocontrol products to the market in the EU by reducing administrative costs, aggregating markets, and allowing companies to begin recouping their investments earlier.
- The measures listed above as well as the Commission's suggestions on how to simplify authorisation from additional uses are in line with the position that the Biocontrol Coalition co-signed with IBMA, CropLife Europe, COPA-COGECA, and the European Landowners' Organization.

What is still missing to have a fit-for-purpose regulatory framework for biocontrol in the EU?

The table below lists key elements of a fit-for-purpose regulatory framework for biocontrol and indicates to what extent the proposed amendments in the Food and Feed Safety Omnibus would provide them.

A harmonised EU definition of biocontrol	The Commission's proposal is a promising starting point to agree on a future-proof and innovation-friendly of biocontrol substances.
Regulatory flexibility with sandboxes	The proposed definition cannot cover all potential innovation of biocontrol solutions. A dedicated framework could ensure flexibility and address future technologies, through experimentation clauses ("sandboxes") as tools for innovation and regulatory learning, with structured context for testing innovation, under supervision of a competent authority, and ensuring that appropriate safeguards are in place. In this light, we welcome the complementary proposals in the draft Biotech Act I also released on 16 December 2025.
Single market coherence, centralised evaluation, and pooling of expertise	As mentioned above, the proposals to treat the EU as a single zone for authorisation of biocontrol products and the reinforcement of mutual recognition are important and useful steps towards a single market. However, it continues to rely on Member State authorities' capacity to deliver the assessments. The Commission also proposes a derogation for biocontrol substances whereby the European Food Safety Authority (EFSA) may "assume the duties of the rapporteur Member State." This would reinforce the resources available to evaluate biocontrol substances by including EFSA resources; but it does not address the issue of divergent interpretations from a decentralised system. Furthermore, these proposals do not address the duplication and additional delays that are inherent to a two-step registration/authorisation process. We believe that the creation of panels specialised in specific biocontrol technologies and composed of experts from both Member States and EFSA would further strengthen the EU's ability to evaluate biocontrol substances. These panels could be mobilised according to the nature of the applications received. Such panels would also provide an opportunity for peer-learning to further grow the pool of qualified experts for the various technologies.
Holistic evaluation of products, not isolated substances	The proposed amendments would not address one of the underlying mismatches between Reg (EC) 1107/2009 and the nature of biocontrol products. The regulation assumes that the fundamental safety and effectiveness of biocontrol substances can be evaluated in isolation. However, in biocontrol products this is not necessarily the case. In some cases, multiple

	substances and/or microorganisms work together to provide biocontrol functions that would not exist if they were applied separately. For this reason, the two-step process of approving active ingredients and then authorising products is ill-adapted.
Enlarged concept of product effectiveness	The effectiveness of conventional crop protection products such as pesticides has been historically measured by yield compared to untreated crops and percentage of pests killed. In modern times, measurement has shifted to crop damage. But these measures cannot be applied in a copy-paste way to biocontrol products, nor do they capture some of the additional value offered by these products.[1]
Risk assessment based on problem formulations	Adapted data requirements, risk assessments and evaluation of product effectiveness should be based on problem formulation aligned with real-world conditions of use.[2] A pragmatic approach can demonstrate safe uses while preventing unnecessary, costly and lengthy data generation without lowering safety standards. Furthermore, we expect significant disruptions to how such evaluations are carried out and how companies prepare as artificial intelligence and other technologies are adopted. This is likely to have major repercussions for how innovations like biocontrol are developed and evaluated by regulators. These are likely to require significant rethinking of the procedures in the current regulatory framework. A dedicated framework would also need to incorporate the outcomes of successful regulatory sandboxes (as proposed in the draft Biotech Act I also released on 16 December 2025) that had been conducted to test "alternative regulatory requirements and appraising their performance."

Omnibus Measures Are Not the End of the Journey

The measures proposed in the Omnibus are an excellent step in the right direction – but if we want to fully realise the potential of biocontrol on the EU market in the coming years we will need more. It is difficult to see how the gaps between the Omnibus and what is needed can be addressed within the constraints of Reg (EC) 1107/2009. However, by reducing resource

[1] Described in more detail in our article "Time to rethink how to measure effectiveness of biocontrol products," such added value includes fewer unwanted environmental impacts, short re-entry times after application, and heling to management pest resistance to other plant protections solutions.
[2] For more details, see the "IBMA Vision on a New Regulatory Framework for Biocontrol in the European Union."

constraints on competent authorities, the provisions in the Omnibus create the capacity to begin work on a truly fit-for-purpose dedicated legislative framework. To ensure the EU can meet farmers' needs for a wide range innovative biocontrol solutions as soon as possible, we believe that work on a dedicated framework should be launched no later than the 2027 Commission work programme.

The need to have a separate framework for biocontrol was first recognised in 2007 when the REBECA project funded by the European Commission reached this conclusion. Since then, we have been seen several more studies and reports also make such recommendations:

- The European Parliament has expressed this view twice, firstly in 2018 and then more recently in November 2025;
- The Commission's own Fit for Future platform Biosolutions report in 2022;
- Organisation for Economic Co-operation and Development (OECD) Data Requirements and Approaches to Biological Pesticide Registration
- Food and Agriculture Organization of the United Nations (FAO) International Code of Conduct on Pesticide Management - Guidelines for the registration of microbial, botanical and semiochemical pest control agents for plant protection and public health uses;

Across these various reports, recommendations have been to assess biocontrol products differently from chemical pesticides and to regulate biocontrol products in standalone legislation.

We want European farmers to have a wide choice of biocontrol solutions on an ongoing basis. To make this happen, we need to go beyond the excellent start in the Omnibus to build dedicated legislation that meets the additional challenges outlined above.

About the Biocontrol Coalition

The Biocontrol Coalition is a multi-stakeholder platform advocating for the European Union to rethink its framework for agriculture and food, particularly for biocontrol, to enlarge the farmer toolbox while ensuring safety and health and protecting the environment.

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