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IBMA – Biocontrol Manufacturers: Making the fast-track of biocontrol products a priority for the next European Commission

The withdrawal of the SUR proposal by the European Commission (EC) following its rejection by the European Parliament (EP) was deeply unfortunate for biocontrol, notably considering that **all amendments relating to biological control –which included measures to fast-track their authorisation– were adopted across political parties**. We strongly support EP's amendments on biocontrol –outlined below in the document *Appendix 1*–, as well as the SUR provisions which highlighted the need for a strong IPM and training for advisors and farmers.

The biocontrol market is 8 Bn globally and 1.6 bn within EU. Biological control are ready and available for submission but are held up by a slow European authorisation process which on average takes 7 to 8 years, up even to 10 years, compared to 1 to 3 years or less in other major markets. These delays are already reducing attractiveness of EU for **biocontrol companies who increasingly invest outside the EU**. Market predictions are that biocontrol industry growth will halve in EU by 2030 compared to the rest of the world if time to authorisation is not reduced to 2-3 years. Furthermore, switching to biocontrol provides climate mitigation opportunities on farm[1] and delivers biodiversity benefits at scale[2].

Measures are still **needed to speed-up the market access of biocontrol**. For many years, European farmers have been reducing the use of chemical pesticides while **facing a lack of sufficient access to effective and safe alternatives such as biocontrol**, endangering their ability to fight pests and ultimately remain productive. Biocontrol has a crucial role to play in making sure the **EU meets its food needs** and ensure **food security and strategic autonomy**. In that context, it should be noted that the EC additional study to the SUR impact assessment (Article 241)[3] pointed to the **129 biocontrol Active Substances** ready for submission between 2023 and 2028 containing 75 new actives and 54 label expansions mainly into arable crops – **highlighting that a priority lane for these Active Substances and their products has the potential to allow biocontrol on over 28M ha of agricultural land**. [4]

To **achieve EU's strategic priorities regarding food security and competitiveness, we call the European leadership to make the priority lane for biocontrol a top goal for the next term,** building on the valuable work carried out by the EC , EP and more recently the SMET.

Below are specific measures that can ensure that market approval for biological PPPs **becomes swifter 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.**

[1] McKinsey Report *The agricultural transition: Building a sustainable future* – June 2023
[2] EC DG Agri Building a partnership on agroecology living labs & research infrastructures – Rice in Albufera
[3] European Commission Additional Study 5th of July (pages 123-136)
[4] Biocontrol in the pipeline data provided by IBMA

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IBMA's key policy asks to provide more biological control to farmers as soon as possible and support EU biocontrol industry and its competitiveness

EU-wide definition of biocontrol

A key element to ensure the uptake of biocontrol is a comprehensive EU-wide definition that reflects the range of biocontrol products available, which accompanies the measures outlined below.

See Appendix 1 for the EP amendments during SUR negotiations on a biocontrol definition that includes macro-organisms and a list of categories of plant protection active substances that exert biocontrol (microorganisms; semiochemicals; natural substances).

1. **Better implementation of existing Regulation No 1107/2009**

The below measures do not require any regulatory changes and are readily implementable at MSs level.

- **Priority lane for biocontrol**

A green priority lane for biocontrol solutions will allow Member States (MSs) to **deliver these alternatives to the market faster** providing farmers with the choice to use biocontrol and **allowing the ongoing competitiveness of European farmers**. Farmers in the rest of the world are already having access to biocontrol. Prioritisation of the biocontrol evaluations within the authorisation procedure in Brazil greatly increased the number of biocontrol products on the market within one year.

The creation of a **green priority lane was supported by the EP** and resulted in the introduction of specific amendments to that end during SUR discussions (See Appendix 2).

- **Mutual recognition**

A lot of resources are often required to obtain product authorisations in different MSs. The zonal system and mutual recognition (Guidance: SANCO/13169/2010 Rev. 11) was developed to facilitate this process but MSs have a lot of latitude to refuse a zonal authorisation and/or mutual recognition and invariably reopen a dossier already evaluated in another MS. The EC can strongly encourage MSs to only reopen dossiers if absolutely necessary and to **stimulate better cooperation between MSs**, particularly within the same zone. Correct implementation of existing mutual recognition provisions would **allow biocontrol products to be available for farmers throughout the zone within a few weeks of the rapporteur MSs authorisation**.

- **Acceptance of label expansions during renewal process of biocontrol**

Label expansion can be implemented at MSs level during the re-registration process for biocontrol products. In practice, MSs do not allow label expansion during the renewal process in case the end points change – however, end points rarely change for biocontrol and this is instead a risk assessment element that relates to chemical PPPs.

- **Where emergency authorisations are considered – prioritise biocontrol**

The EC can advocate better use of this derogation procedure available to MS for phytosanitary problems for which no alternatives are available. While this procedure is frequently used to allow the continued use of old chemistry that has been withdrawn for safety reasons, it should instead be **used to allow accelerated use of biocontrol alternatives**, subject to a satisfactory evaluation.

2. Targeted changes to Regulation No 1107/2009

- **Provisional authorisation for biocontrol**

While emergency authorisations provide an interim solution to the current lack of alternatives for farmers, they only last 120 days and have to be resubmitted each year until the final authorisation is granted in the MSs (likely 7-8 years). By comparison, a provisional authorisation is not renewed annually, having the advantage of saving MS authorities valuable time without compromising safety.

Article 30 of the EU Reg (No) 1107/2009 already provides for provisional authorisation but remains dormant since 14 June 2016. The goal would be to **reinstate this article for biological control, which would shorten time to authorisation to 2-3 years.**

Provisional authorisation for biocontrol was supported by the EP during SUR negotiations via specific amendments (See Appendix 4).

- **Label extension of biocontrol products to pests rather than crops**

Authorisation of label expansion can also be enhanced at EU level by **amending 1107 to enable label expansion to all crops relevant for a target pest and disease**. By virtue of the mode of action and the lack of MRLs for microbials and semiochemicals there is **no safety need to restrict the use by crop**. The use of biocontrol on one crop against one pest or disease is readily extendable to other crops.

Enabling submission and evaluation of all envisaged label uses at one time at MS level will **reduce evaluation timelines as dossiers do not have to be re-opened for each label expansion**. Therefore, it can accelerate availability of biocontrol to growers and save time for MS competent authorities.

Through its Amendments, the EP proposed a form of label expansion that covered an extension of the authorisation to all proposed uses (See Appendix 5). This should be further expanded to cover all uses within a same pest.

- **Removing periodic re-registration**

EU and MS workload is dominated by the re-registration programme reducing available time for new authorisations. **Removal of the biological control re-registration programme reduces EU and MS workload and allows focus on new innovations**. Safety of existing authorisations can be ensured through existing provisions under Article 56 of EU Reg (No.) 1107/2009.

The EP tabled an amendment during SUR negotiations calling on the EC to recommend measures to potentially extend approval periods for PPPs containing solely active substances exerting biocontrol (See Appendix 3). This call should be further expanded to removing periodic re-registration.

Next to the above measures proposed, the EC should assess whether other regulatory instruments, such as a dedicated legislation, could more effectively support the placing on the market of biocontrol alternatives in the long term (See Appendix 6).

To conclude, more generally, we would like to underline further some other key points, which should be kept in mind, from the 2019-2024 mandate discussions:

- **The definition of IPM should also reflect that IPM is an 'agroecological-based strategy'.** In this respect also the contribution from IPM to the EU Biodiversity Strategy for 2030 and the functioning of ecosystems and ecosystem services should be more emphasised.
- **Training in IPM and biocontrol for advisers and farmers. Accompanying the farmers is key in terms of knowledge-sharing, incentives and economic risks management.**

All these measures are already late as highlighted by the farmer protests. Farmers will be able to continue the transition to resilient sustainable only if appropriately supported making sure that economic, social and environmental sustainability are achieved together.

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Appendix 1 – Biological control Definition – European Parliament Amendments

Proposal for a regulation
Recital 37b (new)

Text proposed by the Commission	*Amendment*
	(37b) For reasons of transparency, and to ensure uniform implementation by all Member States, the categories of active substances that exert biological control should be set out in an Annex. Inclusion of active substances or categories of active substances that exert biological control in this Annex does not mean that these active substances are approved in accordance with Regulation (EC) No 1107/2009.
	Member States should prioritise the assessment of applications for plant protection products containing solely active substances exerting biological control and ensure that applicants are given full support in the preparation of their dossiers.

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) For reasons of transparency, and to ensure uniform implementation by all Member States, the methodology for calculating progress towards achieving the two Union and two national 2030 reduction targets and the methodology for the calculation of harmonised risk indicators at Union and national level should be set out in an Annex to this Regulation.	(38) For reasons of transparency, and to ensure uniform implementation by all Member States, [the methodology for calculating progress towards achieving the two Union and two national 2030 reduction targets and] the methodology for the calculation of harmonised risk indicators at Union and national level should ***also*** be set out in an Annex to this Regulation.

Article 3(1)

Text proposed by the Commission	*Amendment*
(1) 'chemical plant protection product' means a plant protection product containing a chemical active substance excluding plant protection products ***using natural means of biological origin or substances identical to them, such as micro-organisms, semiochemicals, extracts from plant products as defined in Article 3(6) of Regulation (EC) No 1107/2009, or invertebrate macro-organisms;***	'chemical plant protection product' means a plant protection product containing a chemical active substance excluding ***invertebrate macro-organisms and*** plant protection products ***containing solely active substances that exert biological control;***

Article 3 (3)

Text proposed by the Commission	*Amendment*
(3) 'chemical active substance' means an active substance ***other than a micro-organism, a semiochemical or an extracts from a plant product as defined in Article 3(6) of Regulation (EC) No 1107/2009;***	(3) 'chemical active substance' means an active substance other than ***an active substance that exerts biological control ;***

Article 3 (23)

Text proposed by the Commission	*Amendment*
(23) 'biological control' means the control of organisms harmful to plants or plant products using ***natural means of biological origin or substances identical to them, such as micro-organisms, semiochemicals, extracts from plant products as defined in Article 3(6) of Regulation (EC) No 1107/2009, or invertebrate macro-organisms.***	(23) 'biological control' means the control of organisms harmful to plants or plant products using ***invertebrate macro-organisms or an active substance that exerts biological control.***

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Article 3 (23a) (new)

Text proposed by the Commission	*Amendment*
	(23a) 'active substance that exerts biological control' means an active substance that is
	(a) a living micro-organism, or
	(b) naturally occurring, with the exception of heavy metals and their salts, or
	(c) if synthesized, identical to a naturally occurring substance
	as referred to in Annex -I.

Article 3 subparagraph 1a (new)

Annex -I lists the categories of active substances that exert biological control. The Commission shall assess, on a yearly basis, the technical progress and scientific developments with regard to biocontrol with a view to making additions, as appropriate, to the categories listed in Annex -1. For this purpose, the Commission is empowered to adopt delegated acts in accordance with Article 40.

ANNEX I

CATEGORIES OF ACTIVE SUBSTANCES THAT EXERT BIOLOGICAL CONTROL

1. ***Living microorganisms***
2. ***Semiochemicals***
3. ***Extracts from natural sources, in particular plants and algae, and substances produced by microorganisms***
4. ***Substances identical to those produced by biological organisms or that are constituents of biological organisms***
5. ***Inorganic substances as occurring in nature, with the exception of heavy metals and their salts***

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Appendix 2 – Establishing green priority lanes for biocontrol – European Parliament Amendments

Article 43a (new) *Text proposed by the Commission*	*Amendment* ***[…] Member States shall require their competent authorities to establish a priority lane for the authorisation of low-risk plant protection products and plant protection products containing solely active substances exerting biological control in the application procedures for the approval of an active substance.***
Article 42 d (new) *Text proposed by the Commission*	***[…] d) the administrative capacity, staffing levels and dedicated budget, at both Member State and Union level, of competent authorities responsible for the assessment of active substances exerting biological control and low-risk active substances as well as the implementation of priority lanes for the authorisation procedure of plant protection products containing solely active substances exerting biological control and low-risk plant protection products at Member State level as provided for in Article 9a;***
Recital 11 *Text proposed by the Commission*	***[…] It is therefore appropriate to define the concept of biological control as a basis for Member States to set targets to increase the percentage of crops on which biological control agents are used and the overall sales of low risk-plant protection products and biological control, to allow for a swifter authorisation process for plant protection products solely containing active substances exerting biological control, to establish provisional authorisation for plant protection products containing solely active substances exerting biological control and to request competent authorities to establish a priority lane for the authorisation of plant***

protection products containing solely active substances exerting biological control.

Appendix 3 – Biological control registrations having no time limit (removal of re-registration process) – European Parliament Amendments

Article 42a (new) *Text proposed by the Commission*	*Amendment*
	1. No later than… [OP: please insert the date = one year after the date of entry into force of this Regulation], the Commission shall present an impact assessment accompanied, where appropriate, by a legislative proposal concerning the placing on the market of plant protection products containing solely active substances exerting biological control, aimed at supplementing Regulation (EC) No 1107/2009 and facilitating the rapid availability of safe and efficient nonchemical alternatives for plant protection exerting biological control. Taking into account the data provided by Member States in accordance with Article 9 and taking into account social, environmental and economic sustainability, the impact assessment shall evaluate the effectiveness of the approval procedure for plant protection products containing solely active substances that exert biological control and consider, inter alia, the differences between chemical plant protection products and plant protection products containing active substances that exert biological control, in terms of data requirements and facilitating the extension of authorisations for plant protection products containing active substances that exert biological control to other crops. Where appropriate, it shall also recommend measures to ensure sufficient resources at Union and Member State level to significantly accelerate the authorisation procedures and potentially extend approval periods of plant protection products containing solely active substances exerting biological control.

Appendix 4 – Provisional authorization – European Parliament Amendments

Article 30a (new) *Text proposed by the Commission*	*Amendment*
	Article 30a ***Provisional authorisations for plant protection products containing solely active substances exerting biological control within the meaning of Article 3(23) of [SUR, reference to adopted act to be inserted]*** ***1. By way of derogation from Article 29(1)(a), Member States may authorise, for a provisional period not exceeding three years, the placing on the market of plant protection products containing solely active substances that exert biological control within the meaning of Article 3(23a) of [SUR, reference to adopted act to be inserted] which have not yet been approved, provided that:*** ***(a) the decision on approval of the active substance(s) that exert biological control has not been finalised within a period of 12 months from the submission of the draft assessment report to the Commission as set out in Article 11(1)(a), extended by any additional period set in accordance with Article 11(3) or Article 12(2) or (3); and*** ***(b) pursuant to Article 9 the dossier on the active substance is admissible in relation to the proposed uses; and*** ***(c) the Member State concludes that the active substance(s) that exert biological control is expected to satisfy the requirements of Article 4(2) and (3) and that the plant protection product is expected to satisfy the requirements of Article 29(1)(b) to (h) and fulfils the requirements set out in Article 29(3); and*** ***(d) where relevant, maximum***

residue levels have been established in accordance with Regulation (EC) No 396/2005.

2. In such cases as outlined in point (1) above, the Member State shall immediately inform the other Member States and the Commission of its assessment of the dossier and of the terms of the authorisation, giving at least the information provided for in Article 57(1).

3. Where a decision on the approval of the active substance(s) exerting biological control referred to in paragraph 1 has not yet been adopted when the period of provisional authorisation for the relevant plant protection product has expired, the Member States which granted the provisional authorisation may extend it for a period not exceeding one year, provided that points (a) to (c) of paragraph 1 still apply. In such cases, the Member State shall immediately inform the other Member States and the Commission.

4. In case the active substance(s) exerting biological control referred to in paragraph 1 is not approved, the provisional authorisation for the placing on the market of the relevant plant protection product shall be withdrawn immediately and the Member State shall inform the other Member States and the Commission accordingly without delay.

Appendix 5 – Facilitated label expansion – European Parliament Amendments

Article 15a (new) *Text proposed by the Commission*	*Amendment*
	With a view to accelerating the authorisation procedure and approval periods of plant protection products containing solely active substances exerting biological control, Member States shall, in accordance with Article 51(3) of Regulation1107/2009, take measures to facilitate the submission of applications to extend the authorisation of already authorised plant protection products containing solely active substances exerting biological control to all proposed uses.

Appendix 6 – The need for a new biological control specific legislation – European Parliament Amendments

Article 42b (new) *Text proposed by the Commission*	*Amendment* ***By 31 December 2026 the Commission shall present a report to the European Parliament and the Council on providing new data requirements to facilitate the approval of biological control products including semiochemicals, extracts from plant-products, peptide- and protein-based products including enzymes and antibodies, RNA, hormones, dead cell and fermentation products. Further to the this, the Commission shall assess establishing a fast-track approval process for low-risk and biological control products under this Regulation and also assess if measures under this Regulation sufficiently facilitate the availability of effective alternatives, or if this would be achieved more effectively in the long term by a new dedicated framework for the approval and authorisation for biological control products.***