4/04/2025

IBMA's proposal of immediate targeted amendments to Regulation No 1107/2009, to be included in any pertinent immediate legislative initiative

This proposal is followed by explanatory notes for each proposed amendments (Annex 1. Pg 8) and IBMA Biocontrol definition (Annex 2. Pg.11).

1. **Biocontrol definition**

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
	Recital 14a (new)
	Biocontrol active substances, products and agents are a sustainable, efficacious alternative to control harmful organisms with minimal harm to humans and the environment. Biocontrol is a cornerstone of IPM systems, within a holistic approach that is essential for the transition while allowing farmers to be productive and competitive. As noted in the Vision for EU Agriculture and Food, as well as in the Strategic Dialogue Report, the accelerated use of biocontrol is needed to achieve a sustainable and resilient agri-food system in Europe. As regards to this Regulation, it is appropriate to facilitate the rapid availability on the market of biocontrol plant protection products. It is therefore appropriate to define the concept of biocontrol active substances to allow for a swifter authorisation process of biocontrol plant protection products containing solely biocontrol active substances; to establish a provisional authorisation for biocontrol plant protection products to request competent authorities to establish a priority lane for the authorisation of biocontrol plant protection products; to establish a centralised evaluation agency (such as EFSA) for an EU-wide evaluation of biocontrol active substances and associated product; to remove the need for renewal of approval of biocontrol plant protection ; to facilitate label extension for biocontrol plant protection products to all proposed uses; and to allow for automatic mutual recognition of biocontrol plant protection products.

Article 3 (8a) (new)

'biological control' means the control of organisms harmful to plants or plant products using invertebrate macro-organisms, which are regulated elsewhere, or a biocontrol active substance

'biocontrol active substance means an active substance that is:
(a) a living or non-viable micro-organism, or
(b) naturally occurring,
(c) if synthesized, identical to a naturally occurring substance
as referred to in Annex -I.

A biocontrol product is a product containing solely one or more biocontrol active substances.

Annex -I
CATEGORIES OF BIOCONTROL ACTIVE SUBSTANCES
lists the categories of biocontrol active substances. 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.

- *(a) Living microorganisms such as fungi, bacteria and viruses or non-viable microorganisms*
- *(b) semiochemicals*
- *(c) extracts from natural sources, in particular plants and algae, and substances produced by microorganisms*
- *(d) Substances identical to those produced by biological organisms or that are constituents of biological organisms such as functionally identical peptides and proteins*
- *(e) Inorganic substances as occurring in nature, such as minerals*

Biocontrol active substances are frequently combined to form blends of semiochemicals, plant extracts or microbial consortia.

Justification: 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. Any definition of biological control that extends beyond EC Reg No 1107/2009, should also include the fourth category of biocontrol (invertebrate), currently regulated at Member State level.

2. Establishing green priority lanes for biocontrol

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
	Article 7(6) (new)
	Member States shall require their competent authorities to establish a priority lane for the authorisation of biocontrol plant protection products in the application procedures for the approval of an active substance. *Member States shall require their competent authorities to establish a priority lane for the evaluation of biocontrol active substances and the authorization of biocontrol plant protection products.* *The Commission shall, where appropriate, recommend measures to ensure sufficient expert staffing capacity on different categories of biocontrol active substances and budget at Union and Member State level to significantly accelerate the authorisation procedures for plant-protection products containing active substances exerting biological control.*

Justification: A green priority lane for biocontrol solutions will allow Member States 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.

3. Establishment of a Centralised evaluation agency

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
	Article 7(7) (new)
	When submitting the application the applicant may choose to submit to a dedicated branch of a centralised agency (focussed on and with expertise in biocontrol), such as EFSA, which will coordinate the evaluations among the Members States to obtain a European wide authorisation of the active substance and associated product.

Justification: A centralised agency of experts could provide a faster and more efficient route to a European wide approval and authorisation. The changes described may also need changes in Article 36 and Article 44, as well in EC Reg No. 178/2002.

4. Removal of re-registration process for biocontrol

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
	Article 14 (3) (new)
	On application the approval of a biocontrol active substance shall be for an unlimited period of time.
	Article 43 (7) (new)
	This article is not applicable for authorisation of biocontrol products, which are unlimited in time.

Justification: EU and Member States workload is dominated by the renewal programme reducing available time for new authorisations. Removal of the biological control renewal programme reduces EU and Member States workload and allows focus on new innovations. Safety of existing authorisations can be ensured through existing provisions under Articles 21 and 56 of EU Reg (No.) 1107/2009. The change proposed may also require changes in the Commission Implementing Regulation EU 2020/1740.

5. Provisional authorisation

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
Article 30 Provisional authorisations	***Article 30*** *Provisional authorisations*
1.By way of derogation from Article 29(1)(a), Member States may authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing a biocontrol active substance not yet approved, provided that:	*1. By way of derogation from Article 29(1)(a), Member States shall authorise for a provisional period not exceeding 3 years, the placing on the market of plant protection products containing a biocontrol active substance not yet approved, provided that:*
(a) the decision on approval could not be finalised within a period of 30 months from the date of admissibility of the application, extended by any additional period set in accordance with Article 9 (2), Article 11 (3) or Article 12 (2) or (3): and	*(a) the decision on approval could not be finalised within a period of **24 months** from date of admissibility of the application; and*
(b) pursuant to Article 9 the dossier on the active substance is admissible in relation to all proposed uses; and	*(b) pursuant to Article 9 the dossier on the active substance is admissible in relation to all proposed uses; and*
(c) the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h); and	*(c) the Member State concludes that the active substance can satisfy the requirements of Article 4(2) and (3) and that the plant protection product may be expected to satisfy the requirements of Article 29(1)(b) to (h); and*

(d) maximum residue levels have been established in accordance with Regulation (EC) No 396/2005.	*(d) maximum residue levels or residue exemptions have been established in accordance with Regulation (EC) No 396/2005.*
2. In such cases 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)	*2. In such cases 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. The provisions laid down in paragraphs 1 and 2 shall apply until 14 June 2016. If necessary, that time limit may be extended in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).	*~~3. The provisions laid down in paragraphs 1 and 2 shall apply until 14 June 2016. If necessary, that time limit may be extended in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).~~*

Justification: A time limited provisional authorisation provides Member States with a fast-track procedure without compromising safety, saving time and penalties associated with 120-day emergency authorisations for biocontrol. Emergency authorisations are increasingly used to cover the lack of authorized solutions for pest and disease control or farmers. 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.

6. Facilitated label expansion for biocontrol

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
	Article 33 (7) (new)
	With a view to accelerating the authorisation procedure and approval periods of biocontrol plant protection products, Member States shall take measures to extend the authorisation of already authorised biocontrol plant protection products to all proposed uses.
	The authorization could then be given on a pest or disease across any crop conditional on (i) an MRL exemption for the biocontrol active substance and (ii) submission of required phytotoxicity tests.
	Label expansion shall be permitted during the review of the approval.

Justification: The mode of action of biological control is different to that of chemicals. Where biocontrols are pest or diseases specific, the label extension to other crops where the same pest or disease are present, is possible with minimal concerns of efficacy, phytotoxicity or crop residues,

allowing extension of use with minimal additional data. In this way new uses of existing authorised products are more rapidly available to farmers.

The tendency of Member States to not review label extensions during any review of the active substance approval should not apply to biocontrol active substances so that label extensions of currently authorised biocontrol plant protection products can be accelerated.

7. Mutual Recognition of Authorisations

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
Article 40 The holder of an authorisation granted in accordance with Article 29 may apply for an authorisation for the same plant protection product, the same use and under the comparable agricultural practices in another Member State under the mutual recognition procedure.	***Article 40*** *An authorisation granted in accordance with Article 29 will be automatically recognised in all Member States.* *Mutual recognition shall be permitted during the review of any approval.*
Article 42 (2) The Member State to which an application under Article 40 is submitted shall issue a justified decision on the application within 120 days.	***Article 42 (2)*** *The Member State to which an application under Article 40 is submitted shall issue a justified decision on the application within 120 days.* *In the event that the decision is not taken within 120 days the authorisation in the targeted Member State would be provisionally granted until the Member State issues a final justified decision.*

Justification: Current Member States practices mean mutual recognition is at best slow and at worst not performed by many Member States, further delaying farmer access to biocontrol already approved at EU level and authorised in some Member States. As a consequence, there is not a single market for biocontrol in the EU. A system of mutual recognition "automatically" applied to all Member States could ensure the single market for biocontrol within the EU. Member States can opt out but only with a serious reason as indicated in the seed treatment Article 49. 1.

8. The need for a new regulatory framework for biocontrol in the longer term

Text in the current EU Reg No 1107/2009	*Proposed Amendment*
	Article 82 (2) (new) *By 2028, the Commission shall present to the European Parliament and Council a new fit-for-purpose regulation for the approval and authorisation of biocontrol products, which consolidates a future-proof regulatory environment for biocontrol and ensures the long-term competitiveness and resilience of the agricultural and crop protection markets in Europe. In doing so, the Commission shall assess*

the need to establish a dedicated Single Agency for biocontrol active substances and products; as well as other key features such as (i) moving away from the current zonal system established under this Regulation so that there would be instead one single zone for biocontrol products ('one market, one assessment'), and (ii) developing a risk assessment procedure fully adapted for all types of biocontrol products.

Justification*:* Post 2035 biocontrol is expected to be the dominant type of pest and disease control. In this situation a regulatory framework wholly adapted to biologicals is required. This necessitates a fundamental review and rework of the existing regulatory framework. Such revision is needed to maintain the competitiveness and resilience of the agricultural and crop protection markets in Europe.

4/04/2025

Annex 1. Explanatory notes

1. EU wide Biocontrol definition

IBMA's proposal reflects IBMA's biocontrol definition. Additionally, we support the original European Parliament approach in the SUR amendments to list category details in the regulation's appendix to allow the European Commission to incorporate new innovations as appropriate, without having to reopen the whole legislation. Each category should include blends of biocontrol active substances such as plant extracts and microbial consortia.

For simplification of Reg.1107/2009 invertebrate macro-organisms should not be included because they are not Plant Protection Products. However, if a broader European definition of biocontrol is envisaged in a piece of legislation such as the Biotech Act, then invertebrates macro-organisms could be included.

2. Establishing green priority lanes for biocontrol

The European Commission Vision for Agriculture and Food states the requirement to create a fast track procedure for the approval and authorisation of biocontrol. The authorisation of plant protection products involves a 2-stage application. The active substances are evaluated at EU-level based on the initial evaluation by the Rapporteur Member State, the peer-review by EFSA and approval by the European Commission. The plant protection product is evaluated and authorized at Member State level. A priority lane is required at each of these stages. This could be enhanced by an adequately resourced and dedicated expert lane for biocontrol in Member States provided that the lane has priority over non-biological dossiers. To be globally competitive, this priority lane must reduce the timelines to less than 3 years from submission of an active substance to authorisation of the product containing this active substance.

3. Establishment of a centralised evaluation agency

In the European Commission's Vision for Agriculture and Food, it is explicitly stated that EFSA should be strengthened with additional resources. The overall goal is to optimize EFSA's role under Reg.1107/2009. Additional expertise in biocontrol is necessary to ensure EFSA evaluations are appropriate to biocontrol, in particular understanding of the biocontrol specificities when justifying waivers to data requirements. With this expertise, EFSA could have direct impact in pre-submission meetings alongside the Rapporteur Member State and provide expertise to Member States on specific data requirements waivers.

Ultimately, IBMA's objective is to establish a central agency dedicated to biocontrol solutions or repurpose an existing agency such as EFSA. The intention of such an agency is to be a cornerstone of a new biocontrol specific regulation. IBMA's understanding is that this would not be part of the simplification package.

In the simplification package directed at 1107, EFSA's role could be to facilitate pre-submission meetings and expert guidance to Member States. In a comprehensive legislative change, such as the Biotech Act or a new biocontrol regulation, EFSA could be repurposed as a centralized agency that would guarantee a coordinated centralized approach for all biocontrol applications (including pre-submission meetings) and assessments (e.g., modeled on the ECHA role within the Biocidal Products Reg.528/2012 (BPR).

In all cases, EFSA would need to be increased in capacity and have the appropriate knowledge and skills on biocontrol.

4. **Removal of renewal process for biocontrol**

As the Vision states, the access to the EU market of innovative plant protection products should be facilitated. The renewal process consumes much of the valuable evaluation resources within Member States. To maximize the use of the Member States' ability to authorize biocontrol, the renewal process should be waived. Competent authorities can, at any time in the event of a scientific question or concern request a review through the existing provisions under Articles 21 and 56 of EU Reg (No.) 1107/2009 that are in place to ensure the safety of existing authorisations.

Furthermore, Member States choose not to evaluate any label amendment, mutual recognition or other authorization during the renewal process of any active substance or its associated products. This is known by the industry as the ''frozen period'' because no extension or market improvement can be made during this time period, which lasts between five and seven years. The concept of unlimited authorization for biocontrol was proposed during 1107 discussions in the European Parliament process in 2008.

5. **Provisional authorisation**

IBMA proposes reinstating Article 30 to allow provisional authorization for all plant protection products containing only biocontrol active substances. This is the primary route to accelerating biocontrol with the risk that competent authorities have to make some adjustments based on revised endpoints. This is an alternative mechanism for temporary registration. Currently, the concept of the emergency authorization is (mis)used regularly, but it requires annual rework for all competent authorities and industry, creating uncertainty. In contrast, provisional authorization would minimize rework and provide a more stable, legally based framework.

6. **Facilitated Label expansion for biocontrol**

Where biocontrols are pest or diseases specific, the label extension to other crops where the same pest or disease are present, is possible with minimal concerns of efficacy, phytotoxicity or crop residues, allowing extension of use with minimal additional data.

7. **Mutual recognition of Authorisations**

Mutual recognition allows for the single market for plant protection products. However, this is not achieved for biocontrol due to poor implementation, differing requests for national specific requirements, and different timescales and approaches in each Member State. Mutual Recognition should be implemented across all Members states automatically for biocontrol with transparency of the first evaluation to reassure the remaining Member states of the safety evaluation. A justification should be provided within 120 days by any Member state wishing to opt out.

Seed treatment registration (Art.49) is granted across all Member States unless there is a justification not to. This justification being subject to peer review by the European Commission.

8. New regulatory Framework

IBMA proposes biocontrol targeted changes to 1107 without ''reopening'' the legislation. The proposed article about a new regulatory framework may not be considered as a simplification measure and so may need to be included in an alternative legislation, such as the Biotech Act.

The target date of 2028 is to maximise the possibility of entry into force of a comprehensive new legislation in the following legislative term (2029-2034).

Annex 2. IBMA Biocontrol Definition

What is biocontrol ?

Biocontrol technologies originate from nature – directly or identical to nature if synthetized. They are used to manage pests, weeds and diseases in agriculture as well as home, garden and forestry. Our Biocontrol solutions achieve the sustainability goals that consumers urgently demand for food safety, human health and protection of the environment.

Microbials
Microbials are based on microorganisms, including but not limited to bacteria, fungi, protozoans, viruses, viroids, peptides, mycoplasmas, and may include entire microorganisms, living and dead cells, any associated microbial metabolites, fermentation materials and cell- fragments.

Semiochemicals
Semiochemicals are substances emitted by plants, animals and other organisms used for intra- species and/or inter-species communication and have a target-specific and non-toxic mode of action.

Natural Substances
Natural substances consist of one or more components that originate from nature, including but not limited to: plants, algae/microalgae, animals, minerals, bacteria, fungi, protozoans, peptides, proteins (e.g. enzymes, antibodies), viruses, viroids, and mycoplasmas. They can either be sourced from nature or are nature identical if synthetized. This definition excludes semiochemicals and microbials, which have their own definition.

Among natural substances, IBMA considers that peptides and proteins containing sequence modifications of a peptide/protein sourced from nature are deemed nature identical provided all of the following conditions are met:
(1) they contain only naturally occurring amino-acids
(2) such modifications do not change the 3-dimensional structure
(3) such modifications do not change the biological function and
(4) the biological breakdown occurs in a predicted way according to a natural pathway.

Invertebrate Biocontrol Agents (Macrobials)
Invertebrate Biocontrol Agents (also called macrobials) are natural enemies such as insect, mite and nematode species providing control of pest populations through predation or parasitism.