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# Principles for defining biocontrol

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On 16 December 2025, the European Commission proposed the Omnibus X simplification package on Food and Feed Safety. As outlined in more detail in other Biocontrol Coalition documents, we support the various proposals from the European Commission to amend Regulation (EC) 1107/2009 to streamline the process for placing biocontrol products on the market and to better align the regulatory framework with the nature of biocontrol product.

We want to emphasise the **importance of the innovation-friendly definition of biocontrol that is proposed by the Commission** and to offer comments on the key principles that the final definition must achieve (with some observations on to what extent the Commission's proposal achieves each).

## Key principles for defining biocontrol

1. **Be clear what we are defining and how it is regulated:** Biocontrol entails a wide range of practices that repel, destroy, mitigate or otherwise control, pests, diseases, and weeds directly or indirectly. Biocontrol practices may or may not entail the use of **biocontrol products** in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and/or technical additives. **We welcome the fact that the European Commission defined "biocontrol substances" and by extension, products** whose active substances are exclusively biocontrol substances. This is a crucial step towards designed a fit-for-purpose framework for biocontrol products. That dedicated framework should focus on the essential quality and safety characteristics of biocontrol products, leaving the choice of the most appropriate products for any given circumstance to growers and their technical advisors. Essential requirements should include the need to provide sufficient information about how to use products and under what conditions they are most effective so that growers can take informed decisions.

2. **The definition of biocontrol products should be innovation-friendly:** Many of the most innovative biocontrol products today do not fall into established positive lists, and it is likely that future innovations will also defy backward-looking positive lists. Therefore, the definition should be based on criteria such as those listed in section **3 below** rather than through positive lists.

**The definition proposed by the European Commission in Omnibus X is open to the wide range of biocontrol innovation available today and is future-oriented:**

> *'biocontrol substance' means:*
>
> *(a) micro-organisms,*
>
> *(b) inorganic substances as occurring in nature, with the exception of heavy metals and their salts or*
>
> *(c) substances of biological origin or produced synthetically that are functionally identical and structurally similar to them.*

With regard to points B and C, there are substances fulfilling these descriptions that are used for other functions in agriculture (such as fertilisers and biostimulants). **We therefore suggest improving this definition by specifying *"when such a substance is a component of a product providing a plant protection function as defined in Article 2 of this regulation."***

3. **Biocontrol products share a set of distinguishing characteristics: We welcome the fact that the Commission's proposed definition is based on the following key characteristics that distinguish biocontrol products** from conventional plant protection products:

   - Biocontrol products are either derived from naturally occurring substances/organisms or from naturally occurring modes of action (i.e. functionally identical substances should be included in the definition even if they have undergone slight modifications);

   AND

   - All biocontrol products decompose in the environment in well-established and predictable manners or are environmentally inert (e.g. kaolin clay may not degrade per se).

   These two criteria could potentially be covered by an umbrella term such as "identical in behaviour" (referring both to function and degradation).

   Taken together, these two criteria provide a clear boundary from conventional products; nonetheless, we recommend that the terms "functionally identical" and "structurally similar" be further defined and clarified wherever possible. Examples of such clarification are below.

   When working with naturally occurring substances such as peptides or nucleic acids, it is likely that many more variants of a chain exist than have been observed, but the variants of those chains are constrained by the amino or nucleic acids that exist in nature. If they do not modify the function or degradation behaviour of the substance in question, such tweaks – which may provide

technical benefits such as enhancing the stability of the substance – should be considered structurally similar.

On the contrary, the examples in the table show that anything beyond modifying a few atoms in a side chain, quickly results in a modified substance being classified as a conventional chemical.

| Substance | Functionally identical | Structurally similar | Notes |
|---|---|---|---|
| Pyrethroids | Y | N | They have undergone significant structural modifications, particularly at their active sites, compared to their naturally occurring counterparts: pyrethrin and nicotine |
| Neonicotinoids | Y | N | |
| Glyphosate | N | N | Apart from having undergone significant structural modifications compared to glycin, Glyphosate exerts a different biological function than its natural counterpart, therefore it is not functionally identical either. |
| Azoxystrobin | Y | N | Compared to naturally occurring strobilurins, azoxystrobin is a much more complex molecule with significantly increased molecular weight. |

4. **The classification of a substance or product as biocontrol for regulatory purposes does not remove, reduce or replace any requirement for risk assessment.** On the contrary, it determines the regulatory pathway under which the substance or product will be assessed, ensuring that the evaluation is conducted using criteria and expertise appropriate to its nature and mode of action.

   Under the Commission's proposal, biocontrol substances and products may benefit from facilitated market access mechanisms, such as provisional authorisation. However, these mechanisms remain fully conditional on the outcome of the risk assessment and subject to the discretion of Member States. For example, where the hazard profile of a substance is unfavourable, provisional authorisation would not be granted.


Metaphorically, the definition allows a substance to enter the biocontrol regulatory pathway, but it does not guarantee that it will remain there. As with a vehicle that exceeds the height limit of a low tunnel, products whose initial assessment reveals an incompatible hazard profile would be required to exit this pathway and be assessed under the conventional framework.

5. **The definition of a substance or product as being a biocontrol product for regulatory purposes does not mean it is approved for organic agriculture.** The existence of a distinct category for biocontrol substances and products under Regulation (EC) 1107/2009 is meant to ensure that these substances are evaluated with appropriate expertise and fit-for-purpose rules for the nature of the product (including the fact that unlike novel molecules, biocontrol products come with lots of empirical data that we can capture from the nature world). The plant protection products that can be used in organic farming in Europe are inscribed in Annex II of Implementing Regulation 2021/1184. Being categorised as a biocontrol product does not automatically qualify a product for organic agriculture, and it should not as these two regulations evolve independently of one another and have different purposes. Regulation 2021/1184 is part of the rules governing a specific commercial label and reflects the preferences of the community producing and buying such products. Regulation 1107/2009 on the other hand is concerned with ensuring public safety and a sufficient toolbox for farmers to protect crops from pests and diseases.

6. **Defining biocontrol products is a first necessary step in systemic change that is needed to augment farmer choice and to increase access to tools that will allow EU farmers to farm sustainably and profitably.** Other important elements of a new framework include a single-step, EU-wide evaluation and authorisation that creates a Single Market for biocontrol products so that all EU farmers have equal access to these products at competitive prices. Data requirements also need to be adapted to various subcategories of biocontrol products.

## About the Biocontrol Coalition

The Biocontrol Coalition is a multistakeholder 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. We strive for a fit-for-purpose Single Market that offers a wide choice of safe and effective biocontrol products so EU farmers can be competitive while coping with shifting pest and disease patterns.

To learn more, visit our website at www.biocontrolcoalition.eu or our LinkedIn profile.

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