

Biocontrol Definition: Suggested Amendments to EU Commission Proposal

IBMA Position - 2026.03.03

IBMA welcomes the biocontrol definition as a key step in accelerating the approval and authorisation of biocontrol.

The EU Food and Feed Safety Simplification package omnibus states:

“A definition for biocontrol substances should include micro-organisms, inorganic substances as occurring in nature, with the exception of heavy metals and their salts, or substances of biological origin or produced synthetically that are functionally identical and structurally similar to them such as semiochemicals, biological macromolecules or molecules comprised of components thereof, as well as substances, including of unknown and variable composition, originating from living organisms or derived by biological processes (e.g. extracts from plant products, metabolites produced by micro-organisms).”

Biocontrol is defined as follows in the Omnibus:

“ ‘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.’; “

IBMA Position

Biocontrol substances contribute to resilient cropping systems by enabling integrated pest management (IPM) strategies where biocontrol provides pest and disease control complementary to existing practices.

Biocontrol substances are nature-based and are identical to nature if synthesised. Structurally and functionally identical biocontrol substances need no further guidance. IBMA's definition of natural substances allows for small modifications in structure under certain conditions and includes innovations that fulfil these requirements. In this context, IBMA is proposing amendments to the EU proposed definition and related guidance.

BIOCONTROL DEFINITION

Suggested amendments to EU Commission proposal

IBMA, established in 1995, represents the biocontrol industry with 137 biocontrol manufacturers proposes the following amendments to the EU Commission proposal:

'biocontrol substance', means

- (a) micro-organisms¹
- (b) semiochemicals,
- (c) inorganic substances as occurring in nature, ~~with the exception of heavy metals and their salts~~
- (d) substances that are structurally similar and functionally identical to natural substances² of biological origin or produced synthetically³

Reasons for definition amendments:

- Semiochemicals have a unique mode of action (e.g. mating disruption, luring, repelling) and so merit their own section.
- Inorganic substances – removal of the exclusion of heavy metals because this was unclearly defined and concerns with toxicity are addressed in the risk assessment process.
- The diversity of natural substance categories needs to be considered and has been clarified to fully encompass the IBMA definition.²

¹ Microorganisms both viable and non-viable are included.

² Natural substances consist of one or more components that originate from nature, including but not limited to: plant extracts, algae/microalgae, non-viable microorganisms, peptides, proteins (e.g. enzymes, antibodies), that are identical as occurring in nature

³ 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



Guidance on structurally similar and functionally identical substances

The use of “structurally similar and functionally identical” as a basis for classifying biocontrol substances provides scope for new innovations to be defined as biocontrol substance. However, it also risks being too broad and opening biocontrol to conventional plant protection products based on natural products. To avoid this confusion, some additional clarification is needed, which should include:

- Identical in behaviour to naturally occurring substances
- Degrade through a known and established biological pathway
- For proteins and peptides contain only naturally occurring amino acids
- Have no changes to the active site of the molecule

EU Regulation 1107/2009

Biocontrol substances, like all other regulated plant protection products, are subject to an evaluation and risk assessment under EU regulation 1107/2009. This process defines the hazard and exposure to the substance and then determines the risk associated with the product and the use. This process is separate to the definition, which should be a stand-alone statement. Any active substance that fits the definition enters the assessment process as biocontrol and can then benefit from the accelerated evaluation process. If data of concern appear during the evaluation process; delays, restrictions of use or possible non approval may result. The assessment of safety remains mandatory for any biocontrol product intended to be placed on the EU market.

Process

The key objective of the Omnibus is to shorten the timelines by the means of simplifying the process and adding resources. Guidance around the biocontrol substance definition risks delivering an additional step in the evaluation process. To avoid this, IBMA proposes to use the existing procedure⁴ of a pre-submission meeting with the risk assessor and including the risk manager to formally agree that the active substance due to be submitted qualifies as a biocontrol substance.

A 2-3 year authorisation process is needed for Europe to be globally competitive in biocontrol approval and authorisation timelines. Acceleration of this level will keep innovation in Europe and provide farmers with biocontrol products to fill the gaps in their pest and disease control toolbox.

⁴ The European Commission response to Council Decision (EU)2022/2572 of 19 Dec 2022 requesting the Commission submit a study complementing the impact assessment of the proposal for the regulation of the European Parliament and of the Council on the Sustainable Use of Plant protection products and amending regulation (EU)2021/2115). 5 July 2023.

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