European Biostimulants Industry Council

# Plant biostimulants in Europe: what's changing and why it matters

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Open Industry Day on Biostimulants

CropLife Denmark

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# The European Biostimulants Industry Council

EBIC is the **European trade association** representing the plant biostimulants industry since 2011

Composed of **75 companies** that place / intend to place plant biostimulants on the EU market

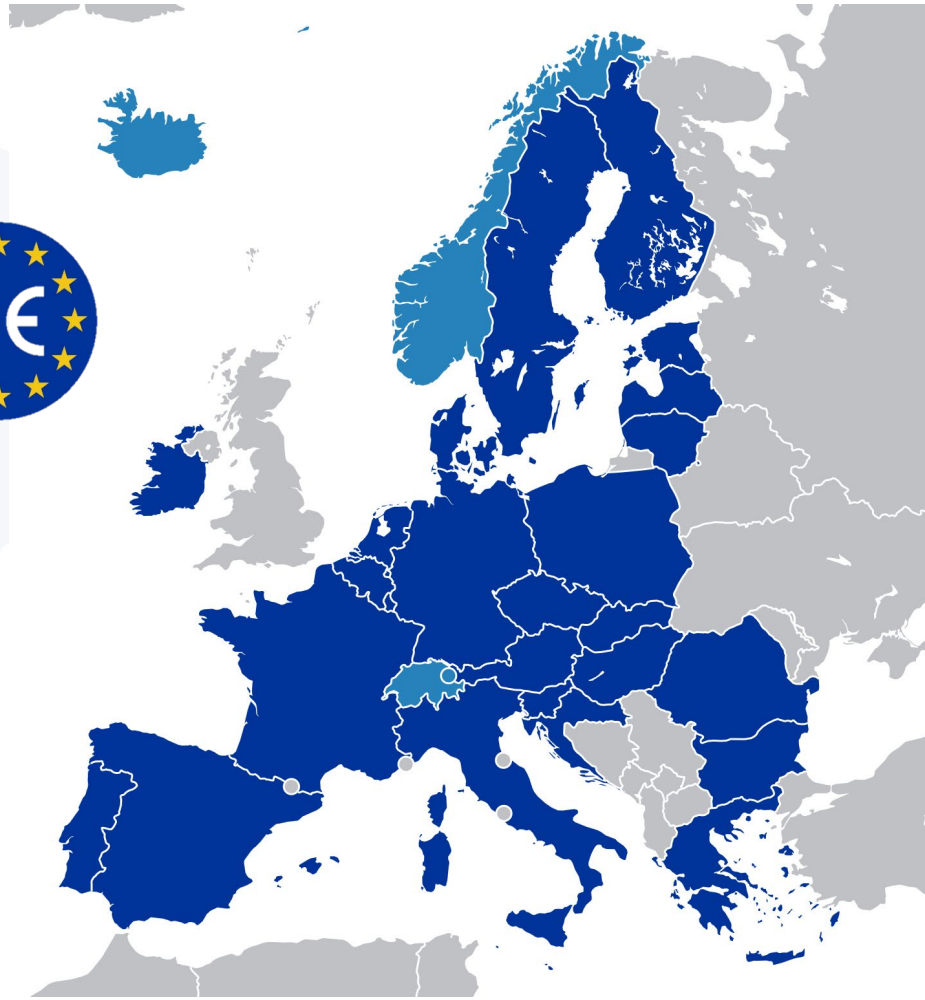



Breakdown of EBIC member companies by size (based on global turnover and headcount) as of 14 October 2026

- EBIC's Mission is to promote plant biostimulants as essential to advanced food systems, providing education, advocacy, and support to members, policymakers, and farmers.
- EBIC's Vision is sustainable agriculture supported by the global adoption of plant biostimulants.

# Plant biostimulants are regulated under the EU Fertilising Products Regulation (FPR)

- Regulates placement of fertilising products on the market (not use)
- Leads to CE-marking: free movement in the EU Single Market, but manufacturers can choose to follow the rules of a single country instead (optional harmonisation)
- Sets out requirements for Product Function Categories and for Component Material Categories
- Regulation (EU) 2019/1009 in the Eur-Lex database



# Beyond mineral fertilisers: a wider range of products and raw materials

## The FPR's 7 Product Function Categories (PFCs):

- PCF 1: Fertiliser
- PFC 2: Liming material
- PCF 3: Soil improver
- PFC 4: Growing medium
- PFC 5: Inhibitor
- PFC 6: Plant biostimulant
- PFC 7: Fertilising product blends

## The Component Material Categories (CMCs) most relevant for plant biostimulants:

- CMC 1: Virgin material substances and mixtures
- CMC 2: Plants, plant parts or plant extracts
- CMC 6: Food industry by-products
- CMC 7: Micro-organisms
- CMC 10: Animal by-products
- CMC 11: Industrial by-products

# EU plant biostimulants undergo a conformity assessment process including trials under the FPR involving an independent Notified Body

To obtain the CE-mark, all PFC 6 Plant Biostimulant products must undergo a type examination by a certified Notified Body

- List of ingredients
- Information about raw materials
- List of harmonised standards used
- Test reports
- Trials to demonstrate claims for PBs
- Product samples
- Other supporting documentation

# What is a plant biostimulant?




A plant biostimulant shall be an EU **fertilising product** the **function** of which is to **stimulate plant nutrition processes** independently of the product's nutrient content with the sole aim of **improving** one or more of the following characteristics of the plant or the plant rhizosphere:

(a) **nutrient use efficiency**,

(b) **tolerance to abiotic stress**,

(c) **quality traits**, or

(d) **availability of confined nutrients** in the soil or rhizosphere

**This definition could change with adoption of the Food & Feed Safety Omnibus X**

# 10 years since the FPR proposal, including the definition of plant biostimulants

**17 March 2016**

The European Commission adopted the Proposal for the FPR, including the definition of plant biostimulants under PFC 6

**16 July 2019**

The FPR was published, establishing the legal definition of plant biostimulants

Regulation (EC) 1107/2009 was amended to exclude plant biostimulants from its scope

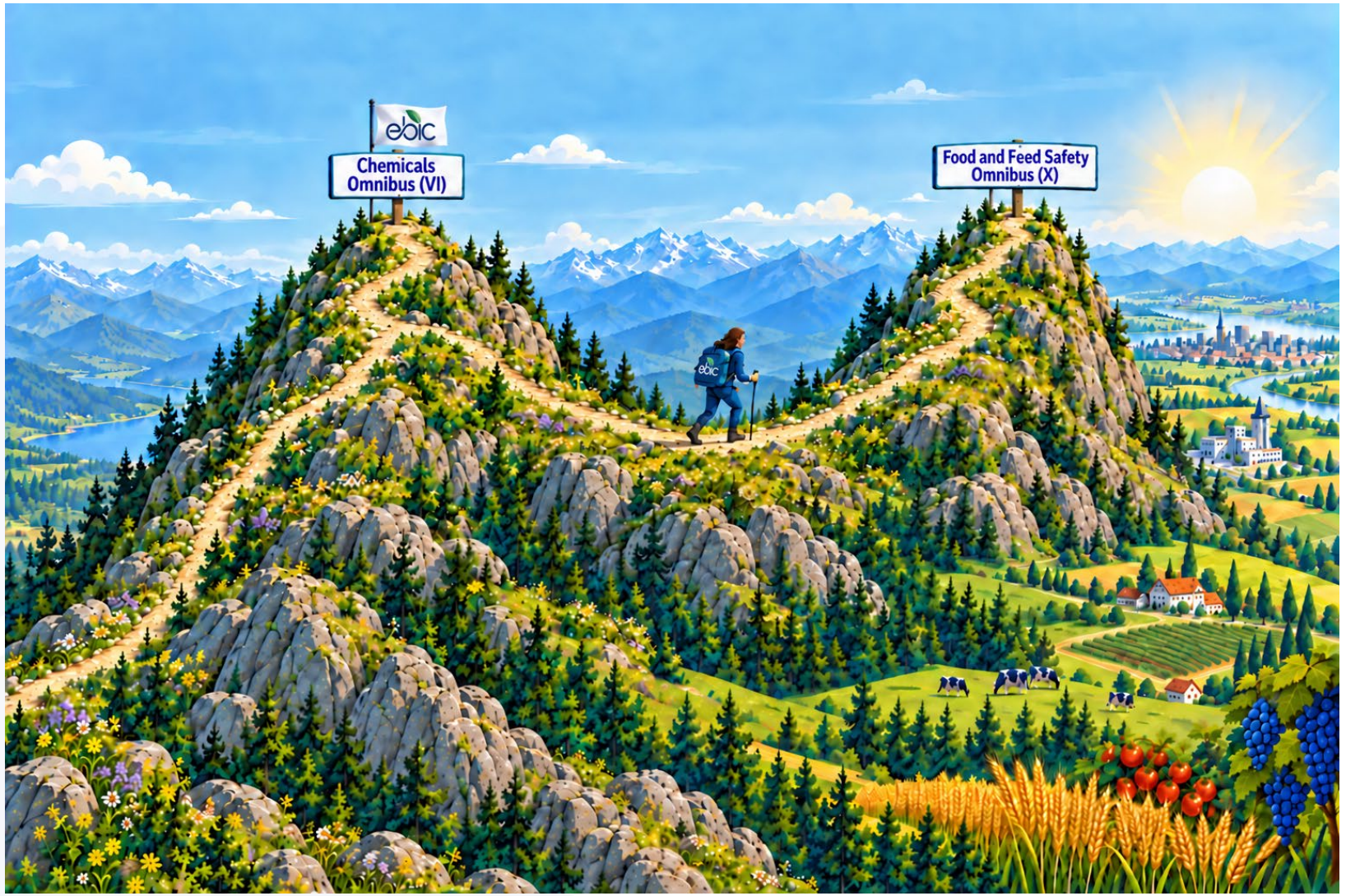
**16 July 2022**

The FPR started to apply, opening the single market to plant biostimulants

**Chemicals Omnibus VI and Food and Feed Safety Omnibus X as ways to address outstanding regulatory blockages for plant biostimulants**

**2015 to 2027**

# EBIC's journey across the Omnibus mountains



# Two omnibuses relevant for plant biostimulants

## Omnibus VI: chemicals

Proposal for a Regulation of the European Parliament and of the Council amending […] as regards simplification of certain requirements and procedures for chemical products

- Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures
- Regulation (EC) No 1223/2009 on cosmetic products
- **Regulation (EU) 2019/1009 on fertilising products**

## Omnibus X: food and feed safety

Proposal for a Regulation of the European Parliament and of the Council amending […] as regards the simplification and strengthening of food and feed safety requirements

- **Regulation (EC) No 1107/2009 on plant protection products**
- Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- 8 more regulations

# Chemicals Omnibus (VI): FPR amendments relevant for plant biostimulants

| | | |
|---|---|---|
| **Digitalisation** | Recitals 26 and 26(a), Article 3 (1) to (8), Annex IV (1) and (3) | Mandatory for manufacturers to draw up the EU declaration of conformity in electronic form and for economic operators to ensure that it can be directly accessed via an internet address or data carrier |
| **Microbial plant biostimulants** | Recitals 27 and 28, Article 3(9)(a) and Article 3(9)(b) | European Commission empowered to adopt delegated acts to set out criteria and a methodology for new microbial strains |
| **New and missing materials** | Recital 28(a), Article 3(9)(ba) | European Commission must adopt delegated act establishing general criteria and a methodology for materials other than those listed in Annex II of the FPR, criteria and a methodology for categories of such materials, or a new component material category, by 36 months after entry into force |
| **Animal by-products** | Recital 29(a), Article 3(9)(c) and (c), Annex IV(g) | Once an end point has been determined under the ABPR, assessment of these materials in terms of risks shall be initiated within 12 months. If there is scientific evidence that they do not present a risk and ensure agronomic efficiency, Commission shall adopt a delegated act to include these materials in CMC 10 without undue delay |
| **Extended REACH requirements** | Recital 30 and Article 3(11) (Annex IV) | Extended REACH registration requirements removed for CMC 1 substances used in EU fertilising products, except for substances with certain severe hazardous properties, identified by reference to specific hazard classes or categories under the CLP regulation |

# New COM empowerment to amend CMC 7

| Current situation | New rules under Chemicals Omnibus VI (est. from 2027) |
|---|---|
| Currently only 4 genera of micro-organisms listed in CMC 7 | COM to assess and amend FPR to include appropriate criteria and methodology, using AIT study as basis |
| Assessment of new microbial strains through a technical study by AIT | Manufacturer demonstrates compliance during conformity assessment of product |
| COM amends FPR and includes new strains based on conclusions of AIT study | Notified Body verifies assessment results |

# New criteria-based approach for microbials

## Omnibus VI

Modification of **Article 42(4)** in the FPR: **empowerment of the European Commission**

European Commission

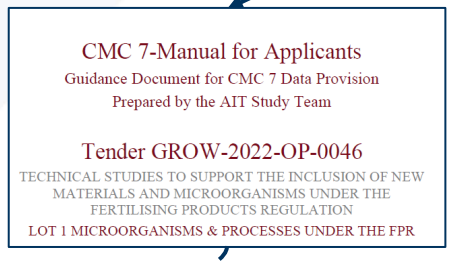
**Delegated Act** to establish **criteria and methodology** under CMC 7
**+**
**Modification of Annex IV** (conformity assessment procedure for microbials)

**NoBos** verify according to criteria and methodology

New microbial plant biostimulants

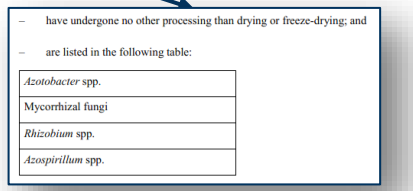
## AIT Study

**Methodology** for strain evaluation, including **possible criteria**
**+**
List of **strains to be added** to CMC 7


CMC 7-Manual for Applicants
Guidance Document for CMC 7 Data Provision
Prepared by the AIT Study Team

Tender GROW-2022-OP-0046

TECHNICAL STUDIES TO SUPPORT THE INCLUSION OF NEW MATERIALS AND MICROORGANISMS UNDER THE FERTILISING PRODUCTS REGULATION
LOT 1 MICROORGANISMS & PROCESSES UNDER THE FPR

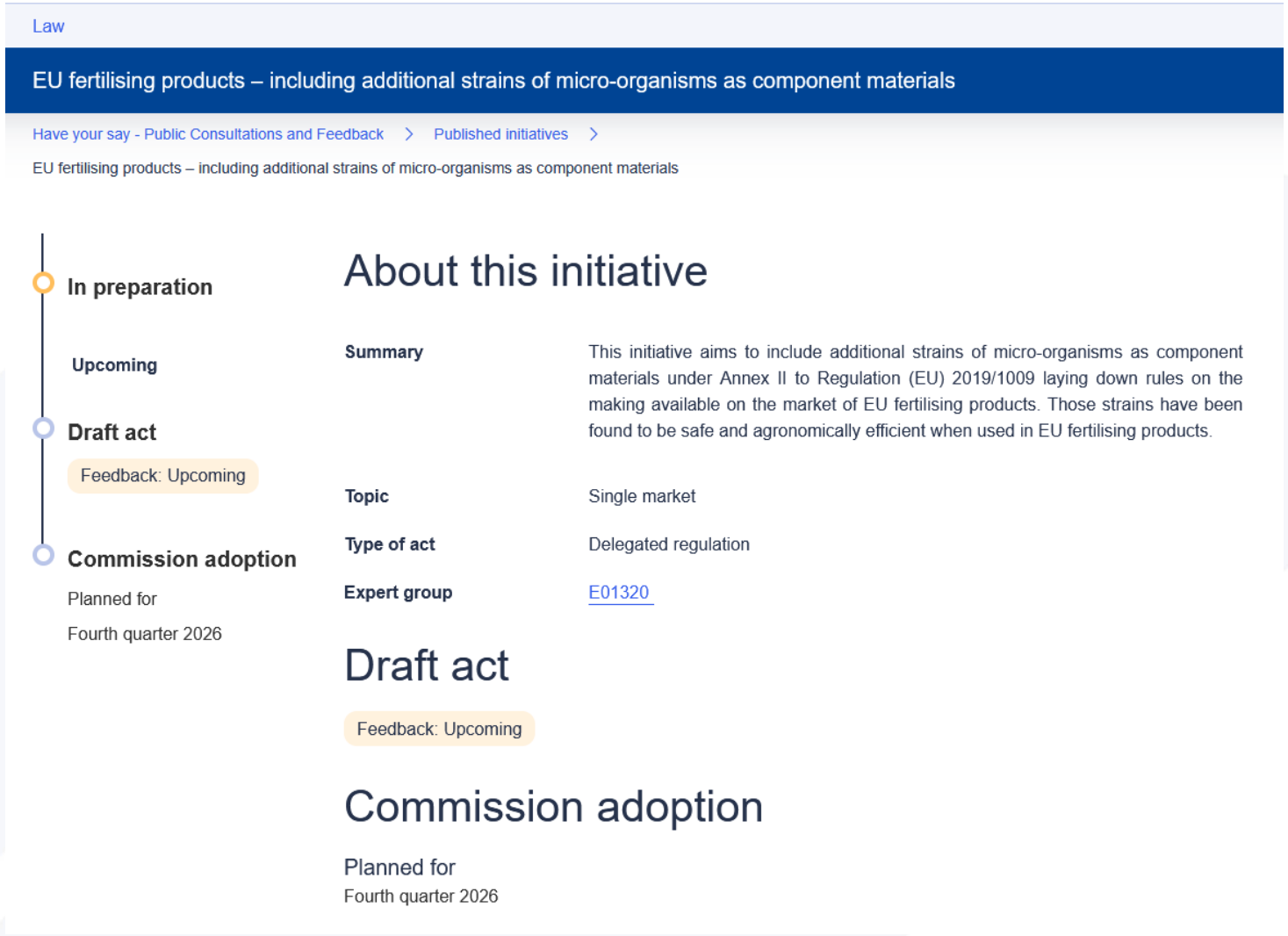

– have undergone no other processing than drying or freeze-drying; and
– are listed in the following table:

| |
|---|
| *Azotobacter* spp. |
| Mycorrhizal fungi |
| *Rhizobium* spp. |
| *Azospirillum* spp. |

| |
|---|
| Strain ABC |
| Strain DEF |
| Strain GHI, etc. |

EFSA, JRC and/or ECHA to review and contribute

# AIT study: delegated act to add strains to CMC 7



Law

EU fertilising products – including additional strains of micro-organisms as component materials

Have your say - Public Consultations and Feedback > Published initiatives >

EU fertilising products – including additional strains of micro-organisms as component materials

In preparation

Upcoming

Draft act

Feedback: Upcoming

Commission adoption

Planned for

Fourth quarter 2026

About this initiative

| | |
|---|---|
| Summary | This initiative aims to include additional strains of micro-organisms as component materials under Annex II to Regulation (EU) 2019/1009 laying down rules on the making available on the market of EU fertilising products. Those strains have been found to be safe and agronomically efficient when used in EU fertilising products. |
| Topic | Single market |
| Type of act | Delegated regulation |
| Expert group | E01320 |

Draft act

Feedback: Upcoming

Commission adoption

Planned for

Fourth quarter 2026

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/16753-EU-fertilising-products-including-additional-strains-of-micro-organisms-as-component-materials_en

- EU Survey open from June to September 2022
- Most data submitted confidentially, some publicly available
- **31 strains** screened for trade potential
- **29 strains** assessed for safety and agronomic efficiency

# Plant biostimulants outside of 1107/2009 since 2019

**PFC 6: PLANT BIOSTIMULANT**

1. A plant biostimulant shall be an EU fertilising product the function of which is to stimulate plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

(a) nutrient use efficiency,

(b) tolerance to abiotic stress,

(c) quality traits, or

(d) availability of confined nutrients in the soil or rhizosphere.

Regulation (EU) 2019/1009

Regulation (EC) 1107/2009

*Article 2*

**Scope**

1. This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

(a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;

▼M6

(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant;

▼B

(c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;

(d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

(e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

These products are referred to as 'plant protection products'.

2. This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'.

FPR Recital 22 acknowledged that

- *plant biostimulants, are not as such inputs of nutrients, but nevertheless stimulate plants' natural nutrition processes*
- *they are by nature more similar to fertilising products than to most categories of plant protection products*

# Omnibus X: EBIC's position

Supported by

**Plant growth regulators**

- *disrupting* life processes
- *regulating* growth

**Nutrients**

- providing nutrients

**Plant biostimulants**

- stimulating *plant nutrition or life processes* to improve
  - NUE
  - quality traits
  - nutrient availability
  - tolerance to abiotic stress

| Element of Omnibus X | Original text in Regulation (EC) No. 1107/2009 | European Commission's proposal | Council mandate |
|---|---|---|---|
| **Article 1(1)(a)** | influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant | **disrupting life processes** of plants, such as substances **regulating their growth**, other than as a nutrient or a plant biostimulant | **regulating** life processes of plants, such as substances regulating their growth, other than as a nutrient or a plant biostimulant; |
| **Article 1(2)(b)** | 34. 'plant biostimulant' means a product stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:<br>(a) nutrient use efficiency;<br>(b) tolerance to abiotic stress;<br>(c) quality traits;<br>(d) availability of confined nutrients in soil or rhizosphere | 'plant biostimulant' means a product having at least one of the following actions:<br>(1) **stimulating plant nutrition processes** independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:<br>(a) nutrient use efficiency;<br>(b) quality traits;<br>(c) availability of confined nutrients in soil or rhizosphere;<br>(2) **stimulating life processes** of crops to improve their **tolerance to abiotic stress**.<br>Substances disrupting life processes of crops which are not fulfilling the definition of plant biostimulants are active substances covered by this Regulation. | 'plant biostimulant' means a product having at least one of the following actions:<br>(1) stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:<br>(a) nutrient use efficiency;<br>(b) quality traits;<br>(c) availability of confined nutrients in soil or rhizosphere;<br>(2) stimulating life processes of crops, **other than plant nutrition processes**, to improve their tolerance to abiotic stress.<br>**Products regulating** life processes **other than in the ways referred to in points 1 and 2, but rather by mimicking, inhibiting, or otherwise interfering with endogenous plant hormonal signalling pathways** are **plant protection products** covered by this Regulation |

## CAM 3 – Plant biostimulant definition

**Recommended position:** Insert one integrated definition covering stimulation of plant nutrition or life processes, listing the four characteristics improved by plant biostimulants together, and delete the final sentence.

**Fallback position:** If deletion of the sentence below the definition cannot secure support, retain it only with product-level wording: 'Products disrupting life processes of plants which do not fulfil the definition of plant biostimulants are plant protection products covered by this Regulation.'

**Proposal for a regulation**
Article 1 – paragraph 1 – point 2 – point (b)
Regulation (EC) No 1107/2009
Article 3 – point 34

| Text proposed by the Commission | Compromise amendment |
|---|---|
| **34.** 'plant biostimulant' means a product having at least one of the following actions:<br>**(1)** stimulating plant nutrition processes independently of the product's nutrient content with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:<br>**(a)** nutrient use efficiency;<br>**(b)** quality traits;<br>**(c)** availability of confined nutrients in soil or rhizosphere;<br>**(2)** stimulating life processes of crops to improve their tolerance to abiotic stress.<br>**Substances** disrupting life processes of **crops** which are not fulfilling the definition of plant biostimulants are **active substances** covered by this Regulation.'; | **34.** 'plant biostimulant' means a product stimulating plant nutrition processes **or life processes** *[AM 308 and AMs 317, 318, 319; similar wording in AMs 309 and 316]* independently of the product's nutrient content, with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:<br>**(a)** nutrient use efficiency;<br>**(b)** quality traits;<br>**(c)** availability of confined nutrients in soil or rhizosphere;<br>**(d)** tolerance to abiotic stress *[AMs 308 and 309, 320, 321, 322, 323 and 336].*'; |

**Amendment basis:** Separate point (2) deleted [AMs 324–328]; final classification sentence deleted [AM 309 and linked AMs 306 and 336].

## EBIC's position and preferred wording of biostimulant definition

### Justification

- This integrated definition is aligned with the structure of the definition of plant biostimulants in Regulation (EU) No 2019/1009, coherently covering stimulation of plant nutrition processes or life processes to improve one or more of the four characteristics targeted by plant biostimulants.
- The final sentence adds no substantive value, deletion is cleaner and avoids duplication or inconsistency. Article 2 of Regulation (EC) No 1107/2009 already establishes its scope, while Article 3 defines a plant biostimulant, which is explicitly excluded from Article 2.

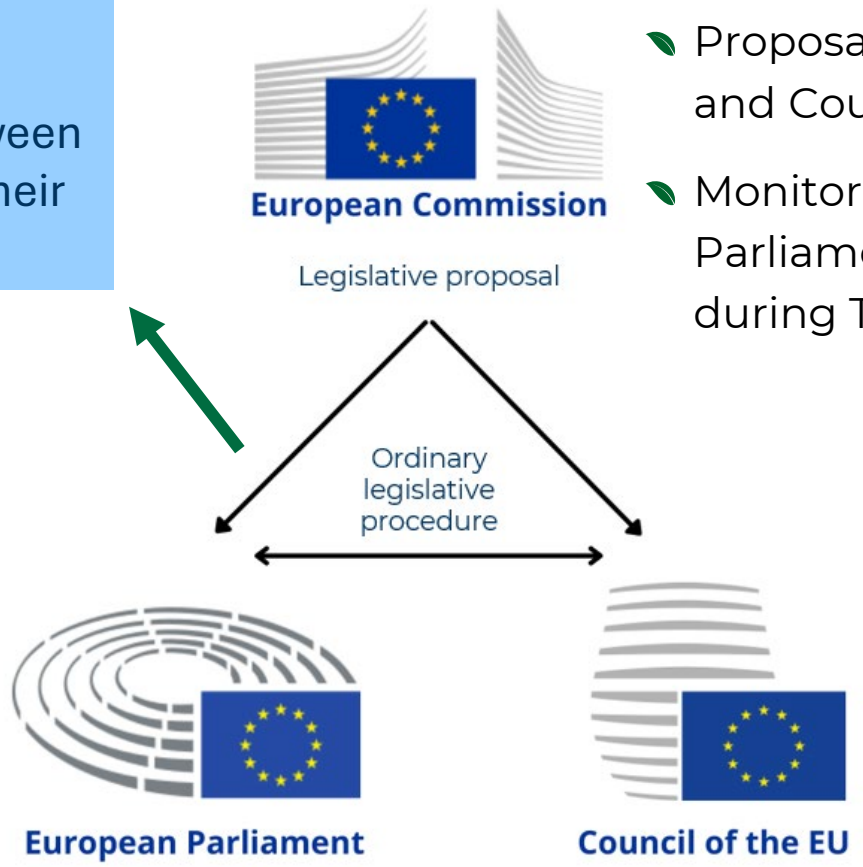
**European Parliament compromise negotiations are ongoing, but amendments tabled to the draft report go in the right direction**



AAB

# Food and Feed Safety Omnibus (X): status

Once Parliament has adopted their mandate (currently scheduled for vote in December), **trilogues** between the three institutions and their positions can begin




- Proposal submitted to the European Parliament and Council of the EU in December 2025
- Monitoring developments in Council and Parliament, will become more involved once again during Trilogue negotiations

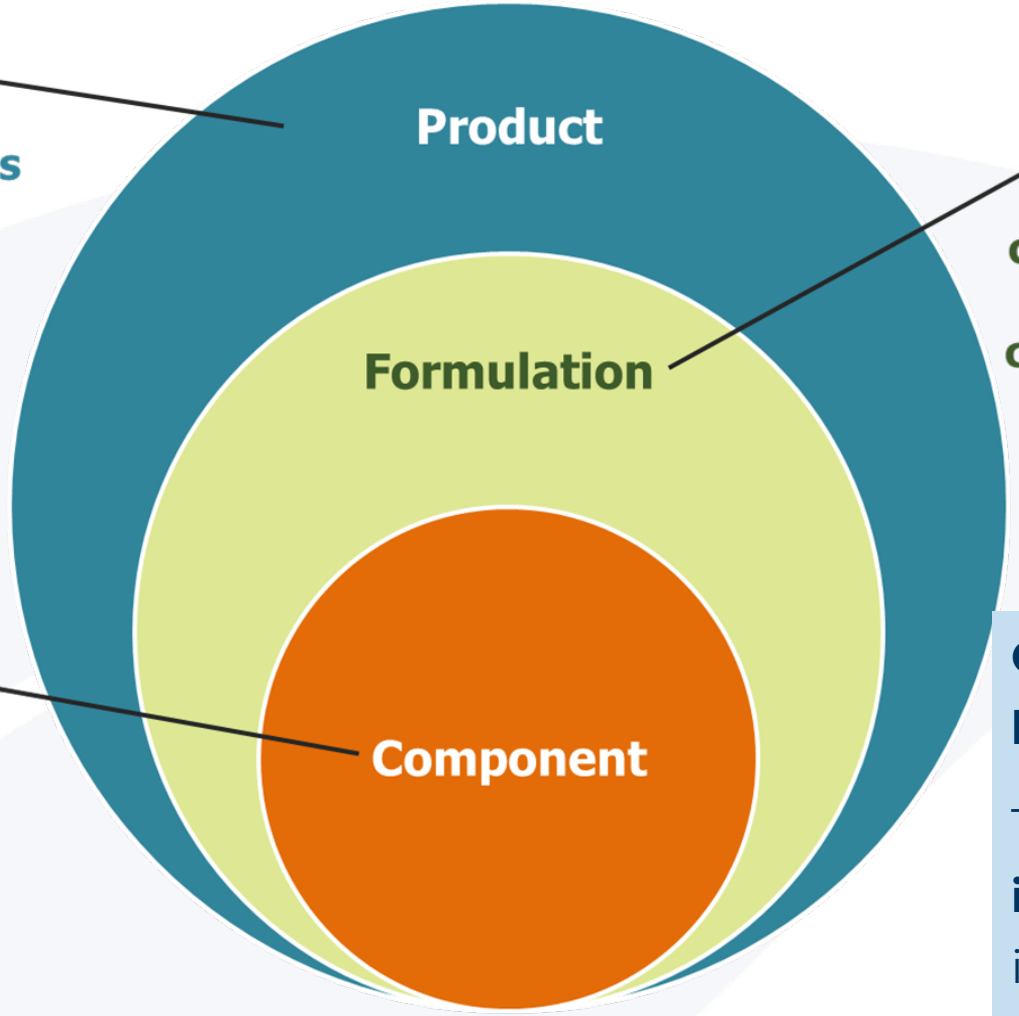
- Negotiations on the final Parliament position are ongoing
- Struggling to find a majority across the Parliament, due to more controversial issues in the file
- Co-Rapporteurs ***hope*** to have Parliament position adopted by end of year

- 30 September: adopted negotiating position
- Difficult to find the necessary qualified majority in the Council
- Many member states unhappy with the Council's position
- Council's language on plant biostimulants unworkable

# Next steps for EBIC

- Continue to engage with European Parliament to secure as workable a position as possible, meetings in Strasbourg where relevant
- Continue to engage with European Commission to ensure adequate support during trilogues (DG SANTE, GROW, AGRI, etc.) to address problematic Council language
- Reach out to Member States to explain the problems with the Council position, particularly to those MS who may have supported the inclusion of the wording during negotiations
- Follow trilogues as closely as possible once they begin

# What is the multiple use principle




**EBIC resources on multiple use**

- Page on EBIC website
- Position paper (2021)

**Only products, not their components, can have plant protection functions**

The **function** of a product is **based on the intended use** of the product, which is indicated on the product label and will be **related to the product's composition and use instructions**.

# EBIC's cooperation framework with NAs

- EBIC members appointed **National Liaisons (NLs) to National Associations** (in countries where there is(are) a National Association(s) covering PBs) **or NLs to National Authorities** (in countries with no NAs but of strategic significance for EBIC)

**National Liaisons**



AEFA 25 years
ASOCIACION ESPAÑOLA DE FABRICANTES DE AGRONUTRIENTES
1997 - 2022

SPEL

CropLife DANMARK
Løsninger til landbruget

ASSOFERTILIZZANTI
FEDERCHIMICA

unifa

CropLifeNL

AFAÏA
ACTEURS D'UNE TERRE PLUS VERTE

Artemis
Natuurlijk

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# Plant biostimulants in Europe: what's changing and why it matters

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Provides the EBIC secretariat