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FROM INNOVATION TO MARKET

Regulatory pathways for biofertilisers
and biostimulants in Europe

Regulatory requirements for biostimulants and biofertilisers

13 October 2026
Online workshop

2- REGULATION

EU 2019/1009

- ANNEX I. Product Function Categories (PFCs)
- ANNEX II. Component Material Categories (CMCs)
- ANNEX III. Labelling requirements
- ANNEX IV. Conformity assessment procedures

Annex I:

Product Function Categories (PFCs)

The regulation defines the following seven product function categories.

1. **PFC 1. FERTILISER**
2. **PFC 2. LIMING MATERIAL**
3. **PFC 3. SOIL IMPROVER**
4. **PFC 4. GROWING MEDIUM**
5. **PFC 5. INHIBITOR**
6. **PFC 6. PLANT BIOSTIMULANT**
7. **PFC 7. FERTILISING PRODUCT BLEND**



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
- d) availability of confined nutrients in the soil or rhizosphere

Annex II:

Component Material Categories (CMCs)

The law was published with 12 CMCs but 15 are available.

1. CMC 1: Virgin material substances and mixtures
2. CMC 2: Plants, plant parts or plant extracts
3. CMC 3: Compost.
4. CMC 4: Fresh crop digestate
5. CMC 5: Digestate other than fresh crop digestate
6. CMC 6: Food industry by-products
7. CMC 7: Micro-organisms
8. CMC 8: Nutrient polymers
9. CMC 9: Polymers other than nutrient polymers
10. CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009
11. CMC 11: By-products within the meaning of Directive 2008/98/EC
12. CMC 12: Precipitated phosphate salts and derivatives
13. CMC 13: Thermal oxidation materials and their derivatives
14. CMC 14 Pyrolysis And Gasification Materials
15. CMC 15 : Recovered high purity materials

CMC extensions and studies

Source: reported by DG GROW on 15 September 2026

CMC 10

Final adoption steps

Additional animal by-product derivatives

Processed frass, glycerine (Cat. 2 and 3), **processed animal protein** (Cat. 3), **dicalcium and tricalcium phosphate, meat-and-bone meal** (Cat. 2), **hydrolysed protein** (including from leather or textile industry residues), **blood products** (Cat. 3), **horns, horn products, hooves and hoof products**. Subject to the conditions of Regulation (EU) 2023/1605.

CMC 7

Technical study

AIT (Austrian Institute of Technology, Austria)

Study on the possible inclusion of **new microbial strains** in CMC 7.

New materials and processes

NMI (Nutriënten Management Instituut, Netherlands)

Study on possible inclusion of **new materials and processes**. New CMC Numbers.

Annex II: Labelling requirements

Some of the labelling requirements	
1	A list of all ingredients whose content exceeds 5% w/w or w/v.
2	The name of the mineral, whether the ingredient is a substance or mixture.
3	All forms of nitrogen shall be named in inorganic fertilisers.
4	All labelling requirements for PFC 7 shall apply to all components of the mixture.
5	If the mixture contains one or more PFC 6, the concentration of each biostimulant must be indicated.
6	Organic-mineral fertilisers (liquid or solid) in which micronutrients (B, Co, Fe, Mn and Mo) are intentionally added, must be declared.
7	If the micronutrients are not added intentionally, it is not mandatory.
8	Cu and Zn must always be declared if they are added intentionally.
9	A chelating or complexing agent is declared with a pH range ensuring stability
10	Liquid inorganic macronutrient fertilisers must indicate whether it is presented in suspension or in solution.

Annex III : Labelling examples

PRODUCT:
[REDACTED] a microbial product designed to increase yields, lower input cost to growers and improve the sustainability of crop production.

Biostimulant product whose action is based on the activity of the bacteria Azospirillum brasilense and Azotobacter chroococcum. This type of bacteria live naturally in the soil near the roots of the plants, from where they establish a mutually beneficial relationship (symbiosis) with the roots. In this relationship, the plants feed the bacteria through sugars produced through photosynthesis and in exchange the bacteria take the nitrogen that is found in abundance in the air and transform it into ammonium, nitrates and nitrites, which they deposit in the soil to that plants can take advantage of through their roots. In turn, bacteria produce hormones that stimulate plant development and compete against bacteria capable of causing root diseases (pathogenic bacteria), reducing the negative effect that harmful bacteria have on plant health. In this way, by improving the plant's nutrition, they stimulate its development and increase its resistance to bacterial diseases. The association with Azospirillum brasilense substantially increases the productivity, quality and appearance of our crops.

INGREDIENTS:
[REDACTED] CMC 1;
[REDACTED] CMC 1
CMC 1: Virgin material substances and mixtures

INFORMATION ON SAFETY AND ENVIRONMENT:
P-102 Keep out of reach of children.
P-270 Do not eat, drink and smoke when using this product.
To avoid risks to people and the environment, follow the recommended instructions for use of this fertilizer product.

STORAGE AND HANDLING:
Store product in a cool environment. Do not exceed 20°C. Product can be stored at or under 20°C for 12 months. For longer storage periods, store under refrigerated conditions for a maximum of 24 months. Open product when ready to use.
Please also refer to the information provided in the Material Safety Data Sheet (MSDS).

GUARANTEED RICHNESS: 2.5 % ACTIVE INGREDIENTS*
Azospirillum brasilense - 1.5 x 108 cfu/g
Azotobacter chroococcum - 1.5 x 108 cfu/g
***total Microbial concentration - 3 x 108 cfu/g**
97.5 % Total other inert ingredients

Use only in case of recognized need.
Do not exceed the application dose.

PFC 6(A): MICROBIAL PLANT BIOSTIMULANT

[REDACTED]

PLANT BIOSTIMULANT WITH GUARANTEED EFFECT:

NUTRIENT USE EFFICIENCY

QUALITY TRAITS

QUANTITY: 1 L
Batch number
Production date
Expiration date

Manufacturer:

Imported and distributed by:

CE

GUARANTEE:
The manufacturer guarantees the composition, formulation and content, as well as the preservation of its products in their original packaging. The end user will be responsible for damages caused by total or partial non-observance of the label instructions.

Other information: Professional use

DOSE:

TYPE OF CROP	CULTURE	APPLICATION RATE	WATER RATE	MOMENT OF APPLICATION AND RECOMMENDATIONS	CLAIM
Broadacre crops	winter cereals, spring cereals corn, Fodder corn rice, sorghum Forage cereal, Grasslands, Grass, sunflower Soy, tobacco Cotton, beet Alfalfa, legumes grains	50 g/ha	250- 300 L/ha	Cereal crops – apply as a foliar at 4-6 leaf stage. Tank mix with non-chlorinated water or add a de-chlorination agent before adding [REDACTED]	Nutrient use efficiency of the crop Quality traits

PRODUCT:
[REDACTED] is a biostimulant for plants formulated so that its components promote the development, growth and quality of the fruit, while supporting the generation of a plant with a good structure.

Nutrient use efficiency and quality traits resulting from the use of [REDACTED] biostimulant has been proven in field with higher concentrations of P, B, Ca, Cu, P, Fe, N and K, it is also positive for increase the number of fruits, weight of fruits and the fruit quality. It has been proven in fruit trees providing better fruit quality data (sugar content, fruit color, firmness and lower acid content and unmarketable fruits.

At broadacre crops it would be positive for increase the number of fruits, the fruit quality and a higher nutrients.

[REDACTED] were able to provide higher height and diameter, higher number and weight of fruits and higher acid content in horticulture crops such as tomato or higher sugar content, firmness, color and lower acid content in cucumber.

INGREDIENTS:
[REDACTED] CMC 1;
[REDACTED] CMC 1;
[REDACTED] CMC1
CMC 1: Virgin material substances and mixtures

PRECAUTIONS
Signal Word: Danger
Hazard statements:
H315 Causes skin irritation.
H360FD May damage fertility. May damage the unborn child.
Precautionary statements:
P201 Obtain special instructions before use.
P280 Wear protective gloves, protective clothing, eye protection, face protection.
P302+P352 IF ON SKIN: Wash with plenty of water and soap.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P321 Specific treatment not defined.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container in accordance with local, regional, national or international regulations.
UFI: X300-E004-V00A-GWC.J

STORAGE AND DISPOSAL
Store in a dry and ventilated place, avoiding exposure to the sun. Please refer also to the information provided in the Material Safety Data Sheet (MSDS).

Use only in case of recognized need. Do not exceed the application dose.

PFC 6(B): NON-MICROBIAL PLANT BIOSTIMULANT

[REDACTED]

PLANT BIOSTIMULANT WITH GUARANTEED EFFECT:

NUTRIENT USE EFFICIENCY

QUALITY TRAITS

LIQUID SOLUTION

QUANTITY: 1 L
Batch number
Production date
Expiration date

Manufacturer:

Imported and distributed by:

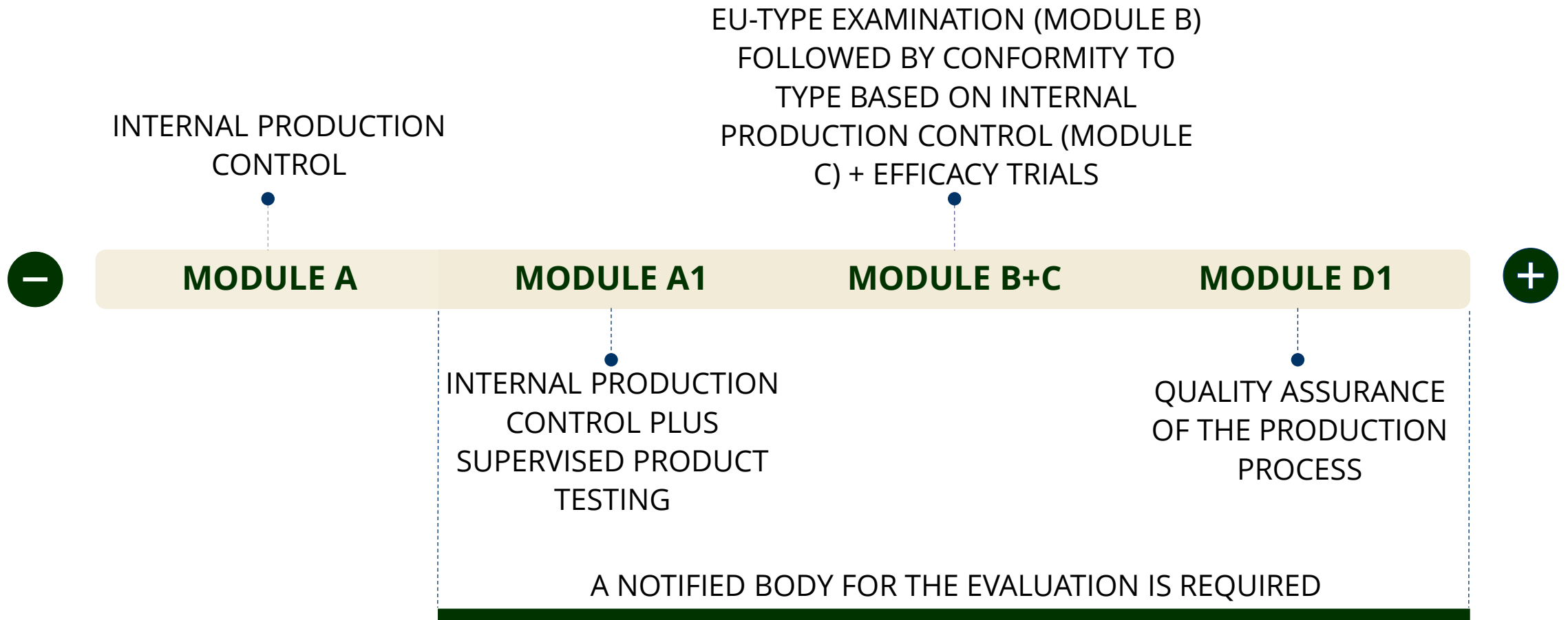
CE

GUARANTEE:
The manufacturer guarantees the composition, formulation and content, as well as the preservation of its products in their original packaging. The end user will be responsible for damages caused by total or partial non-observance of the label instructions.
"In order to avoid risks to people and the environment, follow the instructions of use of this fertilizer product. See product Safety Data Sheet for more information."

DOSE:

CROP	DOSE L/ha	APPLICATION / RECOMMENDATIONS
Pepper, tomato, potato, eggplant, melon, cucumber, watermelon, zucchini, pumpkin, onion, leek, chives, cabbage, cauliflower, broccoli, lettuce, radish, ornamental	10-30	Start applications at startup fruiting and continue for fruit development. Recommended application by drip or drench at least three times at a range of 10-30 L/ha during the culture cycle.
Strawberry, blackberry, raspberry, blackberry, apple, peach, plum, pear, quince, lemon, orange, tangerine, lime, grapefruit, citron, currant, mango, pineapple, papaya, blueberry, walnut, avocado, banana, banana, guava, passion fruit, lychee, vine	10-30	Start applications at startup fruiting and continue for fruit development. Recommended application by drip or drench at least three times at a range of 10-30 L/ha during the culture cycle.
Cotton, sunflower, safflower, alfalfa, broad bean, chickpea, green bean, bean, pea, corn, sorghum, oats, rye, rice, cane sugar, coffee, tobacco.	10-30	Start applications at startup fruiting and continue for fruit development. Recommended application by drip or drench at least three times at a range of 10-30 L/ha during the culture cycle.

Annex IV: Conformity assessment procedures



Applicability of the modules

MODULE	CMC	PFC	MODULE NOT APPLICABLE
A	CMC 1 (Except inhibitors)	PFC 1	PFC 1 (Ammonium nitrate)
	CMC 4	PFC 2	PFC 5
	CMC 6	PFC 3	PFC 6
	CMC 8	PFC 4	PFC 7 (With Ammonium nitrate)
	CMC 11	PFC 7	
A1		PFC 1 (C)(I)(a)(i-ii)(A) Ammonium nitrate	Any PFC that does not contain PFC 1 (C)(I)(a)(i-ii) (A)
		PFC 7 with at least 28% N containing PFC 1 (C)(I)(a)(i-ii)(A)	
B	CMC 1	Any PFC of fertilisers composed of one or more CMCs	PFC 1 (Ammonium nitrate)
	CMC 2 (Mandatory)		
	CMC 4		
	CMC 6		
	CMC 7 (Mandatory)		
	CMC 8	Mandatory for: PFC 5 PFC 6	PFC 7 (With Ammonium nitrate)
	CMC 9 (Mandatory)		
	CMC 10 (Mandatory)		
	CMC 11	PFC 7	
D1	ALL	ALL	
	Mandatory for: CMC 3, CMC 5, CMC 12, CMC 13, CMC 14, CMC 15.		

Notified bodies (15) FRP 2019/1009

Each notified body has its own IT system and certification procedure, but the dossier of technical information is the same for all of them.

Notified bodies (11) Module B

They are private companies, so there are important differences between them:

1. Prices
2. Billing arrangements (upfront, annually, etc.)
3. Different methodology after 5 years. (certification expiration)

The choice of notified body should reflect your budget and preferred working arrangements.

Austria	Estonia	France	Greece	Hungary
				
Italy	Latvia	Netherlands	Poland	Spain
				
Slovakia				
				

Austria	France	Greece	Hungary	Italy
				
Latvia	Netherlands	Poland	Spain	Estonia
				

MODULE B+C

Dossier Preparation

Module B+C – Dossier

The Module B dossier must include at least the following sections:

- **Manufacturer Details**
- **Declaration of responsibility**
- **Declaration of conformity**
- **Product design**
- **MSDS (Both end product and raw materials)**
- **CMC and PFC classification**
- **Manufacturing process**
- **Label**
- **Risk assessment**
- **Certificate of analysis**
- **REACH compliance (Letters...)**
- **Efficacy trials**



Commercial strategy

Clone certificate

Clone strategy

If one company has one valid Biostimulant registration, under Regulation (EU) 2019/1009, it is possible to reach an agreement with a third company to commercialize a CLONE.

A letter of access and the participation of the same notified body will be required.

- **A new certificate will be issued under the name of the new company.**
New manufacturer, New brand. (shown on the new label)
 - **The clone can be repacked but needs to be the same product as the original one.**
No data available for the new product, only LoA.
- B2B business may increase the sales using the clone strategy.

THANK YOU!

Guiding you on your regulatory strategy

Our services

Strategic consulting and EU fertiliser regulation

National registrations and mutual recognition in 27 EU countries.

EU 2019/1009 services.

Offices in Barcelona, Madrid and Turkey

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