



Biostimulants and EU legislation – the track to your CE marked product

ABIM 2023

**Session 2: Biocontrol and biostimulants –
programmes for sustainable agriculture**

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Jungle of definitions

Claims
DualUse
Fork
organic
GreenDeal
GAP
Microorganisms
Regulations
Restrictions
BioticStress
Fertilizer
Biologicals
organic
mineralto
Farm
Biostimulants
AbioticStress
Pathogens
PlantProtectionProducts
mineral Guidelines
MutualRecognition
Biopesticides
LegalFramework
Standardization

- **About us**
- **Legal framework: Biopesticides vs Biostimulants**
- **EU 2019/1009 fertilizer regulation in details**
- **CE Registration**



Since 2001

- Mycorrhiza production
- Scientific projects
- Product development



The function decides

PPP/Biopesticide

Fertilizer/Biostimulant



against

Biotic stress

Abiotic stress



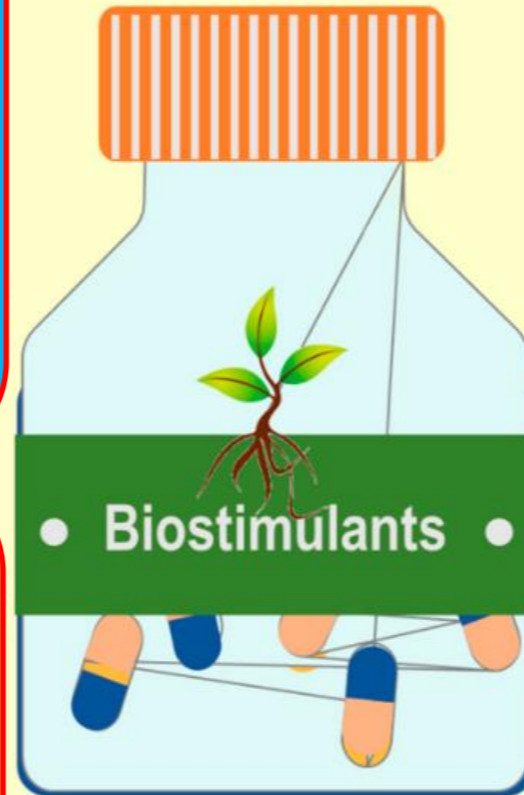


The function decides

PPP/Biopesticide	Fertilizer/Biostimulant
<p>protect plants from</p> <ul style="list-style-type: none">➤ harm➤ diseases	<p>... supplies nutrients/.....enhances</p> <ul style="list-style-type: none">➤ nutrient use efficiency➤ tolerance to abiotic stress➤ crop quality trait➤ availability of confined nutrients in the soil or rhizosphere
<p>Plant Protection act 1107/2019</p>	<p>Fertilizer act 2019/1009</p>

Acids
Humic substances
Humins
Amino acids
Fatty acids
 ...

Extracts
Seaweeds
Polyphenols
Chitosan
 ...



Microbials
Beneficial fungi
Beneficial bacteria
Microbial symbiosis

Others
Proteins
Enzymatic extracts
 ...

But, if double function = Plant Protection Product



PPP/Biopesticide

1. EU wide for active substance
2. National registration for product
3. Mutual recognition of PPP 1107/2009

Fertilizer/Biostimulant

1. National conformity assessment
 2. Mutual recognition 2019/515 (target country)
- or new: CE Registration

EU 2019/1009: data requirements for quantity, efficacy, toxicity



Part I Designations Product function categories (PFCs)

1. Fertiliser

- a) Organic (solid, liquid)
- b) Organo-mineral (solid, liquid)
- c) Inorganic (I. macro-/II. micronutrient)

2. Liming material

3. Soil improver (organic, inorganic)

4. Growing medium

5. Inhibitor

6. Plant biostimulant

- a) Microbial
- b) Non-microbial

7. Fertilising product blend



Part II Requirements of PFCs

- 1. The product should contain (nutrients) or do (claims)**
- 2. The product should not contain (contaminations, pathogens)**



PFC 6: Plant Biostimulant

...stimulate plant nutrition processes independently of nutrient content to improve one or more of the following characteristics of plant or rhizosphere:

- a. nutrient use efficiency**
- b. tolerance to abiotic stress**
- c. quality trait or**
- d. availability of confined nutrients in the soil or rhizosphere**

Thresholds for

- **Cadmium**
- **Hexavalent chromium**
- **Lead**
- **Mercury**
- **Nickel**
- **Inorganic arsenic**

- **Copper**
- **Zinc**





The plant biostimulant shall have the effects that are claimed for the specified plants



Thresholds for

- *Salmonella*
- *Escherichia coli*
- *Listeria monocytogenes*
- *Vibrio spp.*
- *Shigella spp.*
- *Staphylococcus aureus*
- *Enterococcaceae*
- Anaerobic plate count
- Yeast and mould





CMC 1: Virgin material substances and mixtures

CMC 2: Plants, plant parts or plant extracts

CMC 3: Compost

CMC 4: Fresh crop digestate

CMC 5: Digestate other than fresh crop digestate

CMC 6: Food industry by-products

CMC 7: Microorganisms

CMC 8: Nutrient polymers

CMC 9: Polymers other than nutrient polymers

CMC 10: Derived products ...animal by-products

CMC 11: By-products... Waste

CMC 7: Microorganisms

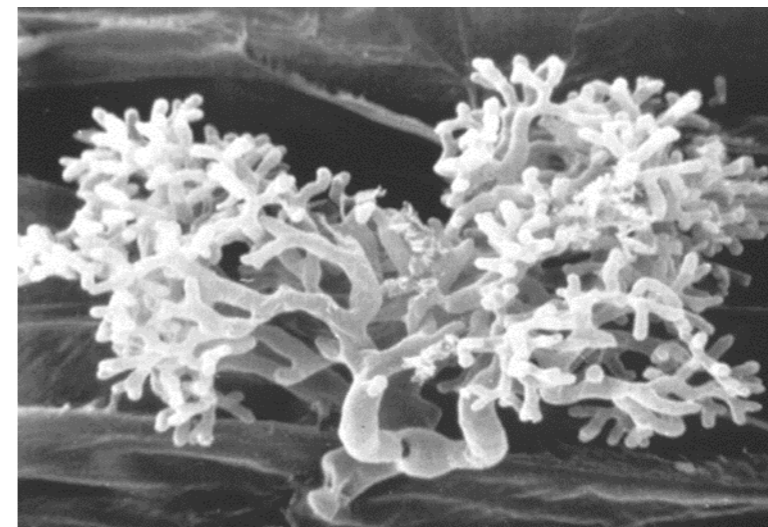
...may contain microorganisms, including dead or empty-cell MOs and non-harmful residual elements of the media on which they were produced, which have undergone no other processing than drying or freeze-drying and are listed in the following table

Azotobacter spp.

Mycorrhizal fungi

Rhizobium spp.

Azospirillum spp.

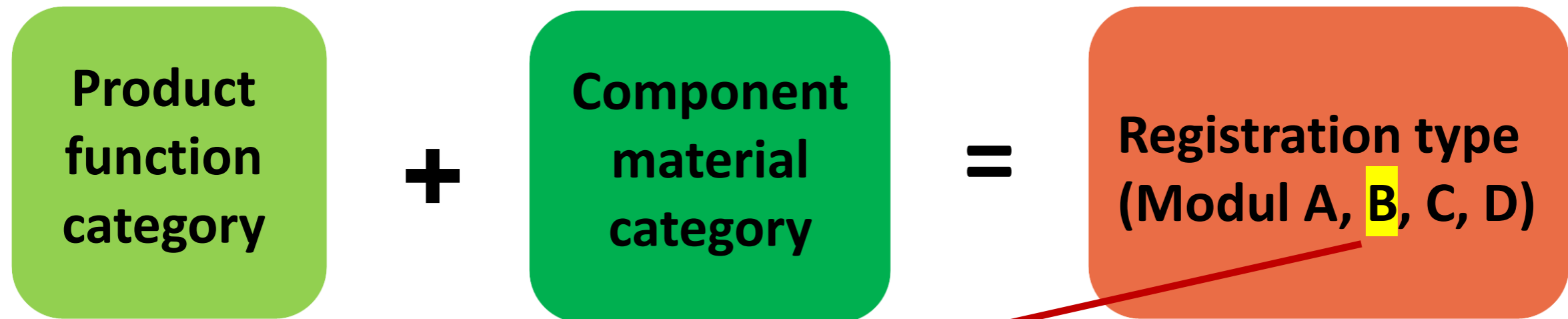


Survey of the EU for adding new microorganisms
Risk assessment of 56 new species resp. strains

Part I General

Part II Product specific labelling



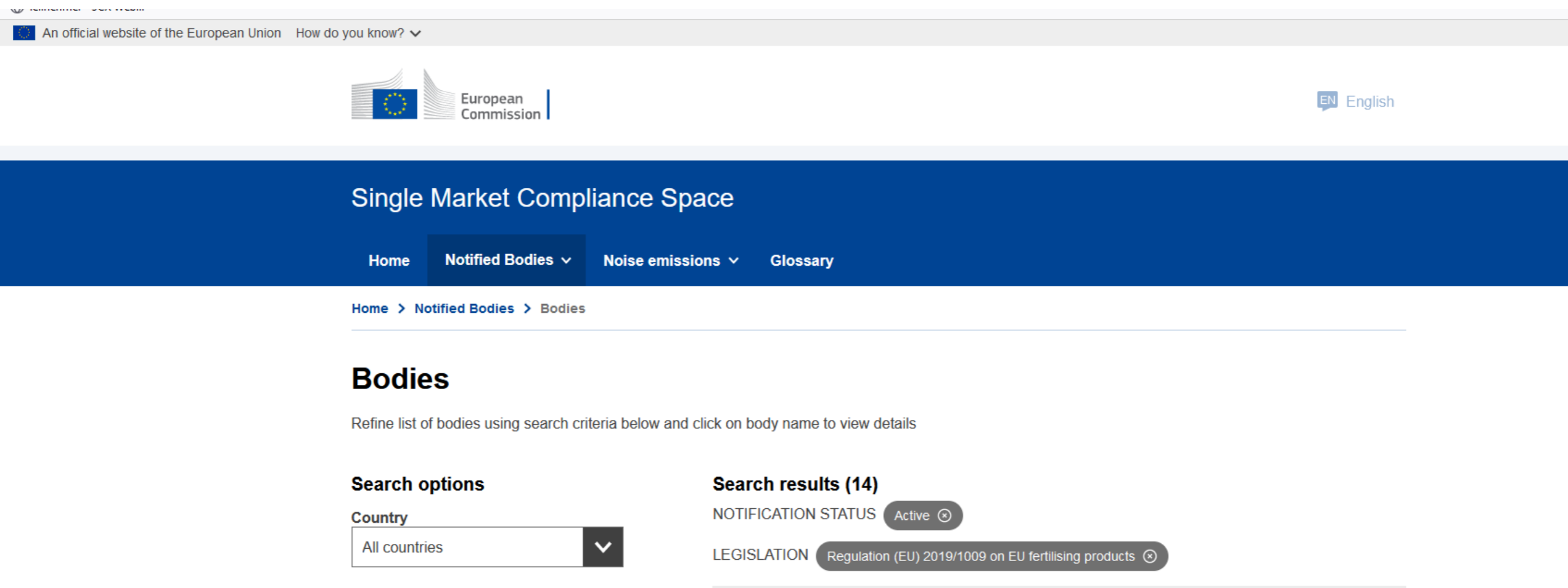


Modul B: Notified body will


- proof your technical dossier (efficacy)
- Examine your product samples (quantity, pathogens)
- report to your national authority for conformity assessment

How to find a notified body?

- EU Nando database,
- search by legislation EU 2019/1009
- List of notified bodies



An official website of the European Union How do you know? ▾

 European Commission EN English

Single Market Compliance Space

[Home](#) [Notified Bodies ▾](#) [Noise emissions ▾](#) [Glossary](#)

[Home](#) > [Notified Bodies](#) > [Bodies](#)

Bodies

Refine list of bodies using search criteria below and click on body name to view details

Search options

Country
 ▾

Search results (14)

NOTIFICATION STATUS [Active](#) ⓧ

LEGISLATION [Regulation \(EU\) 2019/1009 on EU fertilising products](#) ⓧ



General: PFC, CMC, production process, label

Test reports: methodology according to CEN-Norms

WG	title/subtitle WG	CEN Norms
WG 1	Sampling	17702-1 Sampling
		17702-2 Sample preparation
<p>17700-1 General principles define general parameters, requirements and quality criteria and are intended to be applied in order to assess the efficacy of trials used for claims validation as a result of the use of a plant biostimulant.</p>		
<p>17700-2 Nutrient use efficiency resulting from the use of a plant biostimulant Guidance for justifying agronomic NUE claims of plant biostimulants used in agriculture.</p>		
WG 4	other safety parameters	17714 Determination of microorganisms concentration
		17719 Determination of the anaerobic plate count
		17721 Determination of the pH for liquid microbial plant biostimulants
		17703 Determination of chromium (VI)
WG 5	Labelling and denominations	17704 Determination of dry matter
		17705 Determination of phosphonates
		17706 Determination of inorganic arsenic
WG 5	Labelling and denominations	17723 Determination of chloride
		17724 Terminology
		17725 Determination of the quantity (indicated by mass or volume)
	others	17703 Determination of chromium (VI)
		17704 Determination of dry matter
		17705 Determination of phosphonates
		17706 Determination of inorganic arsenic



Summary – track to your CE marked product

- **Decide your claim(s)**
- **Evaluate your PFC and CMC**
- **Select your Modul type**
- **Get into contact with a notified body**
- **Select plant, plant groups**
- **Carry out efficacy trials (provide peer reviewed publications)**
- **Compile all data for technical dossier**
- **Provide sample (for quantification and evaluation of pathogens)**
- **Deliver all to notified body**
- **Wait for questions**



CE ZERTIFIZIERUNG



See you on booth 102



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The Danish Environmental Protection Agency, has initiated a temporary pause in the registration of certain biostimulants due to potential pesticide effects. This development has led to a comprehensive review of these biostimulants by the European Union (EU) Commission.

The matter concerns seaweed extracts based on the following three species:

- *Ascophyllum nodosum*
- *Laminaria digitata*
- *Macrocystis integrifolia*



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