European Biostimulants Industry Council

EBIC and microbial plant biostimulants in the EU

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EBIC Secretariat

Root-Benefit Workshop | 20/09/2024

European Biostimulants Industry Council (EBIC)

EBIC is a trade association that provides a common voice for the plant biostimulant industry in Europe

Founded in 2011

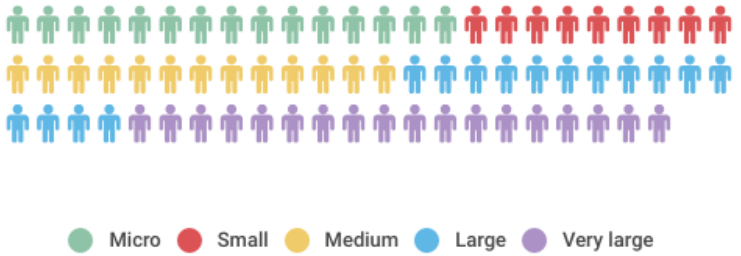
10 member companies (2011)

Breakdown by category (based on global turnover and headcount)

...and still growing

70 member companies

Breakdown by size (based on global turnover and headcount)



As of January, 24 2024

Full list of member companies on EBIC website

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EBIC's history

November 2012

EBIC sponsors 1st **World Congress** on Biostimulants

14 June 2011

First meeting of EBIC with 10 companies

EBIC launches its **Code of Conduct, 2013**

17 March 2016

Plant biostimulants are included as a PFC the EU Fertilising Products Reg Proposal

25 June 2019

FPR published in Official Journal after political agreement between EP and Council and formal adoption

Spring 2020

Launch of Farm-to-Fork Europe Conference series by EBIC (now EBIC Summit)

16 July 2022

The first EU fertilising products were **placed on the EU Single Market!**

Provided companies have:

- CMC listed in the FPR
- REACH registration(s)
- Demonstrate effect
- Pass conformity assessment procedure

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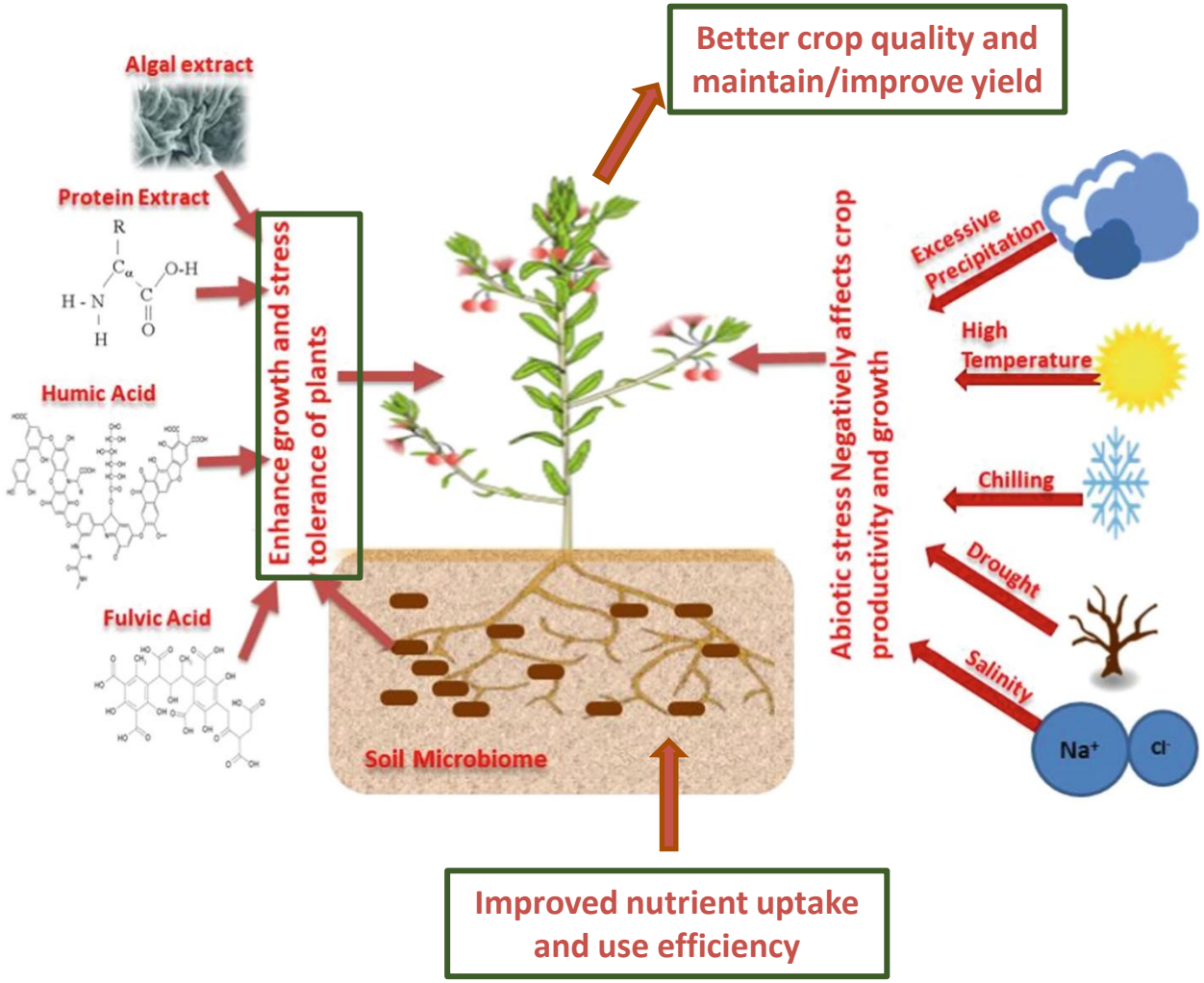
What are plant biostimulants?



Source: Adapted from Pandey et al., 2022. https://doi.org/10.1007/978-981-16-7080-0_9

- Plant biostimulants are **defined by their function**, not by their composition
- Components of plant biostimulants can include seaweed and plant extracts, hydrolysed proteins, microorganisms, humic and fulvic acids, chemical substances, etc.
- Formulations are used following specific instructions to obtain a beneficial effect on a target crop

Legal definition of plant biostimulants in the EU

- 'An **EU fertilising product** [= fertilising product* which is CE-marked when made available on the EU market],
- 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.'

Annex I, Part II, PFC 6,1. Regulation (EU) 2019/1009 (FPR)
http://data.europa.eu/eli/reg/2019/1009/oj [largely inspired by EBIC's definition]
** Art.2(1) FPR*

PFC 6 (A): Microbial plant biostimulant

Microorganism or consortium of microorganisms referred to in CMC 7 (*Azotobacter* spp., mycorrhizal fungi, *Rhizobium* spp., *Azospirillum* spp.)

PFC 6 (B): Non-microbial plant biostimulant

Plant extracts, seaweed extracts, humic substances, chemical substances, amino acids, animal by-products, etc.

The Fertilising Products Regulation: Basic aspects

- Regulation (EU) 2019/1009
- Adopted on 5 June 2019
- Applicable as of 16 July 2022

✓ **Optional harmonization**: manufacturers can choose FPR or national rules

✓ Regulates **placement on the market** (not use)

✓ Leads to **CE-marking**: free movement in the EU Single Market

The Fertilising Products Regulation: Requirements

Product Function Categories (PFC)

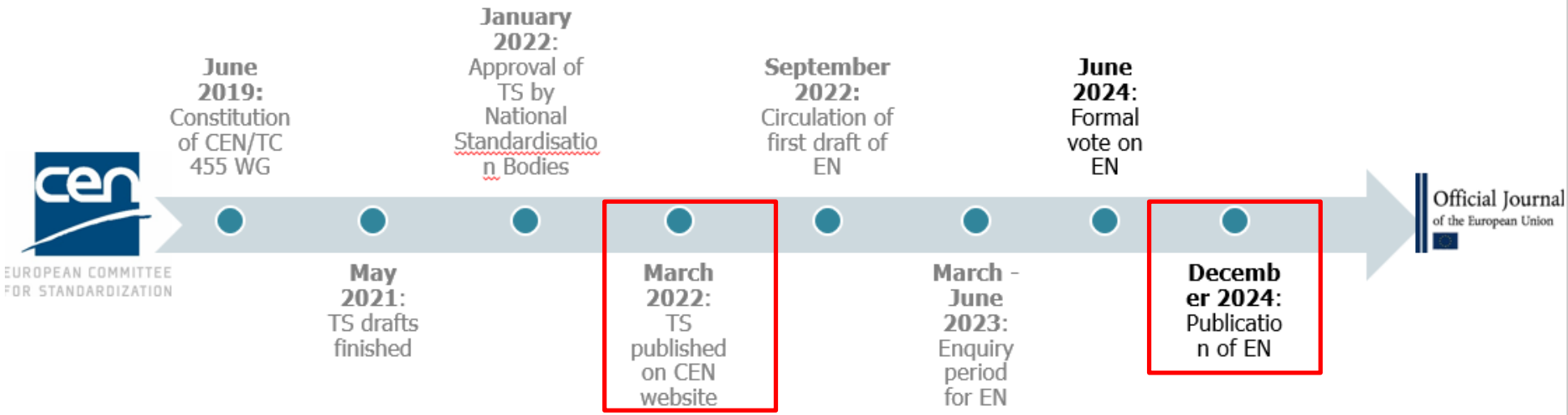
- PCF 1: Fertiliser
- PFC 2: Liming material
- PCF 3: Soil improver
- PFC 4: Growing medium
- PFC 5: Inhibitor
- PFC 6: Plant biostimulant
- PFC 7: Fertilising product blends

Component Material Categories (CMCs) most relevant for PBs:

- 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

3. Conformity Assessment

Development of standards for conformity assessment



CEN/TC 455 has developed 33 TS/EN for plant biostimulants in the FPR

- WG1 Sampling
- WG2 Claims
- WG3 Pathogenic and non-pathogenic microorganisms
- WG4 Other safety parameters
- WG5 Labelling and denominations

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4. CEN Technical Specifications and Standards for PBs

Role of CEN Technical Specifications/Standards is to support compliance

- prEN/TS 17700-1: General principles
- prEN/TS 17700-2: Nutrient use efficiency
- prEN/TS 17700-3: Tolerance to abiotic stress
- prEN/TS 17700-4: Determination of quality traits
- prEN/TS 17700-5: Availability of confined nutrients

EUROPEAN COMMITTEE FOR STANDARDIZATION

- ✓ Technical specifications published by CEN in March 2022
- ✓ Available **for purchase through the National Standardisation Bodies** of the countries that are members of CEN
- ✓ Will be published as harmonised European Standards before end 2024

Two-step conformity assessment procedure

Type examination by a Notified Body

- Description of the formulation of the product (i.e., list of ingredients)
- Information about raw materials (where appropriate)
- List of harmonised standards used
- Test reports (including efficacy)
- Product samples
- Other supporting documentation

Internal production control by the manufacturer

- Monitoring and control to ensure that products are in conformity with the approved type
- Self-certification of products by affixing the CE-mark and providing certificates of conformity

CE **-marked plant biostimulants**

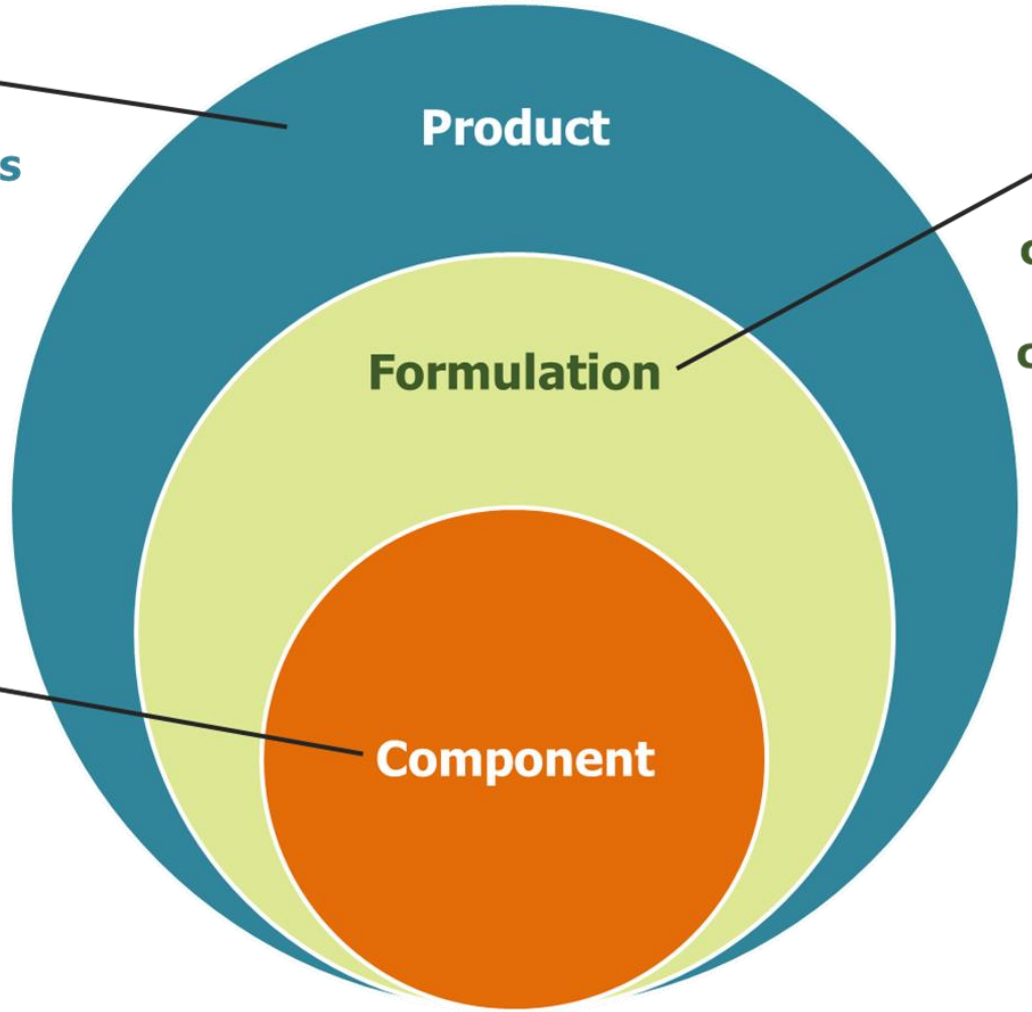
A different path to get products to market

Authorisation/registration (PPPR)	Conformity assessment (FPR)
• Conducted by a **government authority**	• Conducted by a **private entity** (Notified Body) that has become accredited
• **Guidelines and requirements** defined by government authorities	• **Standards** elaborated by transparency, consensus of relevant stakeholders and after approval according to the CEN process
• Legal responsibility for the product falls on the **government authority** once the product is authorised/ registered	• Legal responsibility for the product and its effects remain solely with the **manufacturer** under market surveillance
• **Authorisation/registration number** justifies that the manufacturer has presented the necessary data for the product to be assessed by the authority and the product complies to the requirements defined by **authorities**	• **EU declaration of conformity** justifies that the manufacturer has presented the necessary paperwork to show that the product meets requirements and performs the function it claims

Differences between Component, Formulation, and Product

Regulation applies at the product level (intended use)

Formulation + application rate + timing + target crops + other relevant parameters (e.g., label instructions)



Includes all the components in their relative concentrations and obtained through a specific process

An inorganic or organic substance (seaweed extract, hydrolysed protein, microorganism, etc.). Could be involved in different functions of different products

- FAQs related to Regulation (EU) 2019/1009 on fertilising products, Question 1.3: https://ec.europa.eu/docsroom/documents/58634
- EBIC's position on multiple-use components in plant biostimulants: https://biostimulants.eu/publications/what-is-the-multiple-use-principle/

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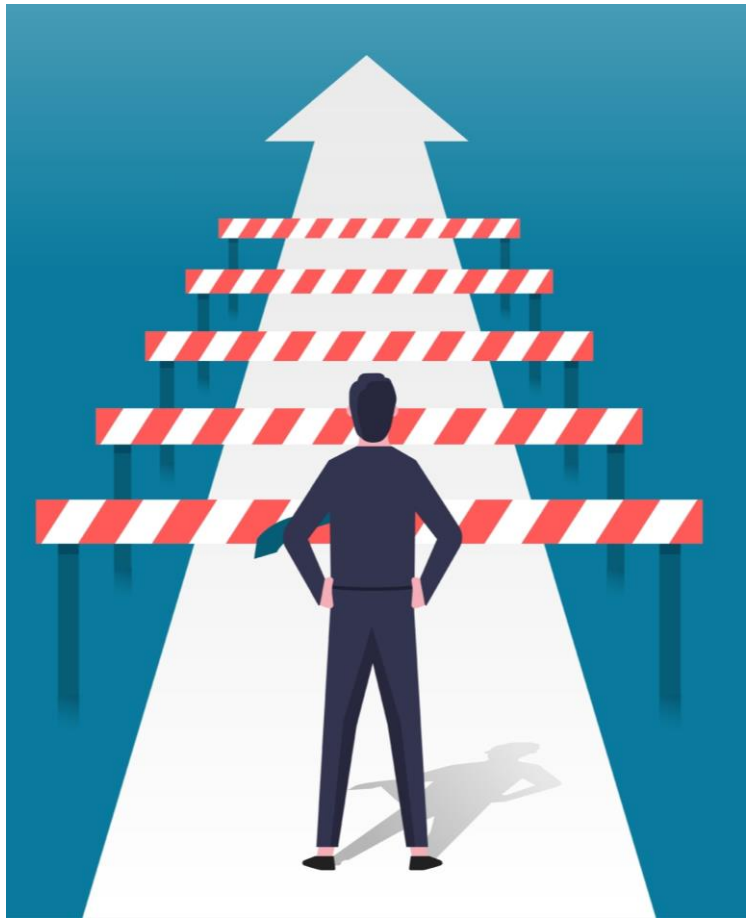
Current situation with the implementation of the FPR



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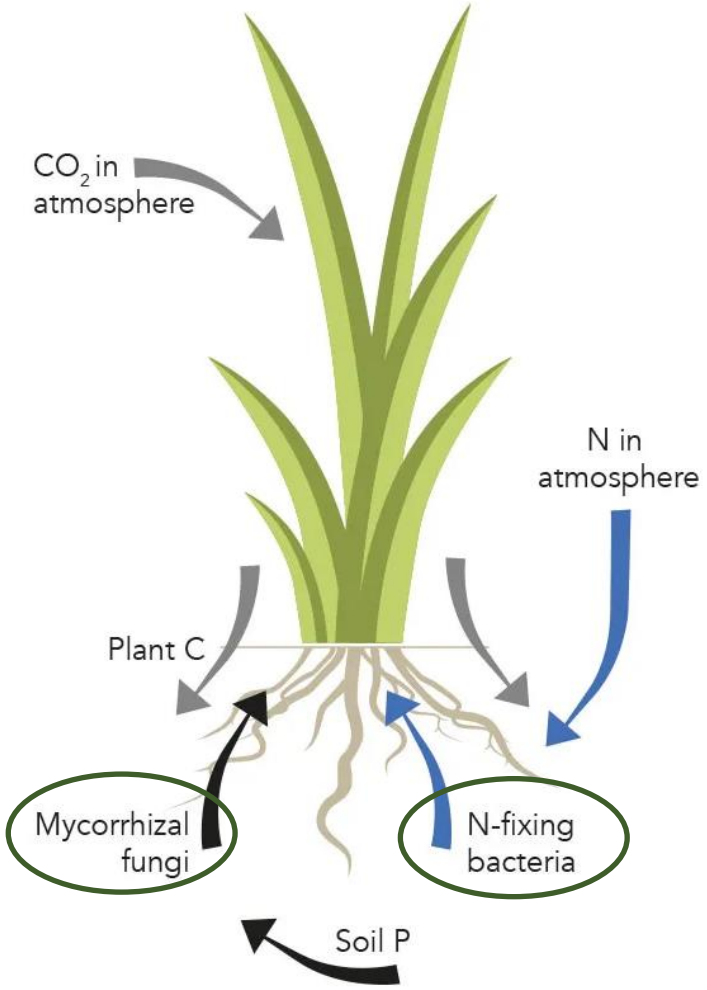
- Since July 2022, many EBIC members have succeeded in obtaining the CE mark for their plant biostimulants
- But several obstacles remain:
  - REACH+ requirements in CMC 1
  - Empty list of animal by-products in CMC 10
  - Phosphites banned from the FPR
  - Limited positive list of microorganisms in CMC 7
  - Application of the multiple use principle
  - "Borderline issues" in the interpretation of claims…

Microbial plant biostimulants

- Current positive list under CMC 7
  - *Azotobacter* spp.
  - Mycorrhizal fungi
  - *Rhizobium* spp.
  - *Azospirillum* spp.

- FPR foresees adding microorganisms to CMC 7, but does not specify a procedure, only criteria (market importance, safety, agronomic efficacy)



Source: Research Features

Limited positive list of microorganisms in CMC 7

June 2019

Publication of the FPR with **four types of microorganisms** that can be used in microbial plant biostimulants

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

Dec. 2023

Technical study contracted to Austrian Institute of Technology (AIT) to assess microorganisms proposed for **agronomic efficiency and safety**

Sep. 2022

More microorganisms proposed for inclusion in CMC 7 through **EU Survey**

Dec. 2025

Recommendation to the CEG-FP for inclusion of new microorganisms in CMC 7?

Monitoring & Advocacy: Shaping CMC 7 for EBIC Members

- **Criteria-Based Framework:**
  - Rational waivers for proven microorganisms
  - Apply clear criteria for new microorganisms, with regular updates for innovation.
- **Proportional, Timely, Tiered Assessment:**
  - Weight of Evidence (WoE) approach for data relevance.
  - Risk assessment based on product-level context (pattern of use, dose, timing).
- **Dynamic CMC 7 List:**
  - Supports a responsive regulatory approach
  - Continuous alignment with innovation and market needs
- **Data Transparency & Confidentiality:**
  - Clear submission guidelines.
  - Protection of proprietary data

Thank you for your attention

For more information:

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https://www.linkedin.com/company/ebic-european-biostimulants-industry-council-/

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