

Placing plant biostimulants on the market in the EU

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Regulatory challenges for plant biostimulants and
borderline cases with plant protection products

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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)



● Micro ● Small ● Medium ● Large ● Very large

...and still growing



70 member companies

Breakdown by size (based on global turnover and headcount)



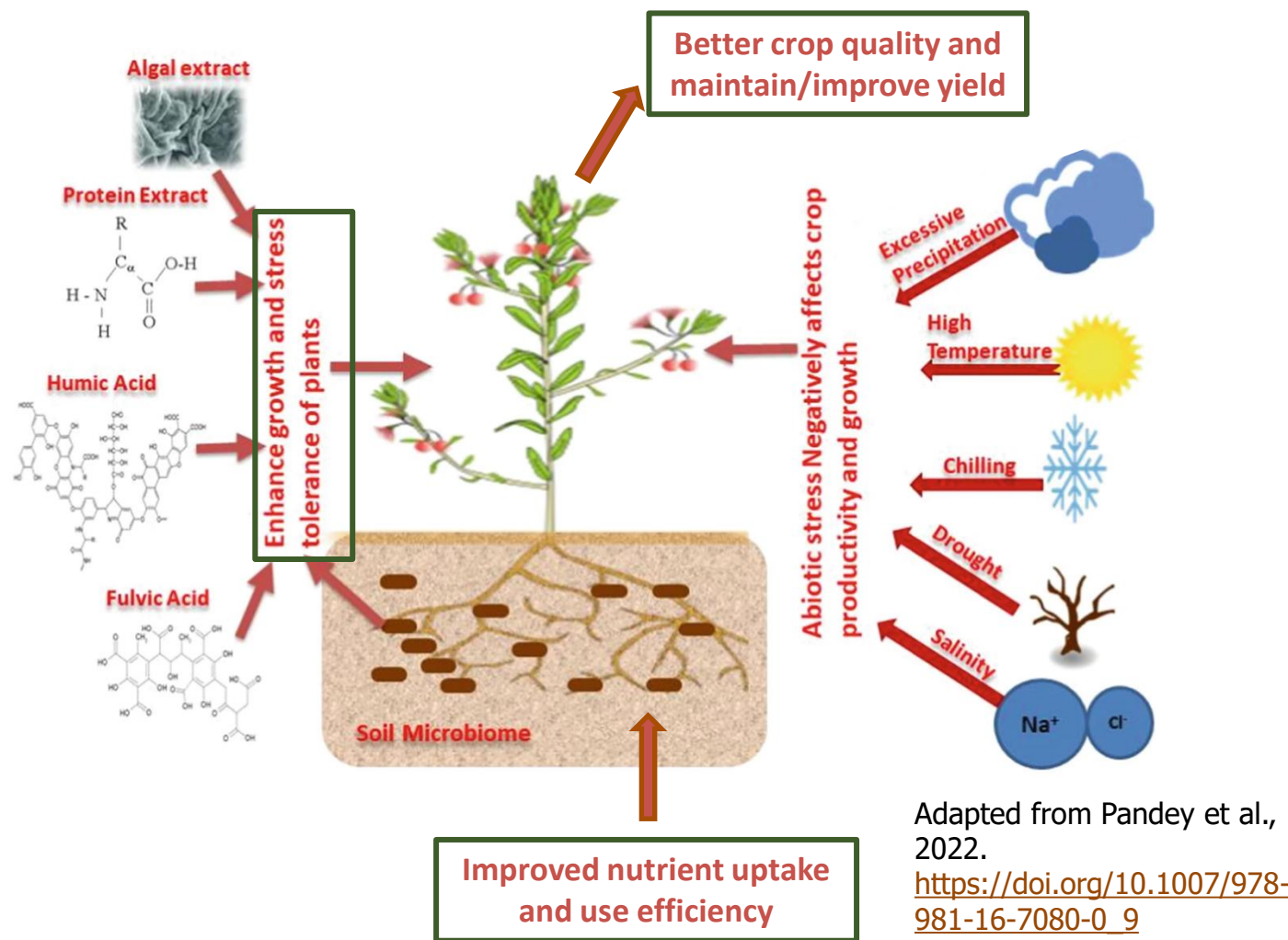
● Micro ● Small ● Medium ● Large ● Very large

As of January, 24 2024

**Full list of
member
companies
on EBIC
website**

What are plant biostimulants?

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



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

Functional definition of plant biostimulants in the FPR

“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:

- **nutrient use efficiency;**
- **tolerance to abiotic stress;**
- **quality traits;**
- **availability of confined nutrients in soil or rhizosphere.”**

PFC 6 (A): Microbial plant biostimulant

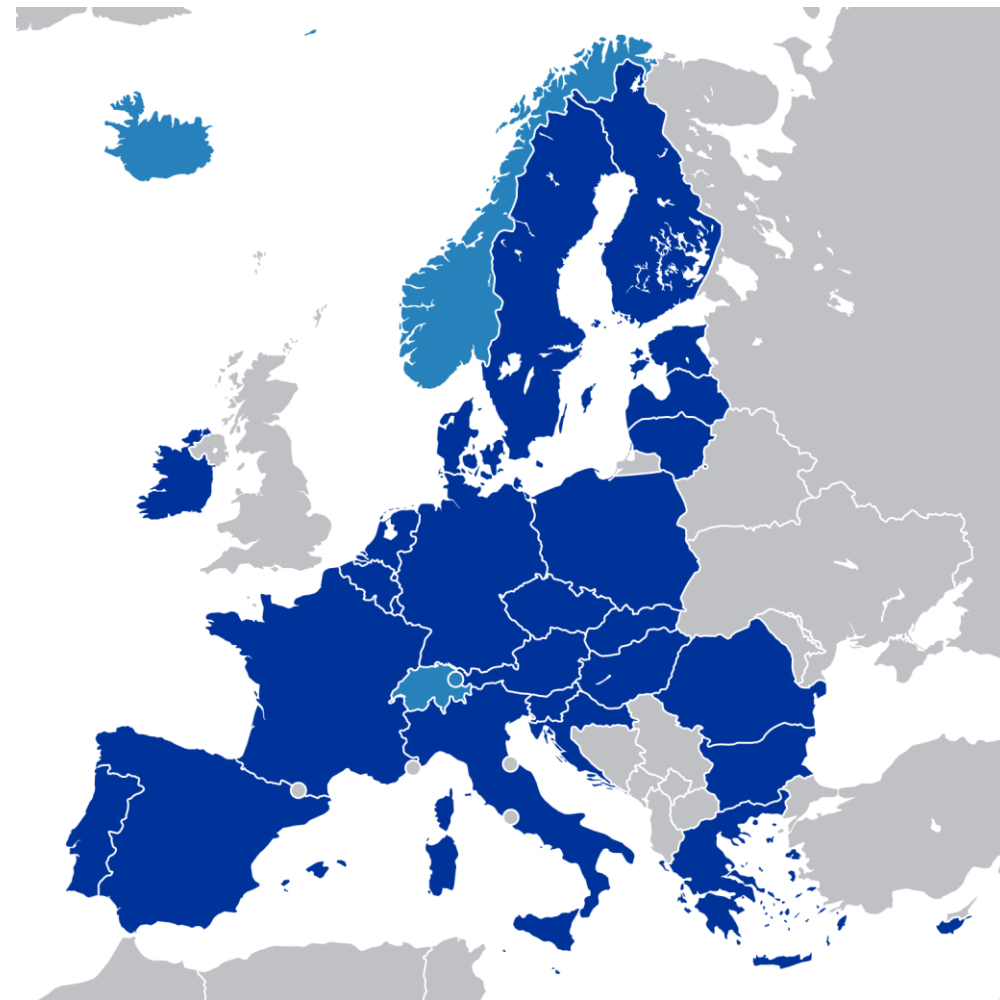
Microorganism or consortium of microorganisms referred to in CMC 7

PFC 6 (B): Non-microbial plant biostimulant

Regulation (EU) 2019/1009, Annex I, Part II. <http://data.europa.eu/eli/reg/2019/1009/oj>

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



An EU fertilising product:

- * meets the requirements for a **PRODUCT FUNCTION CATEGORY**
- * meets the requirement for a **COMPONENT MATERIAL CATEGORY** or categories
- * is **LABELLED** according to the requirements in FPR
- * passes the **CONFORMITY ASSESSMENT PROCEDURE**

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

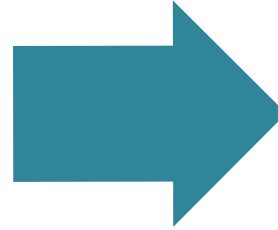
Component Material Categories (CMCs) most relevant for PBs:

- 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

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

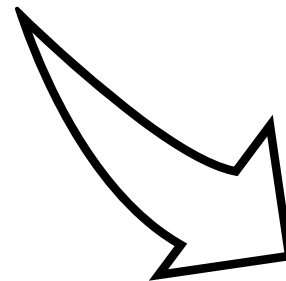


Internal production control by the manufacturer

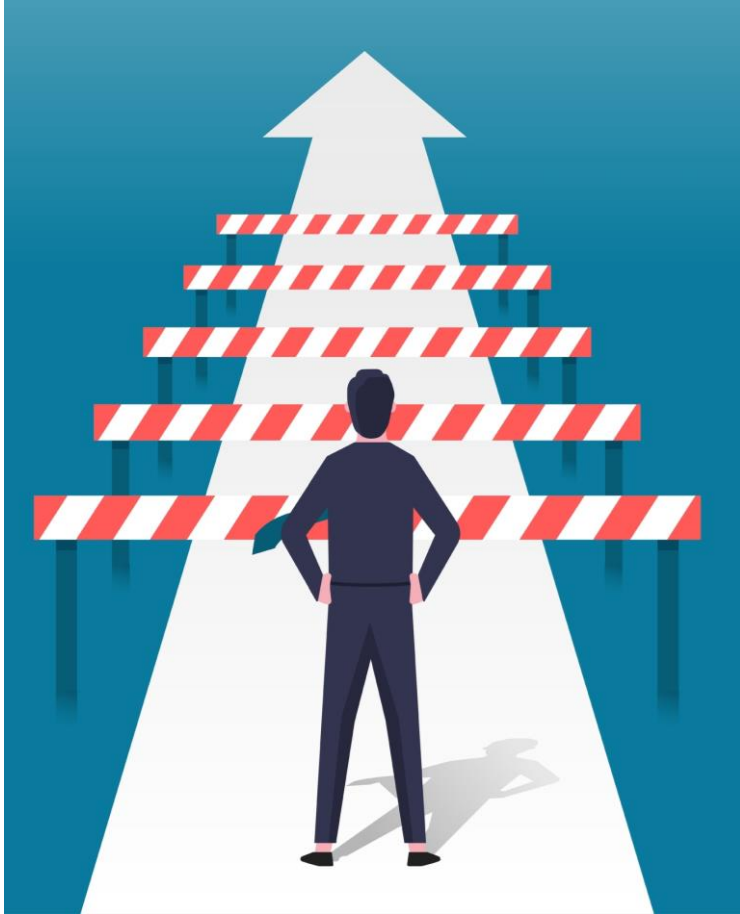
- Monitoring and control to ensure that products are in conformity with the approved type
- Self-certification of products by affixing the CE-mark and providing certificates of conformity



**-marked plant
biostimulants**



Current situation with the implementation of the FPR



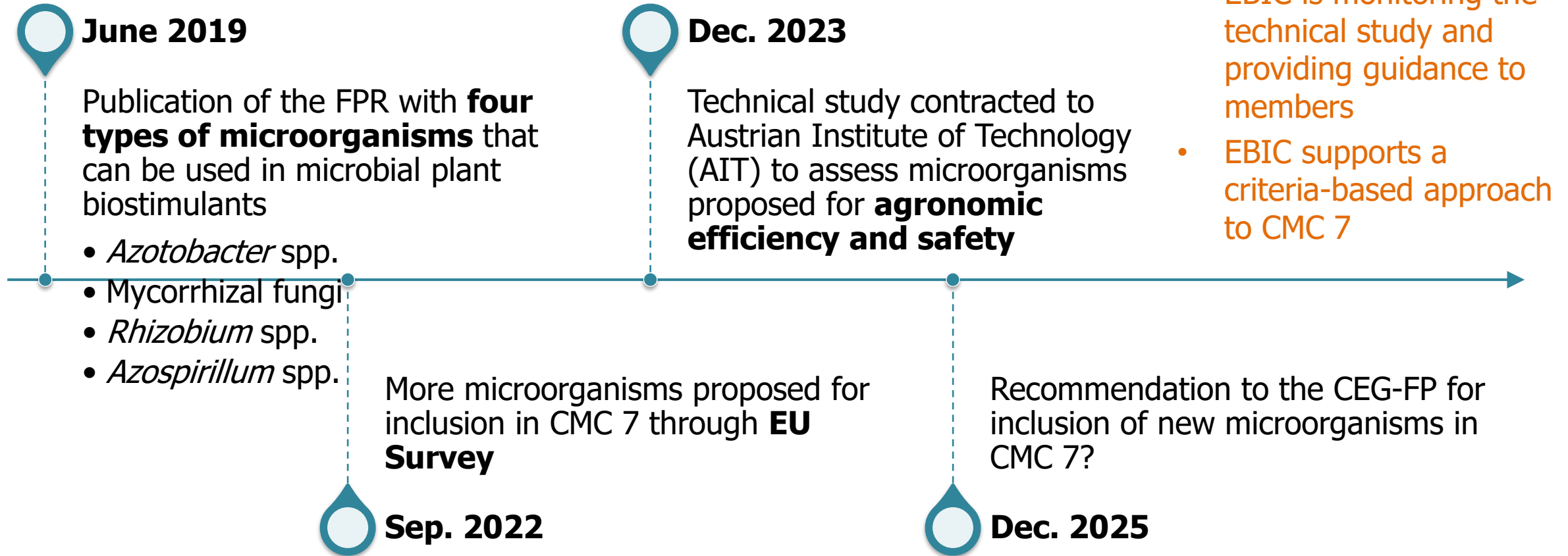
Shutterstock

- 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
 - Limited positive list of microorganisms in CMC 7
 - Empty list of animal by-products in CMC 10
 - Phosphites banned from the FPR
 - Application of the multiple use principle
 - “Borderline issues” in the interpretation of claims...

REACH+ requirements

- The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) normally requires **no data** for substances produced **under 1 tonne per year** and **limited data** for substances produced **1-10 tonnes**.
- However, the FPR:
 - requires data as if **any chemical substance** in an EU Fertilising Product had been produced **at a minimum of 10-100 tonnes**.
 - **annuls some of the exemptions** for REACH registration
- EBIC has convened a **joint industry task force** to elaborate a common position on REACH+
- This position will be submitted as part of the **FPR evaluation**

Limited positive list of microorganisms in CMC 7



Empty list of animal by-products in CMC 10

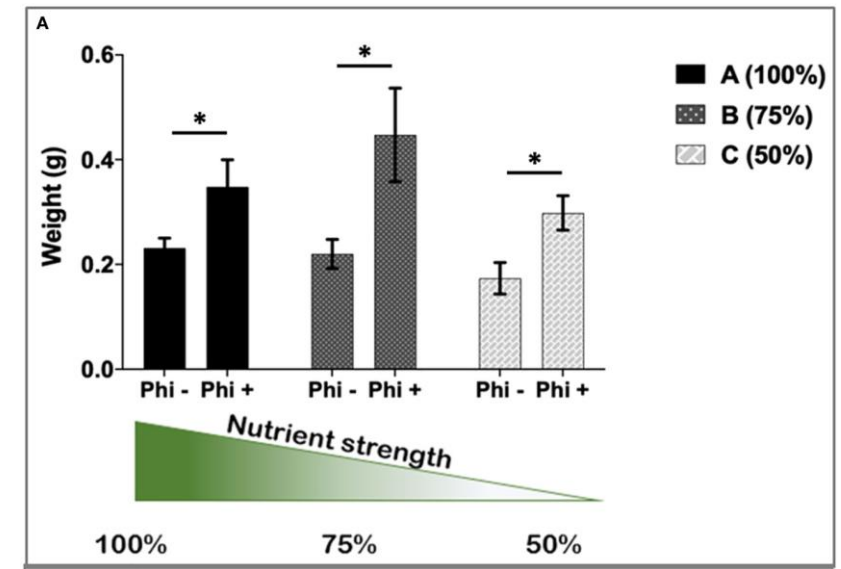
CMC 10: DERIVED PRODUCTS WITHIN THE MEANING OF REGULATION (EC) NO 1069/2009

An EU fertilising product may contain derived products within the meaning of Regulation (EC) No 1069/2009 having reached the end point in the manufacturing chain as determined in accordance with that Regulation, and which are listed in the following table and as specified therein (¹¹):

- Since 2019, **positive list in CMC 10 empty** → ABPs commonly used in plant biostimulants not allowed in the FPR
- Commission Delegated Regulation (EU) 2023/1605 determining **end points** in the manufacturing chain of certain organic fertilisers and soil improvers → Some ABPs (hydrolysed proteins, insect frass) included
- Technical study contracted to QLab in 2023 to assess their agronomic efficiency and safety → Expected to be finished by October 2024
- EBIC is offering expertise to QLab for the technical study
- EBIC has coordinated an **open joint letter** signed by 16 organisations calling for a fundamental review of the EU's approach to the regulation of materials from animal origin in the food chain

Phosphites banned from use in fertilising products

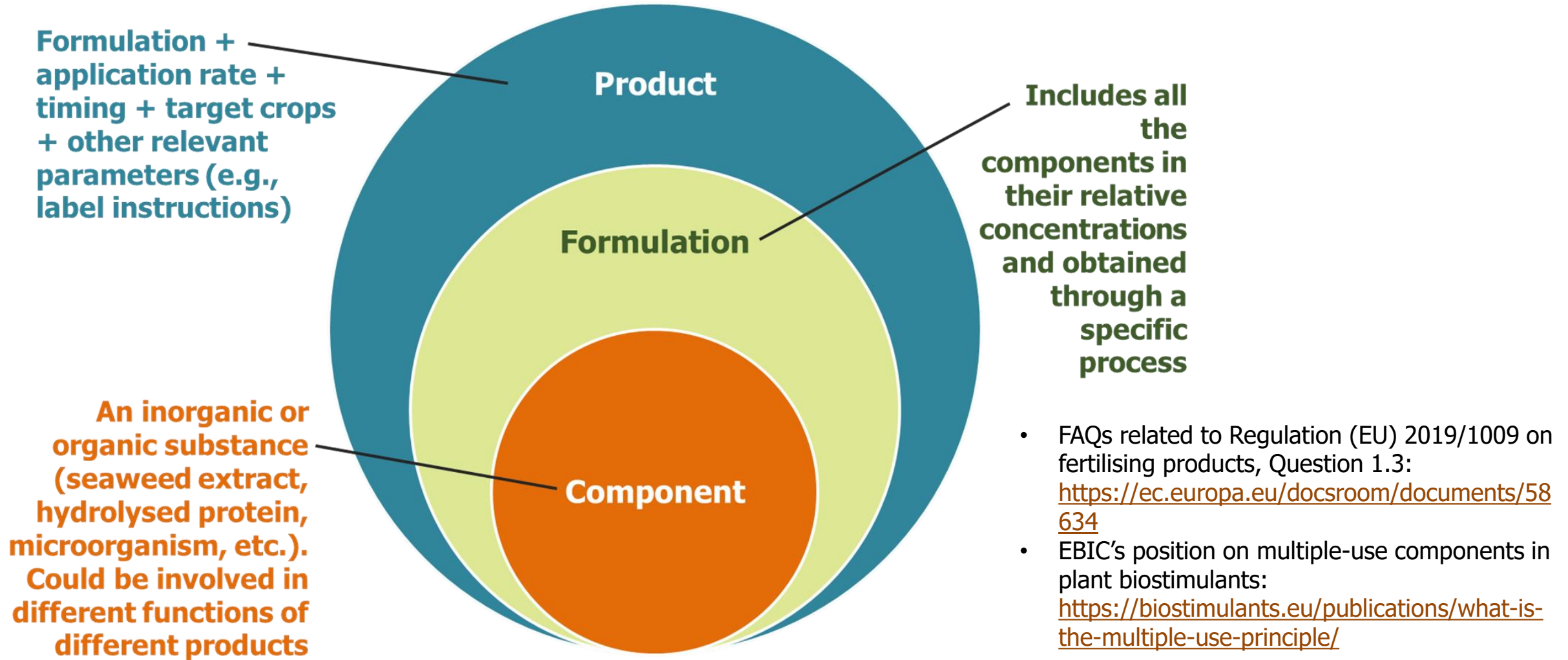
- The FPR states “phosphonates shall not be intentionally added to any EU fertilising product. Unintentional presence of phosphonates shall not exceed 0,5 % by mass” (Paragraph 6, of Part II)
- This language prevents plant biostimulants containing phosphite/phosphonate from being placed on the market under the FPR, despite compelling and growing scientific evidence of phosphites having more than one plant biostimulant function under certain use cases.
- EBIC is working to secure an amendment of the FPR so that phosphite can be used as a component of plant biostimulants



Umar et al., 2022.

<https://doi.org/10.3389/fpls.2022.1017048>

Application of the multiple-use principle

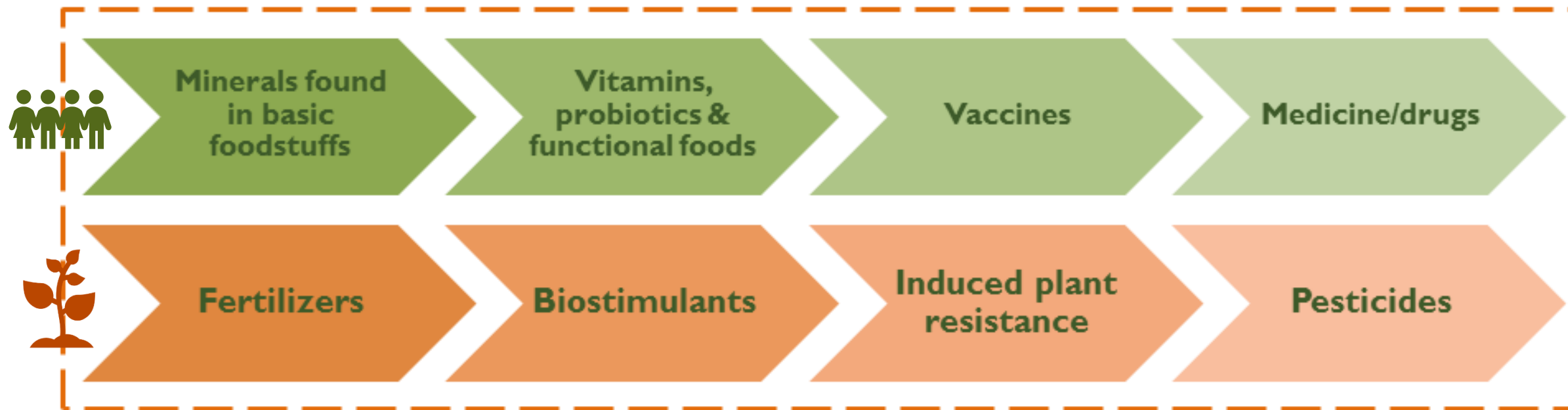


“Borderline issues” in the interpretation of claims

- The Fertilising Products Regulation (FPR) [Regulation (EU) 2019/1009] classifies fertilising products “by virtue of their claimed function” into seven Product Function Categories (PFCs).
 - Plant biostimulants are classified under PFC 6.
 - Their function 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: nutrient use efficiency, tolerance to abiotic stress, quality traits, or availability of confined nutrients in the soil or rhizosphere.”
- The Plant Protection Products Regulation (PPPR) [Regulation (EC) No 1107/2009] applies 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:
 - (b) **influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant”**

In some cases, particularly abiotic stress or quality traits claims, certain words on a plant biostimulant label have triggered an interpretation by some market surveillance authorities that the product falls under the scope of the PPPR

Revisiting the concept of plant health and nutrition





Thank you for your attention

For more information:

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

✕ @biostimulantsEU