



A Definition-Based Approach to Regulatory Classification of Plant Biostimulants

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Overview of the presentation

- Introduction to EBIC and plant biostimulants
- How plant biostimulants are regulated in the EU: the Fertilising Products Regulation
- The regulatory boundary between plant biostimulants and plant protection
- Conclusions

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Introduction to EBIC and plant biostimulants



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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 since 2011

Breakdown by size (based on global turnover and headcount)



● Micro ● Small ● Medium ● Large ● Very large

As of January, 24 2024

Today, EBIC counts more than 70 members from SMEs to multinational corporations

Full list of member companies on [EBIC website](#)



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EU Legal Definition of the Plant Biostimulants Product Function Category

- '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.'

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.

European Union was the first governing body to recognise plant biostimulants legally



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Validated Yield Gains from Biostimulants

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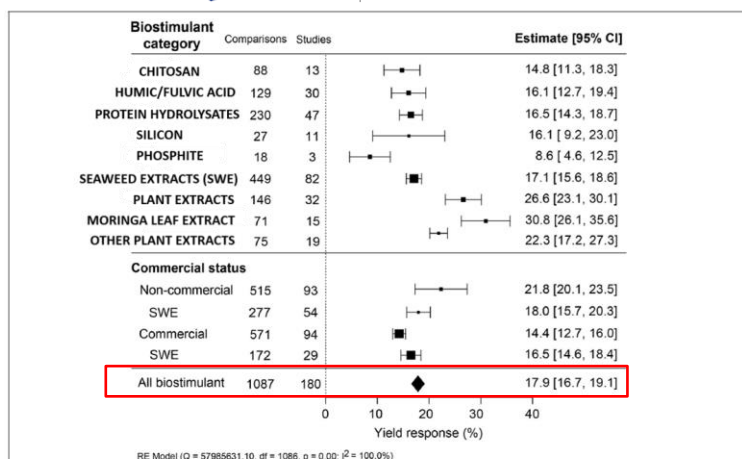


FIGURE 2 | Percentage yield response to biostimulant application affected by the biostimulant category and the commercial status of biostimulant products. The point size correlates to the estimate's precision, and the error bars represent 95% confidence intervals (CI) of mean estimated effect sizes. The number of comparisons and studies is indicated in each line. The combined effect estimates and the heterogeneity test on the random-effect model (RE) are summarized at the bottom, where the heterogeneity test is significant ($p < 0.001$) and $I^2 \geq 75\%$ implies substantial heterogeneity. Chi, Chitosan; HFA, humic and fulvic acids; PHs, protein hydrolysates; Si, silicon; PhI, phosphite; SWE, seaweed extracts; PE, plant extracts; MLE, moringa leaf extract.

- **Average Yield Increase: 17.9%** across diverse conditions.
- **Study Scope: 1,000+ paired observations** from **180 trials**.
- **Crop types:** cereals, legumes, tubers, fruit and vegetables.
- **Global Reach:** Conducted in **various climates** worldwide.

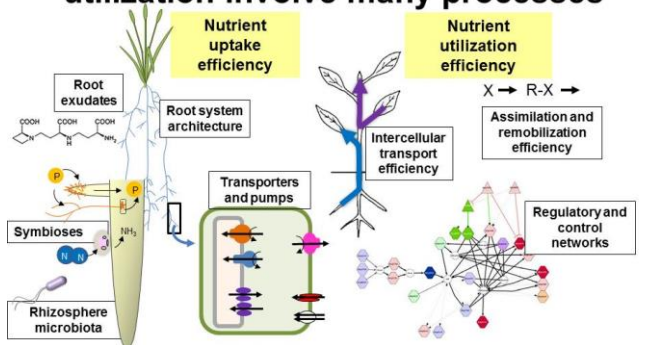
Source: Li et al. (2022), *Frontiers in Plant Science*. [Read More](#).



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Biostimulants increase **nutrient use efficiency (NUE)**

Nutrient uptake, assimilation and utilization involve many processes



NUE can be improved in many ways, which can have side benefits:

Few examples:

- increase root growth, which **improves nutrient and water uptake**, helps anchor soils against erosion, and increase soil carbon
- **solubilize nutrients blocked** in soil such as P into forms plants can absorb
- Impact **nutrient mobilisation, use and transformation** within plants, triggering nutrient uptake by roots
- Certain **microbial biostimulants fix N from the air** and share it with the plants they are in symbiosis with.

Biostimulants can reduce nutrient losses & improve their use within plants.
→ Good for the environment and farmer's incomes!



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Failed harvests = wasted nutrients



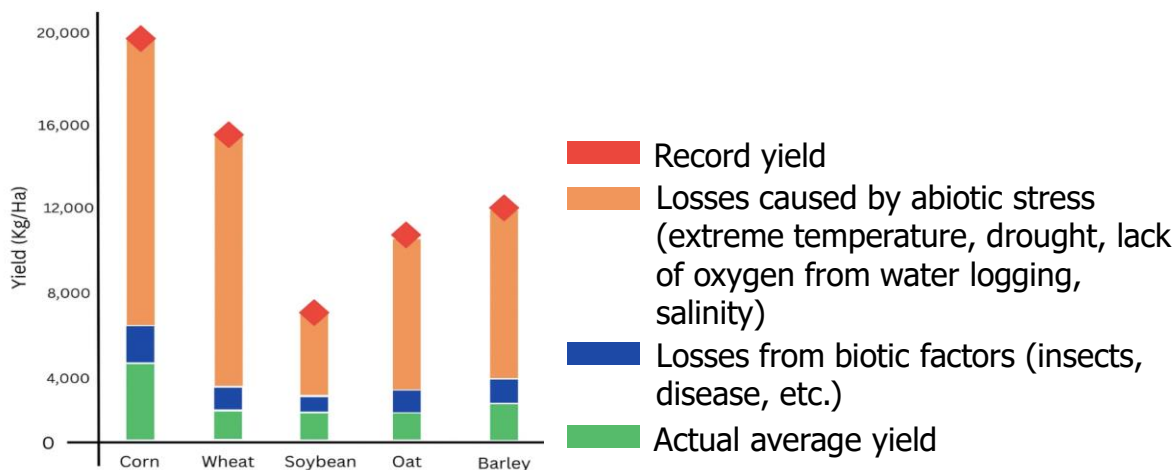
Source: Adobe Stock

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Crop losses due to abiotic stresses dwarf those caused by pests and diseases



Source: Buchanan, Gruissem, Jones: Biochemistry and Molecular Biology of Plants, American Society of Plant Physiologists, 2000

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As well as reducing yields, abiotic stress can diminish quality

Stress type					Physiological response	Prevalent effect on crop quality
Drought	Heat	Salinity	Ozone	UV/light		
✓	✓	✓	✓	✓	Altered gene expression	↑ Anti-oxidants Protein
✓	✓	✓	✓	✓	Oxidative stress	↑ Minerals Sugar
✓	✓	✓	✓	✓	Accelerated senescence	↓ Feed value Starch P/S traits Lipids, PUFA
✓	✓	✓			Reduced water content	
✓		✓	✓		Altered mineral household	
✓	✓	✓	✓	✓	Reduced biomass	



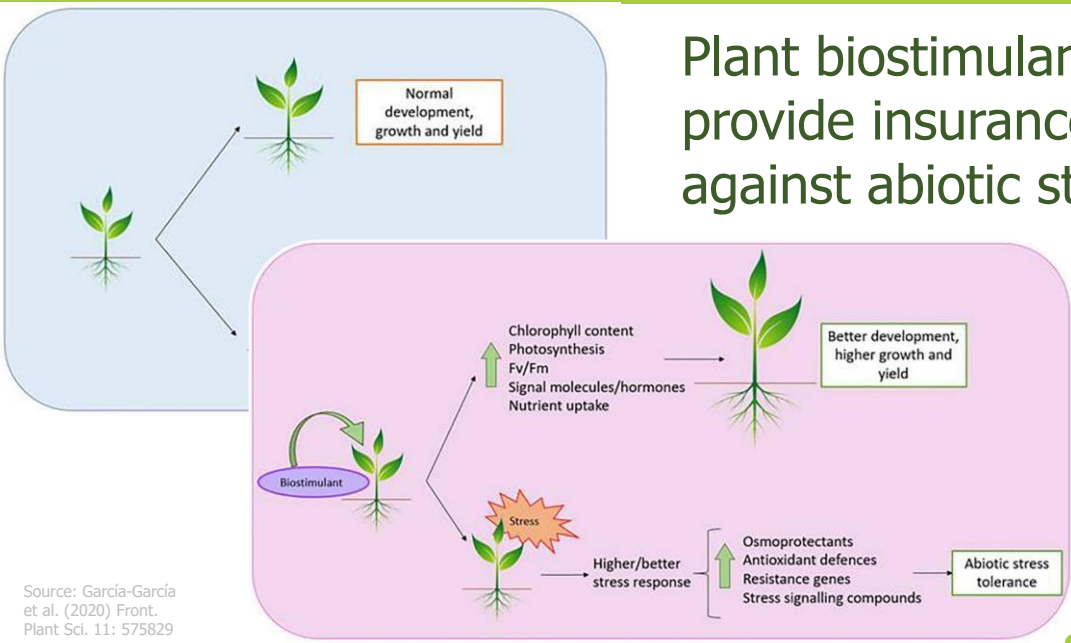
Wang & Frei (2011) Agric. Ecosyst. Environ. 141(3-4): 271-286

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Plant biostimulants provide insurance against abiotic stress



Source: García-García et al. (2020) Front. Plant Sci. 11: 575829

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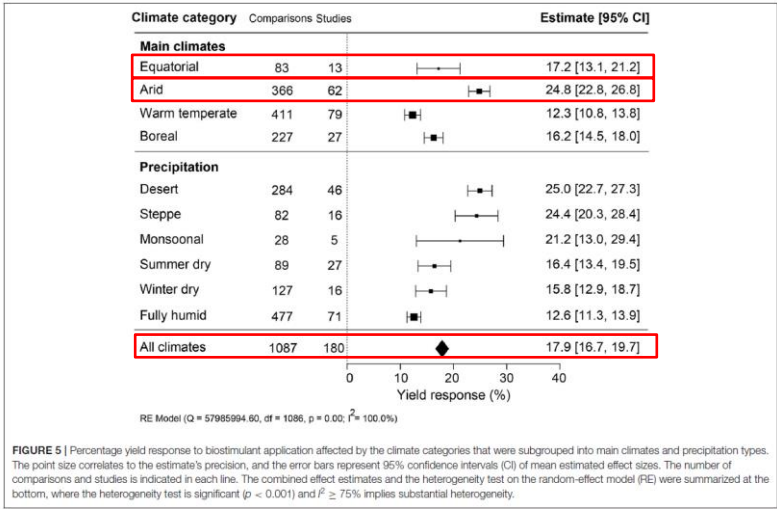
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Superior Performance in Arid and Stressed Conditions

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- **Arid Regions:** Up to **25% yield** boost in drought-prone areas.
- **Equatorial Climates:** Supports resilience in high temperature and humidity.
- **FAO Focus:** Key for food security in vulnerable regions.

Source: Li et al. (2022), *Frontiers in Plant Science*. [Read More](#).



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There are challenges complicating farmers' capacity to use biostimulants effectively

- Effective use is knowledge-intensively requiring training and on-farm calibration
- Access to products remains limited
- Few regulatory frameworks yet recognize these products and help farmers choose reliable products

These challenges are particularly acute for smallholders

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FAO and governments can help farmers use biostimulants effectively

- FAO can support regulatory development through knowledge-sharing, guidelines, and peer-to-peer exchanges
- Governments can put in place appropriate, innovation-friendly regulatory frameworks that are globally aligned so that farmers everywhere have access to similar products on a level playing field
- FAO and governments can support farmer training and partnerships.

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How plant biostimulants are regulated in the EU: the Fertilising Products Regulation



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The Fertilising Products Regulation: Basic aspects

- [Regulation \(EU\) 2019/1009 in the Eur-Lex database](#)
- Adopted on 5 June 2019
- Applicable as of 16 July 2022
- ✓ **Optional harmonisation:** 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



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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
- PCF 2: Liming material
- PCF 3: Soil improver
- PCF 4: Growing medium
- PCF 5: Inhibitor
- **PCF 6: Plant biostimulant**
- PCF 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



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2-step conformity assessment

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 to demonstrate claims)**
- 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

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How conformity assessment differs from registration

Legal requirements defined by government authorities

Authorisation/registration

- Conducted by a **government authority**
- Legal responsibility for the product falls on the **government authority** once the product is authorised/ registered
- **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**

Conformity assessment

- An **accredited private entity** verifies if a product meets the essential quality and safety requirements listed in the regulation
- **Standards**, developed in a multistakeholder process, **define methodologies** allowing presumption of conformity
- Legal responsibility for the product and its effects remain solely with the **manufacturer** under market surveillance
- **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

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Standards are developed in a multistakeholder, expert context

Technical Committee 455 on Plant Biostimulants brings together academics, regulators, laboratories, regulatory consultants, industry representatives, consumer and environmental representatives, and other interested parties to develop standards on key parameters:

- 33 standards so far
- Working Group (WG) 1 – Sampling
 - WG 2 – Claims
 - WG 3 - Pathogenic and non-pathogenic microorganisms
 - WG 4 - Other safety parameters
 - WG 5 - Labelling and denominations

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5 European standards are about to be published* on justifying plant biostimulant claims

These standards provide guidance for a consistent approach to **justify the claims** associated with the use of plant biostimulants in agriculture, focusing on the specific context of placing products on the market

- FprCEN/TS 1770-1: **General principles**
- FprCEN/TS 1770-2: **Nutrient use efficiency**
- FprCEN/TS 1770-3: **Tolerance to abiotic stress**
- FprCEN/TS 1770-4: **Determination of quality traits**
- FprCEN/TS 1770-5: **Availability of confined nutrients**

* Preliminary texts are already available in the form of **Technical Specifications (TS)**, the term used by the European Committee on Standardisation for methodologies that have not yet undergone interlaboratory testing

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The regulatory boundary between plant biostimulants and plant protection



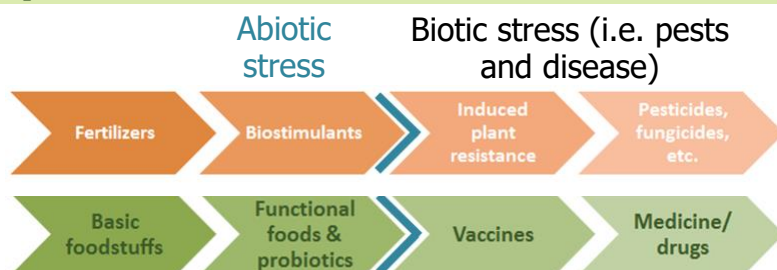
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The FPR drew a boundary between plant biostimulants and plant protection



FPR amended the EU definition of a plant protection product in Regulation 1107/2009 to explicitly exclude plant biostimulants from the EU definition of plant protection products.

*"This [plant protection] Regulation shall apply to products...**intended for one of the following uses**:...influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient **or a plant biostimulant**".*



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The European definition, anchoring plant biostimulants in a wider concept of plant nutrition and soil fertility has been widely adopted across the globe

The following jurisdictions have either adopted or are considering definitions in line with the European definition: **Argentina, Canada, Chile, China, Ecuador, India, Mexico, USA, and the International Organization for Standardization (ISO).**

The notable exception is Brazil, where this definition exists alongside a "second group" of biostimulants under plant protection rules that correspond to plant defence elicitors.



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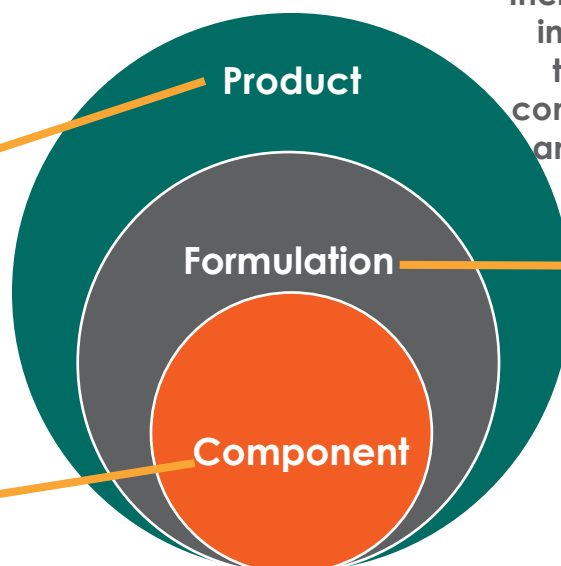
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Differences between Component, Formulation, and Product

Regulation applies at the level of the Product Level and not one of its component parts:

Preparation + application rate + timing + target crops + other relevant parameters

Could be involved in different functions in different products



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

Clarifying Product Function and Regulatory Scope

- European regulation clearly distinguishes between the '**function**' of a product and the '**effects**' of substances that may be contained therein.
- As articulated in **COMMISSION DELEGATED REGULATION (EU) 2021/1768** of 23 June 2021, which amends Regulation (EU) 2019/1009:
 - "An EU fertilising **product** may contain an active **substance** within the meaning of Article 2(2) of Regulation (EC) No 1107/2009 only if that EU fertilising product does not have a **plant protection function** within the meaning of Article 2(1) of that Regulation."

So what is the function of a plant protection products under EU Regulation?

The scope of the Plant Protection Products Regulation (Regulation (EC) No 1107/2009), says it "shall apply to **products, in the form in which they are supplied to the user...and intended for one of the following uses**"

- Protecting plants or plant products against harmful organisms
- Influencing the life processes of plants other than as a nutrient or a biostimulant
- Preserving plant products, provided the substance is not classified as a preservative under special Community provisions
- Destroying or preventing the growth of undesired plants, except in certain exempt cases

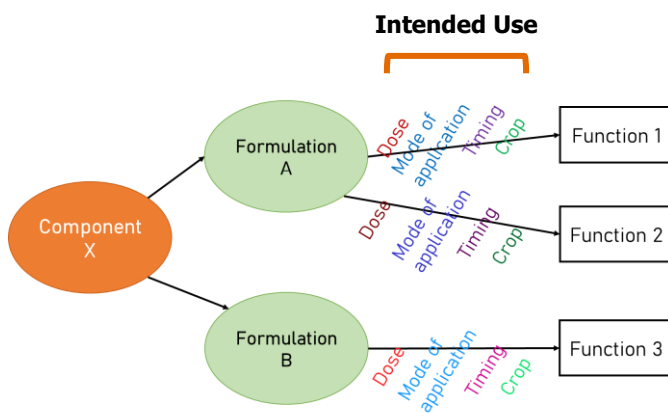


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The multiple-use principle

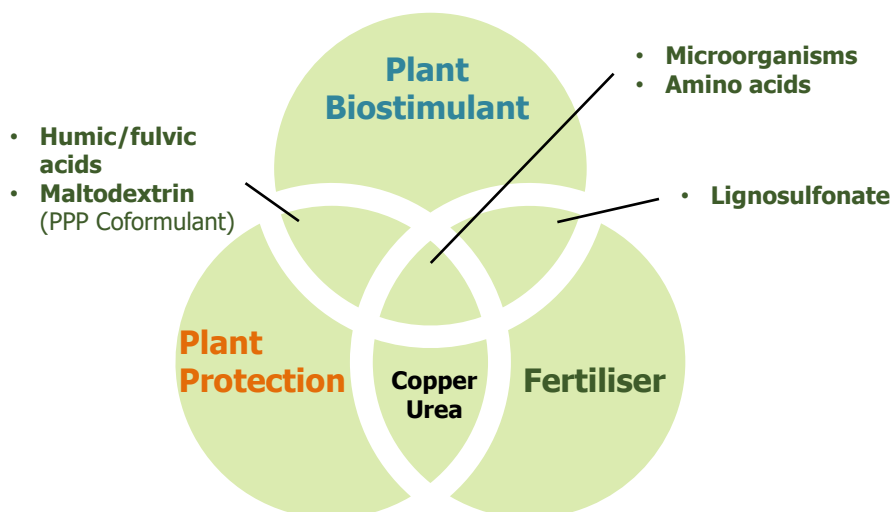
The **same component** (e.g. seaweed extracts, hydrolysed proteins, microorganisms, etc.) can be used **in different products** that fulfill **different functions** and therefore may be regulated under different frameworks



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Examples of multiple-use ingredients in agriculture



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Recognition and Regulation of Multiple Use Substances

Regulatory Recognition:

- Multiple use substances/organisms are recognised in EU Fertilising Products Regulation 1009/2019.
- Explicitly recognised in the [FAQ](#) for EU FPR 1009/2019.

Product-Level Focus:

- ➔ **The FPR defines function at the product, not component, level.**

Supporting Innovation:

- This approach fosters innovation while ensuring safety and effectiveness.
- Conformity assessments and market surveillance prevent misuse and uphold regulatory integrity.

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Follow the Claim - It Determines the Classification

- **The Claim is the Key:**

- Regulation follows claims, **not incidental effects** of the product and/or its components

- **Dual Claims lead to PPP:**

- A product with multiple use claims (e.g., **both biostimulant and plant protection**), it must be regulated as a **PPP**.

- **Avoiding Confusion:**

- Focus on what the product is claimed to do, not what its components may be observed to do in other contexts.

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Ensuring Compliance & Coordination

Conformity Assessment:

- Ensure products meet essential safety and quality requirements and comply with their **intended use** as stated on the label.
- Supporting documentation (e.g., historical data, studies) backs the claims, without requiring testing to prove the absence of a PPP effect.



Market Surveillance & Enforcement:

- Ensure products comply Market surveillance officers, with cooperation from national authorities and manufacturers, enforce off-label use.
- Coordination with frameworks like PPPR is key to maintaining regulatory integrity

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Preventing Off-Label Use

Maintaining Regulatory Integrity

- Off-label use is inappropriate and managed through **market surveillance**.
- **EBIC**: Off-label plant protection use of non-authorised products is unethical and forbidden by our Code of Conduct.
- **Key Approach**: Product claims must be clear, supported by robust data, and reviewed during the **conformity assessment process** to prevent misuse.

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Conclusions



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The right regulation can foster farmer access to vital tools for improving nutrient use and tolerance to abiotic stress

Intended use and claims determine plant biostimulant classification

- Components (seaweed extracts, hydrolysed proteins, microorganisms, etc.) can be used in different products to fulfil different plant biostimulant, fertilizer, or plant protection functions.

Fostering innovation and enhancing farmer toolboxes

- Being able to **combine components** in different formulations to fulfil different product functions is crucial for **innovation**.

Key Principle

- **Products with one or more functions**, one of which is covered by the scope of Regulation (EC) No 1107/2009, are plant protection products, but the absence of any PPP effect for a product's components is not a useful condition for determining that a product is a fertilising product.

Market Surveillance:

- **Ongoing market surveillance** ensures products are used in accordance with their **intended use** and claims, preventing off-label use and maintaining regulatory integrity.

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By fostering global collaboration, FAO can help plant biostimulants contribute meaningfully to helping farmers cope with climate change and improve food security



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Resources

- [Regulation \(EU\) 2019/1009 in the Eur-Lex database](#)
- [FAQs](#) related to Regulation (EU) 2019/1009 on fertilising products, Question 1.3
- [EBIC's position paper on multiple-use components in plant biostimulants](#)
- www.biostimulants.eu

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[Prospero & Partners](#) provides the secretariat of the European Biostimulants Industry Council



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