



Regulatory framework of plant protection products and biostimulants

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From soil to life

Triferto
FERTILIZERS



Triferto - active in the fertilizer market since 1899

Commodities

Blends

Specialty products

From soil to life

Triferto
FERTILIZERS

Why registration?

Why regulation matters

- Protection of human health and the environment
- Scientific assessment of risks and benefits
- Credibility of products and claims
- Facilitation of trade and innovation

Regulation defines the boundary between science and market

The products

Two distinct product concepts

Biostimulants

- Act on plant metabolic processes
- Indirect effects on plant performance
- No direct action on pests or pathogens

Plant Protection Products (PPP)

- Direct action against pests, diseases and weeds

Different biological targets → different regulation

EU definitions #1

What is a biostimulant? (EU definition)

A biostimulant is a product that:

- Stimulates plant metabolic processes
- Independently of nutrient content (not a fertilizer)
- Improves (examples):
 - Nutrient use efficiency
 - Tolerance to abiotic stress
 - Quality traits
 - Nutrient availability in soil or rhizosphere

Excludes pest and disease control

EU Definitions #2

What is a Plant Protection Product?

A Plant Protection Product is intended to:

- Protect plants or plant products against harmful organisms (fungicides, insecticides)
- Influence plant physiological processes (e.g. growth regulators)
- Preserve plant products (e.g. 1-MCP)
- Destroy or prevent growth of unwanted plants (herbicides)

Claim determines regulatory status

EU Legal framework – Biostimulants

Fertilizing Products Regulation (EU) 2019/1009

- Fully applicable since July 2022

Key elements:

- Product-based regulation
- CE marking for EU market access
- Safety, quality and claims control

No classical “registration” procedure

EU Legal framework – PPP

Regulation (EC) No 1107/2009

Core principles:

- Precautionary principle
- Risk-based assessment

Two-level system

- Active substances assessed at EU level (EFSA)
- Products authorized at Member State level

Highly structured and science-intensive

Degree of harmonization in the EU

Biostimulants

- Two possible routes:
 - EU route (CE marking under FPR)
 - National fertilizer legislation
- Market access still partly fragmented

PPPs

- Only EU regulatory pathway
- No national alternatives
- Fully harmonized system

Key difference in regulatory maturity

Data and scientific requirements

Biostimulants

- Safety-focused assessment
- Limited agronomic evidence
- No formal efficacy evaluation

PPPs

- Mandatory efficacy trials
- Extensive toxicology, residues and ecotoxicology
- Full risk assessment

Reflects different risk profiles

Time to market in the EU

Biostimulants

- Typically 6–18 months

PPPs

- Typically 5–7 years

Regulatory complexity scales with biological risk

Biostimulants outside the EU

United States

- No federal regulation
- State-level approaches

Brazil

- National framework under development
- Increasing alignment

Asia

- Country-specific systems
- Often regulated as fertilizers

High global heterogeneity

PPP regulation outside the EU

United States

- Federal registration (EPA)

Brazil

- Joint evaluation (MAPA, ANVISA, IBAMA)

Asia

- National authorities
- Variable data and timelines

Scientific principles similar, implementation differs

Biostimulants vs PPPs: summary

Aspect	Biostimulants	PPPs
Biological target	Nutrition & stress	Pests & diseases
EU framework	FPR 2019/1009	Reg. 1107/2009
Harmonisation	Partial	Full
Data requirements	Limited	Extensive
Time to market	Short	Long

Take home messages

Implications for research and innovation

- Early definition of product claims is critical
- Scientific evidence must match regulatory category
- Innovation may be constrained by regulatory scope
- Increasing interaction between research and regulation

Regulation influences research directions

Conclusions

- Biostimulants and PPPs address different biological questions
- EU PPP regulation is fully harmonized and risk-driven
- EU biostimulant regulation is newer and still evolving
- Understanding regulation is essential for translating science into products

Thank you for your attention!