European Biostimulants Industry Council

Ensuring the safety of plant biostimulants under the Fertilising Product Regulation

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EFSA STaDG-ER 7-8 June 2023

EUROPEAN FOOD SAFETY AUTHORITY

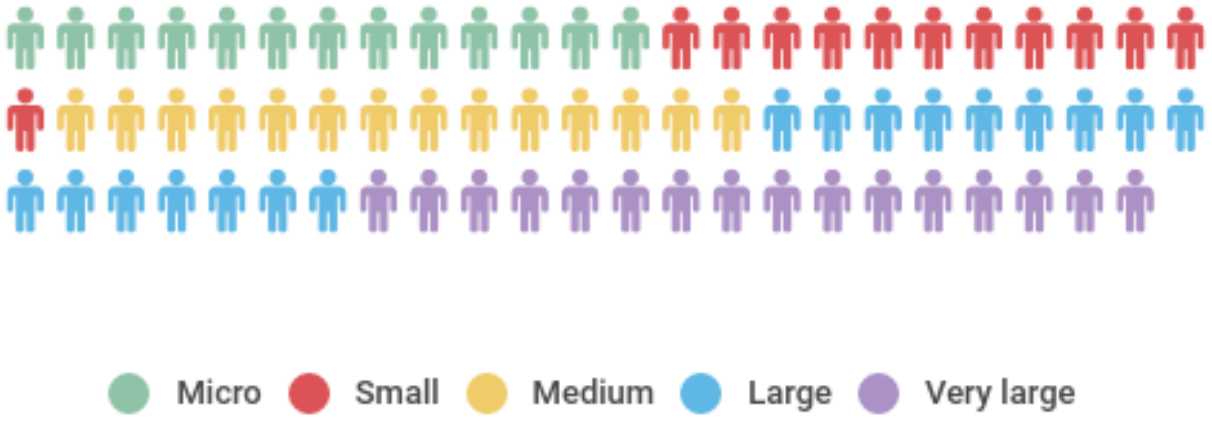
Outline of content

- About us (EBIC & Prospero)
- What are Plant Biostimulants (PB)?
- How are Plant Biostimulants regulated?
- Conclusion

European Biostimulants Industry Council (EBIC)

71 member companies

Breakdown by size (based on global turnover and headcount)



As of March 14, 2023

Mission: To ensure biostimulant technologies are valued as **integral to sustainable agriculture**, while securing an **enabling regulatory framework** for all of them.

The Secretariat of the **European Biostimulants Industry Council (EBIC)** is provided by **Prospero & Partners**, an independent consultancy that works at the interface between technological innovation, public policy, stakeholder relations and organizational development. Prospero applies this human-centred approach to spaces such as:

Bio-based innovation

Food and Agriculture

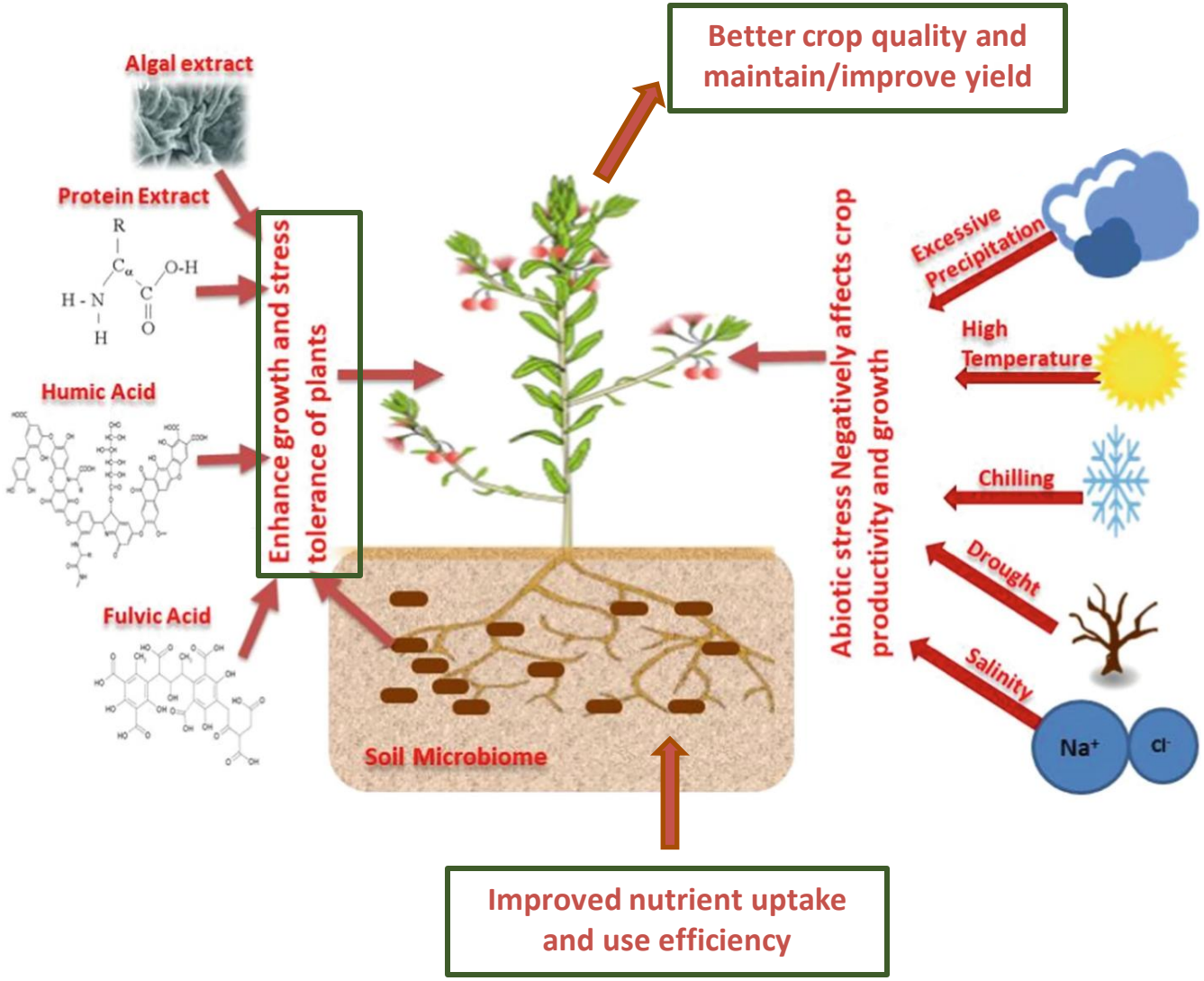
Healthcare and well-being

Environmental security and sustainability

Energy and climate.

European Biostimulants Industry Council

What are plant biostimulants?



- Plant biostimulants are **defined by their function**, not by their composition
- Components of plant biostimulants can 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

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

How are plant biostimulants regulated?

The Fertilising Products Regulation

- ✓ **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

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

How does FPR apply to biostimulants?

PFC 6: Plant biostimulants

"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 biostimulants

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

When the FPR was adopted in 2019, it modified the definition of the PPP regulation to exclude plant biostimulants

Article 2

Scope

1. This Regulation shall apply 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:

(a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;

▼M6

(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant;

A different path to get products to market

Authorisation/registration (PPPR)

- Conducted by a **government authority**
- **Guidelines and requirements** defined by government authorities
- 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 comply to the requirements defined by **authorities**

Conformity assessment (FPR)

- Conducted by a **private entity** that has become accredited
- **Standards** are elaborated by transparency, consensus of relevant stakeholders and after approval according to the CEN process
- Legal responsibility for the product and its effects remain solely with the **manufacturer** with 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

What safety data are required?

Some of the Component Material Categories (CMCs) rely on REACH for safety data

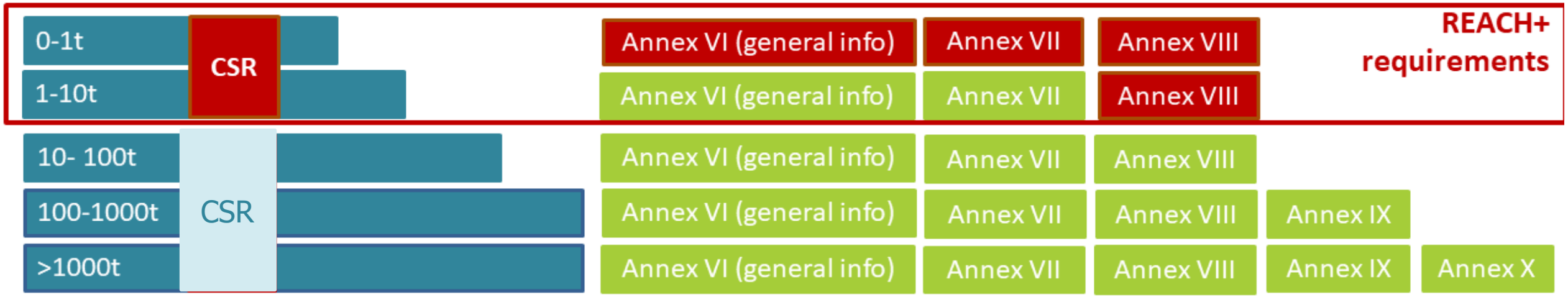
- **CMC 1**: Virgin material substances and mixtures
- **CMC 3**: Compost (additives)
- **CMC 4**: Fresh Crop Digestate
- **CMC 5**: Digestate other than fresh crop digestate
- **CMC 6**: Food industry By-Products
- **CMC 11**: By-products within the meaning of directive 2008/98/EC

However, the REACH requirements are reinforced in the FPR!

REACH → **REACH+**

The REACH requirements applied in the FPR are stricter than the normal REACH requirements

REACH+ requirements in the Fertilising Products Regulation versus normal REACH requirements in Reg (EC) 1907/2006



REACH+ in FPR does not recognize the registration exemption in Regulation (EC) 1907/2006, Annex V, point 4.

Chemical Safety Report & Exposure Scenario

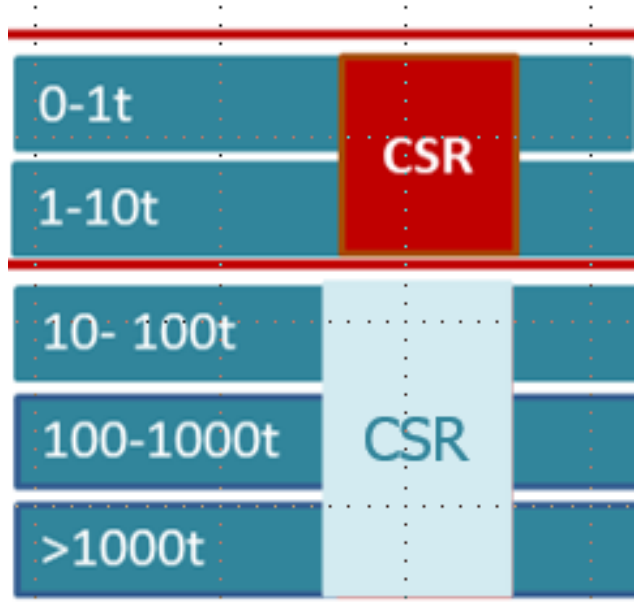
The **chemical safety report** documents the chemical safety assessment undertaken as part of the REACH registration process, and is the key source from which the **registrant provides information to all users of chemicals through the exposure scenarios**. It also forms a **basis for other REACH processes including substance evaluation, authorisation and restriction.**

The chemical safety assessment is carried out to **demonstrate that the risks from the exposure to a substance, during its manufacture and use, are controlled when specific operational conditions and risk management measures are applied.** These conditions of use of a substance constitute the **exposure scenario**, which is an essential component of the chemical safety report.

Source: Chemical safety report - ECHA (europa.eu)

REACH+ requirements

REACH requirements



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Chemical Safety Report - content

The elements to be included in the chemical safety report are listed in Annex I, section 7 of REACH Reg. 1907/2006.

PART A

1. Summary of risk management measures
2. Declaration that risk management measures are implemented
3. Declaration that risk management measures are communicated

PART B

1. Identity of the substance and Phys-Chem properties
2. Manufacture and uses
3. Classification & labelling
4. Environmental-Fate properties
5. Human Health Hazard Assessment
6. Human Health Hazard Assessment of Phys-Chem Properties
7. Environmental Hazard Assessment
8. PBT and VPVB assessment
9. Exposure assessment
10. Risk characterisation

Degradation, Environmental distribution, Bioaccumulation, Secondary poisoning

Toxicokinetics, Acute tox, Irritation, Corrosivity, sensitisation, Repeated dose toxicity, Germ cell mutagenicity, Carcinogenicity, Tox for reproduction, Others effects, Derivation of DNEL(s)

Explosivity, Flammability, Oxidising potential

Aquatic, Terrestrial, Atmospheric compartment
µbiological activity in sewage treatment system

Additional safety requirements apply at the product level

Microbial PB - PFC6(A)

Contaminant must not exceed **limit** values for:

- Ca, Cr VI, Pb, Hg, Ni, As, Cu, Zn

PB shall have the effects that are claimed on the label for the plants specified thereon

Microbial PB - PFC6(B)

Contaminant must not exceed **limit** values for:

- Ca, Cr VI, Pb, Hg, Ni, As, Cu, Zn

Pathogens must not exceed **limits** set out for:

- *Salmonella, E. coli, Listeria monocytogenes, Vibrio spp., Shigella spp., Staphylococcus aureus, Enterococcaceae,*

Anaerobic plate count unless the microbial plant biostimulant is an aerobic bacterium

Yeast and mould count unless the microbial plant biostimulant is a fungus

Conclusion

- Plant Biostimulant are now regulated by the FPR
- Plant biostimulants are not under the EFSA scope
- Safety requirements are articulated according to the specific CMC & PFC to ensure high levels of protection in a proportionate manner

Thank you for your attention

For more information:

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