



Proposal for a revised Fertilising Products Regulation

An update on the proposed Biostimulants Regulatory process in Europe

**Advisory Group Food Chain and
Animal and Plant Health**

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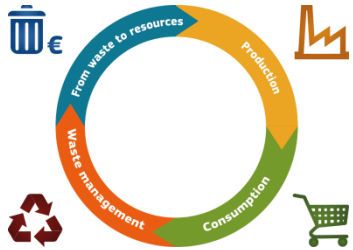
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First part – some reminders

Regulation proposal

- **Commission proposal adopted on 17 March 2016: COM(2016) 157 final**
- **On-going co-legislative process with Council and European Parliament**



The objectives of Fertilising Products Regulation Proposal

- To create a level playing field between all fertilising products
- To better protect health and environment
- To facilitate nutrient recovery and reduce dependency from critical raw materials: make fertilisers industry more sustainable
- To reduce administrative burden and legal uncertainties (e.g. type listing, wastes status, animal-by-products status, overlap with PPP ...)

A few basic principles to be reminded

- Optional harmonisation
- New legislative framework
- Safety and Environmental performance
- Dynamics and adaptability of the proposal

1. Definitions

- *Article 1: apply to CE-marked fertilising products, **NOT** to Plant Protection Products covered by Reg 1107/2009*
- *Article 2:*
 - (1) **'fertilising product'** means a substance, mixture, micro organism or any other material, applied or intended to be applied, either on its own or mixed with another material, on plants or their rhizosphere or on fungi or their mycosphere for the purpose of providing plants or fungi with nutrient or **improving their nutrition efficiency**;
(..)

1. Definitions (2)

- *Annex 1: PFC 6 – 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 :*
 - **(a) nutrient use efficiency;**
 - **(b) tolerance to abiotic stress;**
 - **(c) crop quality traits;**
 - **+ (d) availability of confined nutrients in the soil and rhizosphere."**

2. Scope demarcation (exclusion of biostimulants from scope of PPP Reg.)

Article 46: Amendments to Regulation 1107/2009 (PPPR)

(1) Article 2(1) (b) is replaced by the following:

PPP is"influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient or a plant biostimulant;"

(2) Article 3, the following point is added:

"34. "plant biostimulant" means... (same definition as in Fertilising products Regulation)

2. Scope demarcation (2)

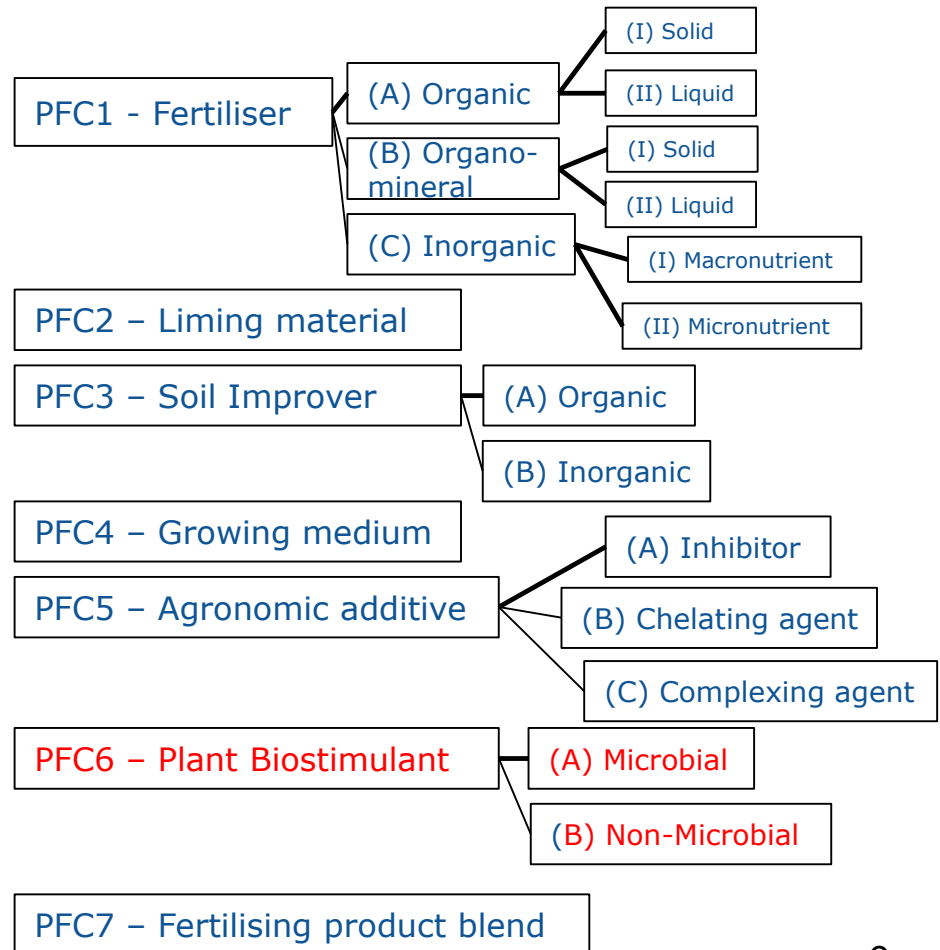
- *In other words, for multiple functions product:*
A PPP shall always be authorised according to the Reg.1107/2009 and may not be CE-marked as a fertilising product.
Otherwise CE-mark would allow free circulation of the product although PPP Regulation requires a national authorisation !



Exhaustive list of component material categories ('CMC')

- CMC 1: Non-polymer virgin materials (REACH)
- CMC 2: Simple plant parts or extracts
- CMC 3: Compost
- CMC 4: Energy crop digestate
- CMC 5: Other digestate
- CMC 6: Food industry by-products
- CMC 7: Micro-organisms
- CMC 8: Agronomic additives
- CMC 9: Nutrient polymers
- CMC 10: Other polymers
- CMC 11: Animal By-products

Exhaustive list of product function categories ('PFC')



3. Requirements for Plant Biostimulants– Annex 1 - PFC6 (2)

- **Safety requirements** through contaminants limits: Cd, CrVI, total Cr, Pb, Hg, Ni, As, Cu, Zn
- **Efficiency** as claimed on the label (guidance needed !)
- **Additional safety requirements for microbials:**

→ Consists of a microorganism or a consortium of microorganisms (= "positive list" in CMC7)

→ Limits for Salmonella, E.coli, Enterococcaceae, Listeria, Vibrio, Shigella,.....

4. Requirements for Component Material Category Annex 2 (2)

- **CMC 6: Micro-organisms**

incl. Dead or empty-cell + production media
dried or freeze-dried
listed in the table:

Azotobacter spp.

Mycorrhizal fungi

Rhizobium spp.

Azospirillum spp.

**Extend the list + criteria for
acceptability**

6. Amendment to Annex 2 – CMC6 **(article 42 §2)**

- **New Micro-organisms:**

- Data requirements: name, taxonomy, historical data of safe production and use, relationship with QPS-ed microorganisms (EFSA), residue level of toxins, production process.

Case by case approach (no standards, no criteria)

➔ New expert group on microbial PB...

Take-away on plant biostimulants

- **New category of fertilising products**
- **Associated to plant nutrition**
- **Distinct from plant protection products**
- **Different mode of action and functionalities, variable group, chemicals and microbials**
=>Not easy to regulate
- **Specific regulatory approach (no standards, no criteria to assess plant biostimulants in particular microbials, but a positive listing, although not authorisation !)**
- **Co-legislative procedure ongoing: everything remains possible !**

**Thank you for your
attention !**



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Background slides

Basic principles of the proposal in more details

1. Optional harmonisation

- Member States may allow other fertilisers on their markets without the CE marking
- Harmonise rules at EU level for products :
 - where scientific consensus exists,
 - where need to freely circulate exists
- Less market disruptive: CE-products compete with national ones

Feedback from co-legislators:

2. The regulatory approach: the New legislative framework

- Generic safety and quality requirements
- Harmonised standards or common specifications
- Conformity assessment procedures
- Flexibility , less administrative costs, adaptability compared to current type-listing or even ingredients listing
- But proposal is not a "straight" NLF as:
 - Exhaustive list of component material categories
 - Administrative control of compliance is not uniform but adapted to level of concern of product/component categories

Feedback from co-legislators:

3. Safety and Environmental performance

- Double safety net : REACH registration (where relevant) + limit values for known contaminants:
 - Concern nr 1 = cadmium :
 - Concerns nr 2 = other chemical contaminants: heavy metals, organic contaminants, microbials, physical impurities (plastics : biodegradability criteria)

Feedback from co-legislators:

4. Dynamics/adaptability of the proposal

- Proposed scope is "limited" to PFCs/CMCs where realistic safety and quality standards available
- Scope will be more and more inclusive (on-going works with JRC, plastic mulches, **plant biostimulants**): mechanisms to adapt the annexes (delegated acts) to technical progress
- If new safety concerns arise, reactivity to new risks (delegated acts), safeguard mechanisms

Feedback from co-legislators:

5, Conformity assessment

Annex IV Part 1:

For plant biostimulants (PFC 6), apply Modules B and C!

The manufacturer chooses a conformity assessment body, notified by an authority of a Member State

The notified body examines technical documentation and a product specimen, and certifies the technical design

The manufacturer ensures that products conform with type examination certificate

Technical documentation and type examination certificate are provided to national authorities upon request