

Biofertilizer/Biostimulant Concept

A European perspective of the development of product concept and definition, and it's implications for product placement in EU regulatory frameworks

Objectives

1. Development of the definition of biofertilizers/biostimulants
 - ▶ Process whereby they have been defined as a discrete class of products, distinct from other product categories
2. Implications of definition for product placement within EU legislations
 - ▶ The importance of definition in developing appropriate regulatory frameworks

Outline

- ▶ Introduction
- ▶ Overview of the development of product concept and definition
- ▶ Official industry definition
- ▶ Significance of definition
- ▶ Implications for product placement in existing EU regulations
- ▶ Revisions to EU fertilizer laws - New Legislative Framework (NLF)
- ▶ Looking forward - take home message

Introduction to biological crop chemistry

- ▶ Gained considerable attention as a new crop chemical segment
- ▶ No longer considered a 'fad' product segment → structural component of the market
 - ▶ Considered one of the most attractive investment segments in the crop chemicals industry

- Piper Jaffray 2014 - Industry Note on Biological Crop Chemistry

- ▶ Both drivers and barriers for growth are varied and multiple
 - ▶ Factors that affect the biologicals industry as a whole, as well as factors specific to each product sub-category

Today's focus: Plant nutrition products → Biofertilizers

- ▶ Other terms: biostimulants, metabolic enhancers, phytostimulators, plant elicitors, biogenic stimulators....etc.
- ▶ The term biofertilizers in South Africa = biostimulants in Europe
- ▶ To draw on the European scenario: refer to biofertilizers as biostimulants for the remainder of this discussion

Key barrier: Definition of product segment

- ▶ Large variability in terminology and definition of this product segment
- ▶ Negative implications for market development
 - ▶ Market information
 - ▶ Product registry
 - ▶ Industry validation
 - ▶ End-user acceptance/mistrust
 - ▶ **Regulatory frameworks** that distinguish these products from existing legislative product categories

Development of the biostimulant definition

- ▶ Currently there is no regulatory or legally-accepted definition of biostimulants
- ▶ In 1997, the term was first used in a web journal for turf professionals (*Ground Maintenance* <http://grounds-mag.com>)

“materials that in minute quantities promote plant growth”

- Zhang and Schmidt, 1997

- ▶ In 2007, the term was first defined in scientific literature:

“Biostimulants are materials, other than fertilizers, that promote plant growth when applied in low quantities”

- Kauffman et al. 2007

- ▶ Over the years used to describe an ever-wider range of substances
 - ▶ Descriptor of any substance beneficial to plants without being a fertilizer, PPP or soil improver
 - Calvo et al., 2014; du Jardin, 2012; Halpern et al., 2015
- ▶ Commercial imperative to clarify the status of biostimulants & rationalise them as a discrete class of products

Clarify the status of biostimulants

Step 1: Component-oriented approach

- ▶ Literature reviews to identify, list & categorize substances covered by the concept
- ▶ Many diverse materials, variable, and/or poorly characterized composition
- ▶ 7 widely accepted biostimulant component categories
 - ▶ Substances
 - ▶ Humic acids/fulvic acids
 - ▶ Protein hydrolysates and N-containing compounds
 - ▶ Seaweed extracts and botanicals
 - ▶ Chitosans and other biopolymers
 - ▶ Inorganic compounds
 - ▶ Micro-organism

- ▶ Beneficial fungi
- ▶ Beneficial bacteria



Biofertilizers

Biofertilizers may also be defined as microbial biostimulants improving plant nutrition efficiency'

- Du Jardin 2015

'A biofertilizer is any bacterial or fungal inoculant applied to plants with the aim to increase the availability of nutrients and their utilization by plants, regardless of the nutrient content of the inoculant itself'

- Du Jardin 2015

The rationale for adopting the term biofertilizer is that it derives from "biological fertilizer", that, in turn, implies the use of living microorganisms

- Malusá and Vassilev 2014

Step 2: Outcomes-oriented approach

- ▶ Literature reviews to collect, describe and categorized positive effects of biostimulant applications
- ▶ Descriptions were multiple and on many scales
 - ▶ Cellular, physiological, agronomic, environmental and economic
- ▶ However, effects of applications on measurable crop performance only, can be categorized into a discrete set of agronomic outcomes
 - ▶ e.g. Growth promotion, modification of development, improved quality traits and enhanced tolerance to stress

Results: Common features of biostimulants

Laying down a science-based foundation for a definition

1. The nature of biostimulants are diverse

- ▶ Substances and/or micro-organism; single or groups of compounds; from single or multiple sources

2. Physiological functions are diverse

- ▶ Diverse mechanisms of action in the plant on a cellular and physiological level e.g. protection of photo-machinery, ROS scavenging, hormone regulation/modification, root growth etc.

3. However, scientifically demonstrated effects of biostimulants converge into at least one or several of a discrete set of agronomic targets

- ▶ Enhanced nutrition, enhanced tolerance to stress & improved crop quality traits
- Du Jardin, 2015

Official European industry definition

- ▶ Proposed by European Biostimulant Industry Consortium

“Plant biostimulants contain substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality.”

Significance of definition (1)

“Plant biostimulants contain substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality”

1. Definition focuses on agronomic outcomes of application

- ▶ This is the crux of the definition: the outcomes distinguish biostimulants as a discrete product category
 - ▶ Nutrient efficiency - nutrient mobilization, nutrient uptake from the soil, root development, N fixation, transport, storage and assimilation ...
 - ▶ Abiotic stress - enhanced tolerance to physical or chemical stressor of non-biological origin such as drought, salinity, cold...
 - ▶ Quality traits - can include a diverse range of outcomes such as enhanced nutritional value, grain protein content, shelf life, coloration, ripening uniformity...
- ▶ Distinct from PPPs so ‘biotic stress’ has not been included in the scope of the definition

Significance of definition (2)

“Plant biostimulants contain substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality.”

2. Components of a biostimulant product are not restricted

- ▶ Use of the word «substance»
- ▶ Single compound, group of compounds, variable, poorly characterized or of unknown chemical composition
- ▶ Congruent with the use of the word «substance» in other EU legislation
 - ▶ REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) (EC No 1907/2006)
 - ▶ *‘UVCB substances (substances of unknown or variable composition, complex reaction products or biological materials) may be registered as a single substance under this Regulation, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification’*

Significance of definition (3)

“Plant biostimulants contain substance(s) and/or micro-organisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to enhance/benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and crop quality.”

3. A biostimulant is a final finished product

- ▶ Recognition of multi-component nature of biostimulants
- ▶ Importance of the formulate in a commercial context
- ▶ Enforces confidentiality, protection of intellectual property, and industry innovation

Implications of definition for product placement in existing EU regulatory frameworks

- ▶ EBIC definition has not yet been yet been legally recognized
- ▶ No distinct product placement in current EU legislation
- ▶ Biostimulants can be placed on the EU market by one of two routes:
 1. National fertilizer laws of each member states in the EU
 2. European law for PPPs (EC No 1107/2009)

EU Regulation of PPPs (EC 1107/2009)

- ▶ National and supranational provisions
- ▶ Very broad definition of PPP

Article 2

'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) (...)

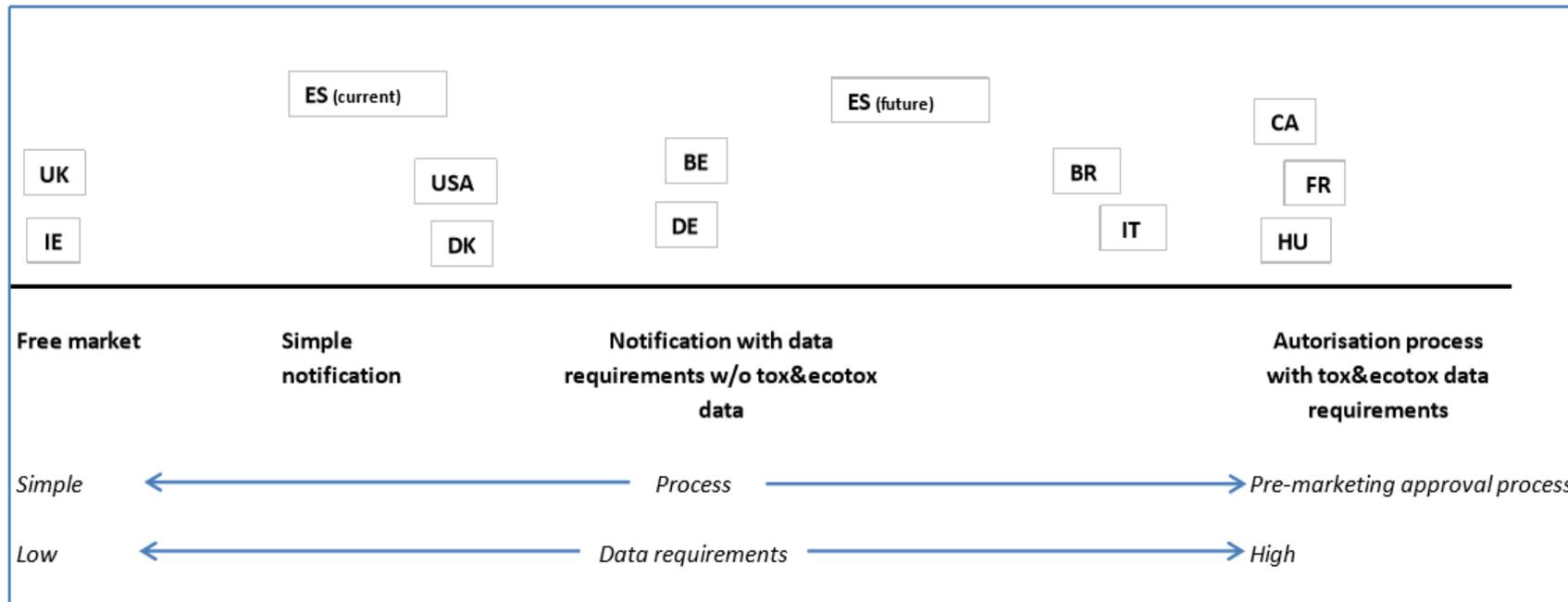
(b) *Influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient.'*

- ▶ PGRs & herbicide in the EU are registered under this framework
- ▶ Costly & lengthy

National fertilizer laws of EU member states

- ▶ Very large differences in national fertilizer laws

Figure 2 EU & TC regulatory processes for placing of PB (and AFA) on the market



Source: compiled by Arcadia International

EU fertilizer legislation (EC 2003/2003)?

Not possible: the definition of fertilizers laid down in the regulation is too restrictive

Article 2 of EC 2003/2003

'For the purposes of this Regulation the following definitions shall apply:

(a) 'Fertiliser' means material, the main function of which is to provide nutrients for plants.

(b) 'Primary nutrient' means the elements nitrogen, phosphorus and potassium only.

(c) 'Secondary nutrient' means the elements calcium, magnesium, sodium and sulphur.

(d) 'Micro-nutrients' means the elements boron, cobalt, copper, iron, manganese, molybdenum and zinc essential for plant growth in quantities that are small compared with those of primary and secondary nutrients.'

- ▶ Not appropriate for biostimulants & many other fertilizer products
 - ▶ 50% of fertilizer products on the market are not covered by the regulation
- ▶ 2 issues:
 - ▶ EC 2003/2003 does not cater for the needs of EU fertilizer market
 - ▶ There is a need to create EU laws that make provisions for all fertilizer categories (including biostimulants) for an effective internal market

Revisions to EC 2003/2003

- ▶ In 2010: the European Commission (EC) commits to reform EC 2003/2003
- ▶ In 2015: revisions are fast-tracked as fertilizers are included in the EU 'Circular Economy' action plan
- ▶ In 2016: EC releases the first draft
- ▶ Revisions have taken the form of a completely **New Legislative Framework (NLF)**
 - ▶ Innovative: hybrid/building-block legal model
 - ▶ Product registration must simultaneously be considered according to two categories
 1. A Component Material Category
 2. A Product Function Category.

New legislative framework (NLF)



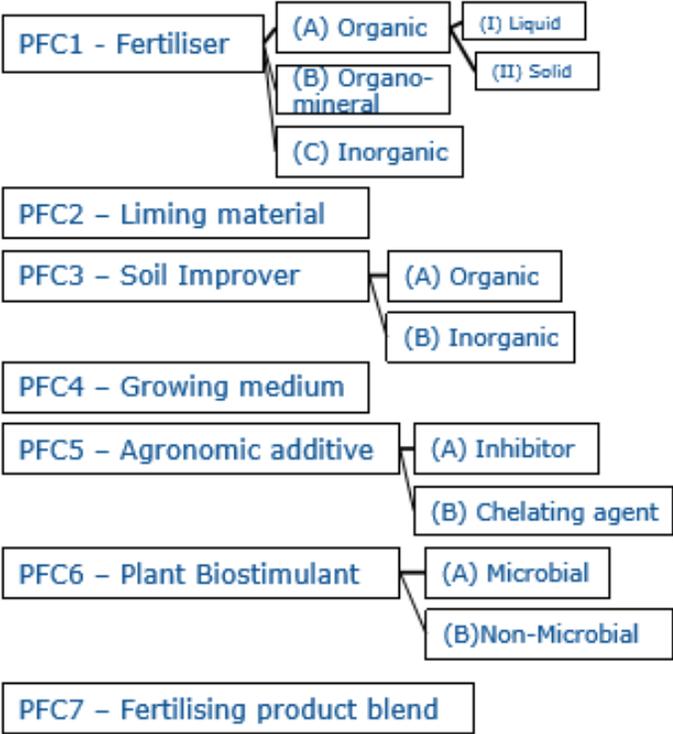
A CE fertiliser is composed of...

Component Material Categories

- CMC1 Virgin material
- CMC2 "Simple extracts"
- CMC3 Compost
- CMC4 Energy Crop Digestate
- CMC5 Other digestates
- CMC6 Food industry by-products
- CMC7 Microorganisms
- CMC8 Agronomic Additives
- CMC9 Biodegradable polymers
- CMC10 Animal By-products
- CMC11 Nutrient polymers

A CE fertiliser belongs to...

Product Function Categories

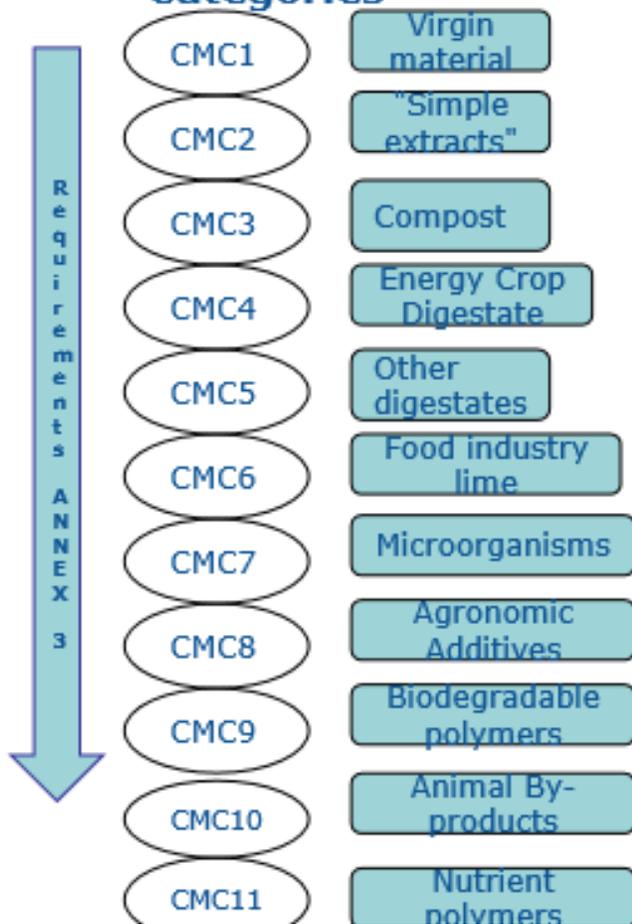




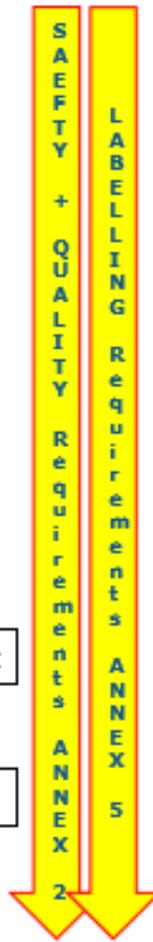
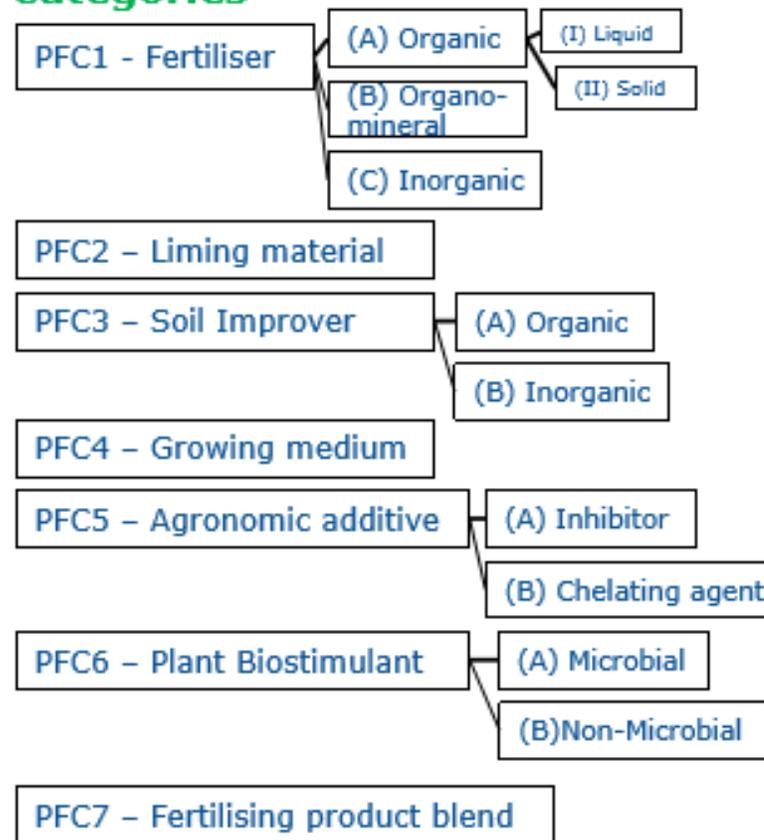
European Commission

A CE fertiliser shall meet the requirements...

Component Material Categories



Product Function Categories



Achievements for biostimulants

1. Biostimulants are included in NLF: new definition of fertilizers
 - ▶ Overview of nutrition market in EU
2. Biostimulants have a distinct place in the framework
 - ▶ Product function category 6
3. Must have a legally recognized definition
 - ▶ Definition proposed by industry has been largely accepted
4. Amendment of PPP Reg. (EC 1107/2009) will exclude biostimulants

Article 2 (1) (b) will be replaced by the following '*Influencing the life processes of plants, such as substance s influencing their growth, other than a nutrient or plant biostimulant*'

6. Other: technically valid and practical legislation
 - ▶ Use of existing legal frameworks (e. g. REACH)
 - ▶ Component Material Categories (CMC) make provisions for nature of biostimulant products, recognition of biostimulant as a finished product etc.

Uncertainties for biostimulants

1. Efficacy trials
 - ▶ A range of outcomes
 2. Issues regarding product claims
 3. Many uncertainties on micro-organisms
 4. Dual-use products
 - ▶ How to make distinguish the dual nature of products
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- ▶ Discussions on the EC draft proposal for NLF are still on-going
 - ▶ More revisions and amendment
 - ▶ Final version in 2018? – 8 years after initial commitment to revise
 - ▶ Challenging, lengthy & costly process

Looking forward: take home message

1. The right definitions are the foundation for everything
 - ▶ The bedrock of any regulation as it defined the products but also the terms of its use
 - ▶ Utility and relevance of laws e.g. EU fertilizer and PPP regulations
2. Analysis of other definitions and pre-existing frameworks
 - ▶ National MS laws
 - ▶ Frameworks in other industries: suitability for assessment, data sharing, history of use...
3. In depth evaluation of the industry - context-specific regulatory framework
 - ▶ Background studies to help support the case for defining and implementing laws
 - ▶ Nature of the market, business environment, characterization of companies, growth forecast (e.g. no. of requests per year etc.), product innovation etc.
4. Transparency and multi-stakeholder engagement by EC
5. Strong industry associations
 - ▶ Common industry voice, objectives & coordinated action
 - ▶ High level of involvement - organic producers, consumers, retail chains, chemical manufacturers etc.
6. Get the right footing

End: Thank you for your attention

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