

Placing biostimulant products on the EU market: scientific and regulatory challenges

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This talk

- ✓ Plant biostimulants as a new category of CE-marked fertilising products on the EU market.
- ✓ How to draw a line separating biostimulant products and Plant Protection Products?
- ✓ Which microbial plant biostimulants are covered by the regulation and should be in the future?
- ✓ Validating the claims of biostimulant products is challenging.

Plant biostimulants, as defined by Regulation (EU) 2019/1009 on Fertilising products ('FPR')

*A plant biostimulant shall be 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;

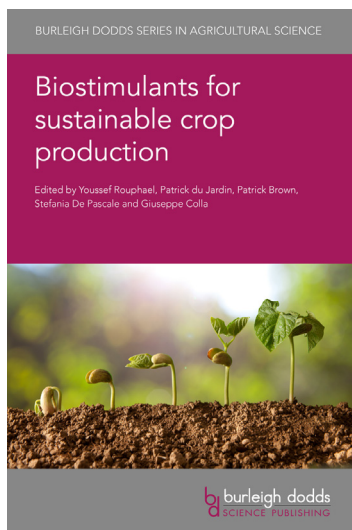
(b) tolerance to abiotic stress;

(c) quality traits; or

(d) availability of confined nutrients in the soil or rhizosphere.

Biostimulant products are defined by 'claims', i.e. by their agricultural functions, not by their composition, not by their modes of action.

From du Jardin, P. in : Rouphael, Y., du Jardin, P., Brown, P., De Pascale, S. and Colla, G. (ed.), *Biostimulants for sustainable agriculture*, Burleigh Dodds Science Publishing, Cambridge, UK, 2020, (ISBN: 978 1 78676 336 5; www.bdsppublishing.com)



Biostimulants

Non-microbial	Microbial
<ul style="list-style-type: none"> • Humic/ fulvic acids • Seaweed/ plant extracts • Protein hydrolysates • Poly-/oligosaccharides • Beneficial minerals • Others 	<ul style="list-style-type: none"> • Rhizobia • Mycorrhiza • Azotobacter • Azospirillum • Others



Treatments

- Foliar spray
- Soil drenching
- Seed coating
- Fertilizer coating
- Fertigation / nutrient solutions



Crops


- Agricultural crops
- Horticultural crops
- Turf-/pasture grass
- Trees nurseries



Claimed functions

- Improved nutrient use efficiency
- Enhanced tolerance to abiotic stress
- Increased crop quality
- Increased yield


Regulation (EU) 2019/1009: a double typology in place



Fertilizing products are defined by:

PRODUCT FUNCTION CATEGORIES	COMPONENT MATERIAL CATEGORIES
PFC 1: Fertilizer A. Organic fertilizer B. Organo-mineral fertilizer C. Inorganic fertilizer	CMC 1: Virgin material substances and mixtures
	CMC 2: Plants, plant parts or plant extracts
PFC 2: Liming material	CMC 3: Compost
PFC 3: Soil improver A. Organic B. Inorganic	CMC 4: Fresh crop digestate
	CMC 5: Other digestate than fresh crop digestate
PFC 4: Growing medium	CMC 6: Food industry by-products
PFC 5: Inhibitor A. Nitrification inhibitor B. Denitrification inhibitor C. Urease inhibitor	CMC 7: Micro-organisms
	CMC 8: Nutrient polymers
PFC 6: Plant biostimulant A. Microbial B. Non-microbial	CMC 9: Other polymers than nutrient polymers
	CMC 10: Derived products within the meaning of Regulation (EC) No 1069/2009
PFC 7: Fertilising product blend	CMC 11: By-products within the meaning of Directive 2008/98/EC

Placing on the EU market of biostimulants and of PPPs: contrasting approaches

Biostimulant products	Plant Protection Products
<u>Verification of compliance of marketed products to relevant legal provisions covered by the FPR</u>	<u>Case by case authorization of active substances & of formulated products</u>
CE-marking  (+ CLP labelling and specific requirements)	CLP labelling and specific requirements
Safety requirements for maximal levels of contaminants	Case by case safety assessment
No mandatory characterization of the modes of action	Modes of action, <i>i.e.</i> primary targets of the active substances, to be characterized.

What if ...

... a substance or microorganism protects against diseases *and* biostimulates plants?

Examples: chitosan, laminarin in/from seaweed extracts, many rhizospheric microorganisms, etc.

How to separate biostimulation and plant protection?

➤ Standpoint of the EU Regulation:

'Products with one or more functions, one of which is covered by the scope of Regulation (EC) No 1107/2009, are plant protection products falling within the scope of that Regulation. Those products should remain under the control developed for such products and provided for by that Regulation.'

But how to understand this?

Should any biostimulant with biocontrol activity be *de facto* excluded from the FPR regulation?

How to separate biostimulation and plant protection?

➤ Standpoint of the EU Regulation:

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No! The key is the understanding of the **‘function’**, which is more than an **‘effect’**.

Shedding some light:
Q&A on the CIRCA website, November 2021 

Q: Does the FPR cover fertilising products containing substances or microorganisms which have a pesticide **effect, such as copper compounds or calcium cyanamide?**

A: *'If a fertilising product, which complies with all requirements set in the FPR, happens to contain a substance or microorganism known to have a pesticidal or other plant protection effect, it could still be covered by the FPR, as long as this fertilising product does not have a pesticidal or other plant protection **function within the meaning of the PPPR.***

Function is described in Article 2 of the PPPR. This does not mean that a substance or a microorganism does not possess any intrinsic pesticide property.'

Function vs. Effect (functionality vs. effectiveness)

Function	Effect
<p>Intended effect of using a product, with specific formulations, application rates and times, for specific crops</p> <p><i>Cfr. Article 2 of Regulation (EC) No 1107/2009: 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:...</i></p>	<p>Consequence of the intrinsic property of a substance or microorganism when applied on any recipient organism</p>
Functionality	Effectiveness
<p>Capacity of a product to fulfil some desired function under specified conditions of use</p>	<p>Intrinsic capacity of a substance or microorganism to affect any recipient organism</p>

Still: can biostimulants contribute to plant health?



Plant Pathology (2012) **61**, 1–15

Doi: 10.1111/j.1365-3059.2011.02501.x

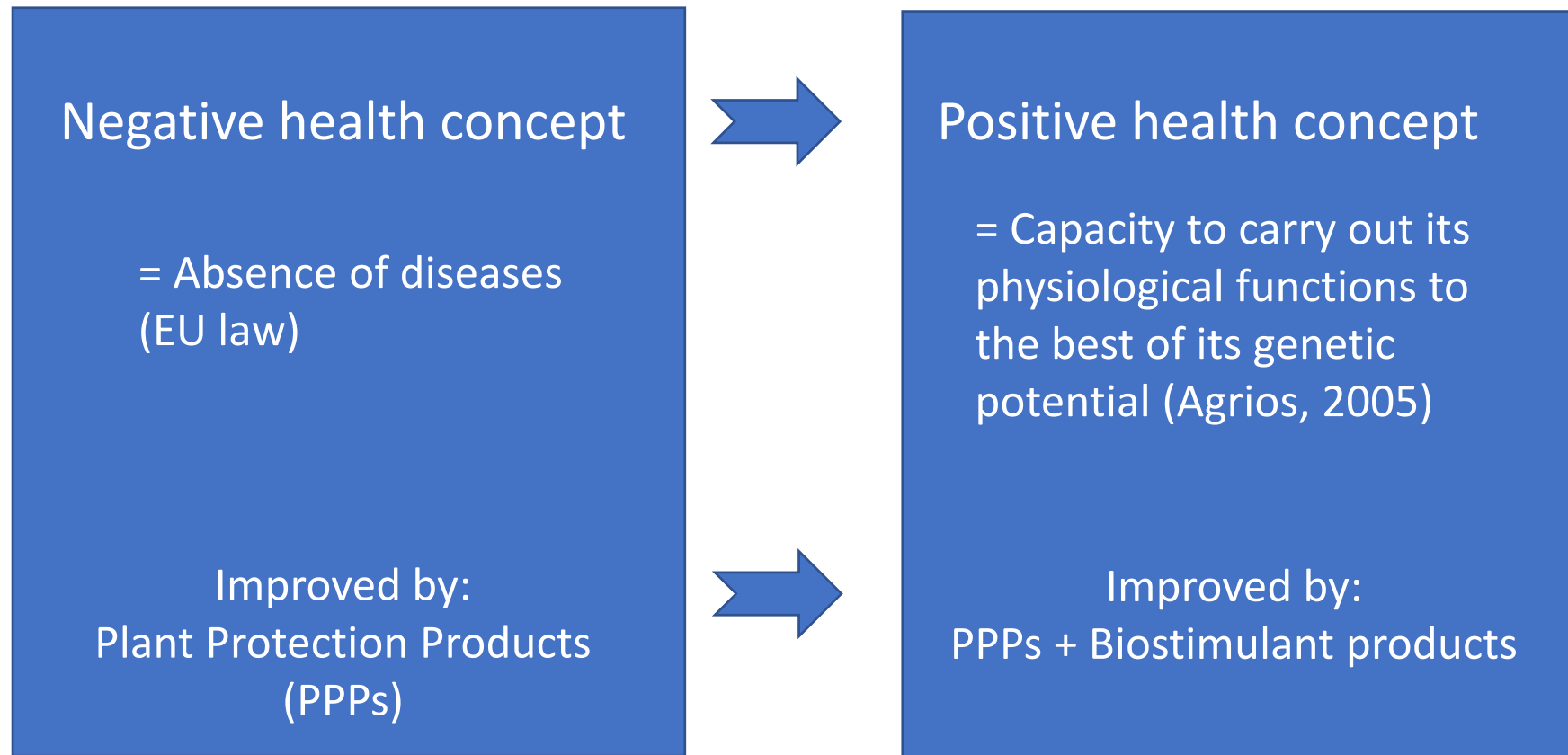
REVIEW

Concepts of plant health – reviewing and challenging the foundations of plant protection

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Still: can biostimulants contribute to plant health?



Which of the negative or positive concepts of Plant Health best fits with the objectives the *Green Deal*?



You know the answer!

Microbial Plant Biostimulants: how to reap the benefits of plant-associated microorganisms?

- PFC 6(A) are '*micro-organism or a consortium of micro-organisms referred to as CMC 7 in Part II of Annex II*' (FPR (EU) 2019/1009)
- CMC 7 (Part II of Annex II) contain: « *Azotobacter* spp., Mycorrhizal fungi, *Rhizobium* spp., *Azospirillum* spp. »

Microbial Plant Biostimulants: Issues

- The positive list of Annex II is ill-defined, under the light of molecular taxonomy.

Entry	Issue
« <i>Azotobacter spp.</i> »	Taxonomy under review: closely related to <i>Pseudomonas</i> , not separable from related genera within <i>Pseudomonaceae</i> .
« <i>Mycorrhizal fungi</i> »	All types included (beyond AMFs)? NB: some produce toxins.
« <i>Rhizobium spp.</i> »	Taxonomy under review: rhizobia contain about 18 genera belonging to alpha- and bêtaproteobacteria.
« <i>Azospirillum spp.</i> »	Taxonomy under review: monophylism established but exclusion of <i>A. irakense</i> .

(After Hendriksen, in press)

Microbial Plant Biostimulants: Issues

- The positive list of Annex II is ill-defined.
- How to expand the positive list of Annex II?
 - Criteria set by FPR (EU) 2019/1009:
 - ✓ **General criteria for delegated acts** by the COM (Article 42(1) of the FPR): Potential to be the subject of **significant trade** on the internal market (otherwise: should stay under MS laws!)
 - ✓ **Specific criteria**: to verify **which strains** of the additional micro-organism are **safe** for health and the environment as well as **agronomically efficient**. Article 42(4) lists the information to be used for this assessment.
(Taxonomy, natural occurrence, relatedness with 'QPS microorganisms', production process, etc.)

Microbial Plant Biostimulants: Issues

- The positive list of Annex II is ill-defined.
- How to expand the positive list of Annex II?

➤ Criteria?

➤ Procedure?

Assessment by JRC or an external contractor?

Or Assessment by a subgroup of the Commission expert group on Fertilising products?

Or Assessment by a National Authority?

Microbial plant biostimulants: where to start

✓ EFSA assessment of microorganisms in the food/feed and environmental sectors in the EU:

Sector	Legal framework
Food additives	Regulation (EC) No 1333/2008; EFSA guidance
Food flavourings	Regulation (EC) No 1334/2008; EFSA guidance
GM food	Regulation (EC) No 1829/2003; EFSA guidance
Feed additives (preservatives, silage additives or gut flora stabilisers)	Regulation (EC) No 1831/2003; Commission Regulation (EC) No 429/2008; EFSA Guidance on the characterisation of microorganisms used as feed additives or as production organisms.
Plant Protection Products	Regulation (EC) No 1107/2009; EFSA Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances. Other guidance documents concerning specifically microorganisms as active substances or active substances in general.

(Adapted from : 'Note to the Commission expert group on Fertilising Products on procedural options for future developments of CMC 7, micro-organisms', CIRCA, November 2021)

Microbial plant biostimulants: where to start

- ✓ Assessment of microorganisms in the food/feed and environmental sectors in EU
- ✓ Survey of the MS regulations of microorganisms used in agriculture: in progress (COM expert group on FP).

Microbial plant biostimulants: where to start

- ✓ Assessment of microorganisms in the food/feed and environmental sectors in EU
- ✓ Survey of the MS regulations of microorganisms used in agriculture: in progress (COM expert group of FP).
- ✓ Case studies: more information expected from the industry!

« COM received frequent questions about the procedure to apply for the development of CMC 7, but no concrete information on micro-organisms for which there would be an intention to submit a proposal »

(Note to the Commission expert group on Fertilising Products on procedural options for future developments of CMC 7, micro-organisms', CIRCA, November 2021).

Placing biostimulants on the market: further challenges

- How to standardize biology ?

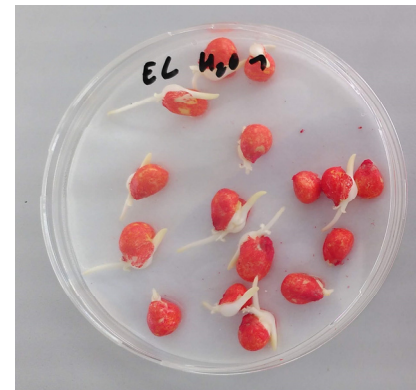
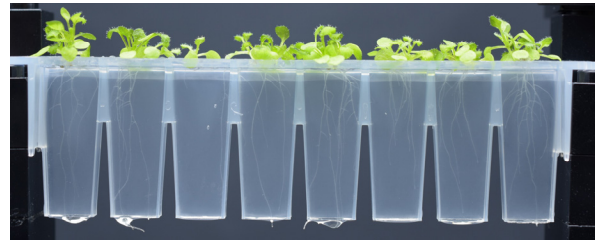
Mandate to CEN (European Committee for Standardisation) for developing Technical specifications ('CEN/Ts') and harmonised European Standards ('Ens') for the CE-marking

➤ Data quality requirements, consensus definitions, protocols, etc.

CE

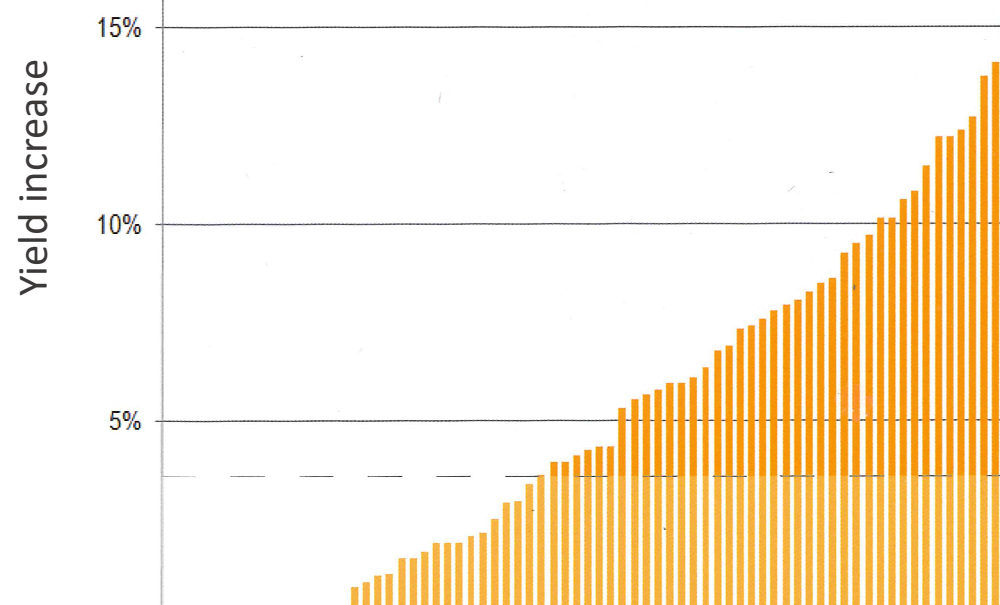
Which protocols for validating the biostimulant claims?

BioStimTest project (Walloon government), BE academia and Redebel SA



Field trials to demonstrate the claim?

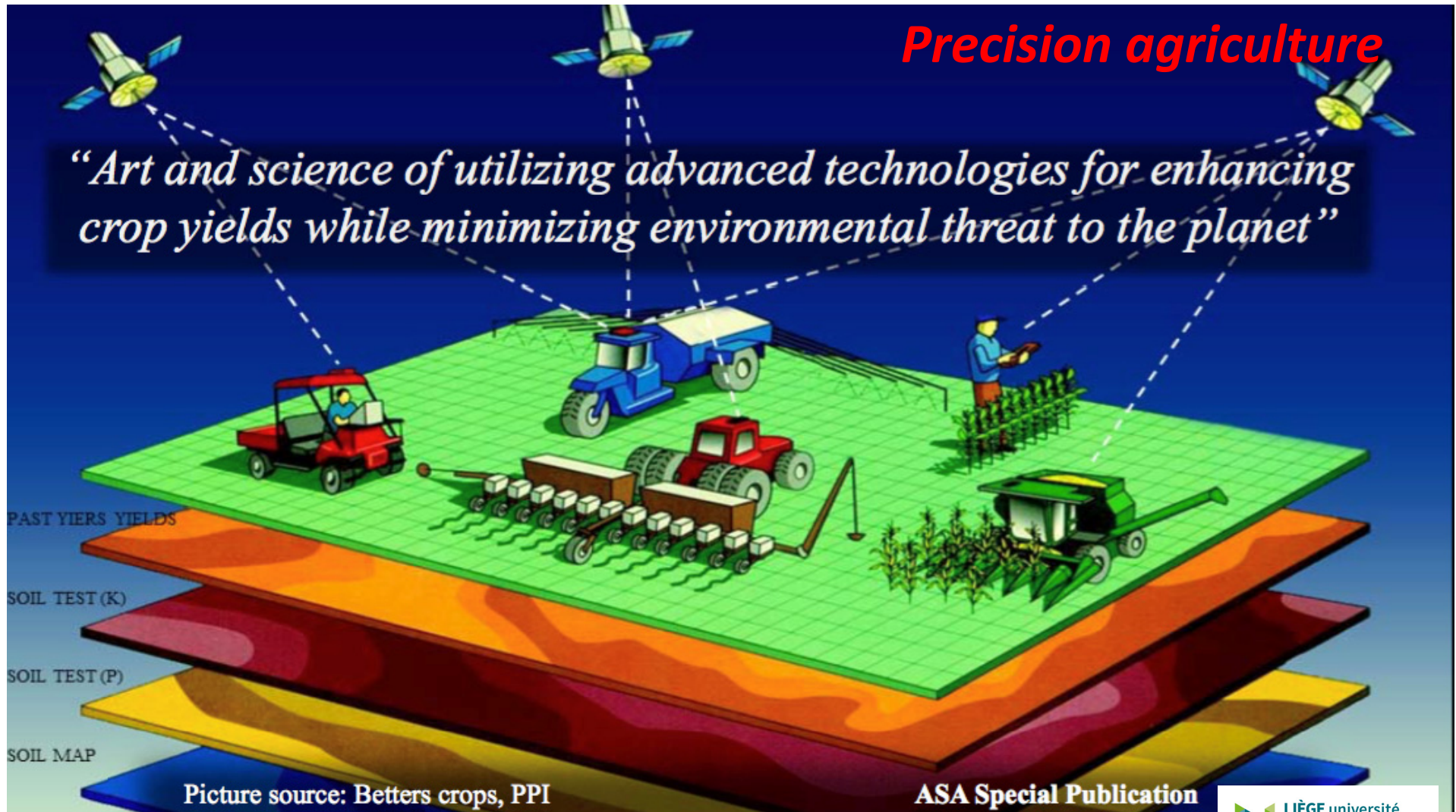
Effects on Yield of a seed-coated biostimulant (humic/fulvic acids-based) in winter wheat



“The plant biostimulant shall have the effects that are claimed on the label for the plants specified thereon.” (Regulation (EU) No 2019/1009)

(Source: commercial leaflet!)

How to make biostimulants work?



How to make microbial biostimulants work?

MPMI Vol. 28, No. 3, 2015, pp. 212–217. <http://dx.doi.org/10.1094/MPMI-10-14-0334-FI>

CURRENT REVIEW

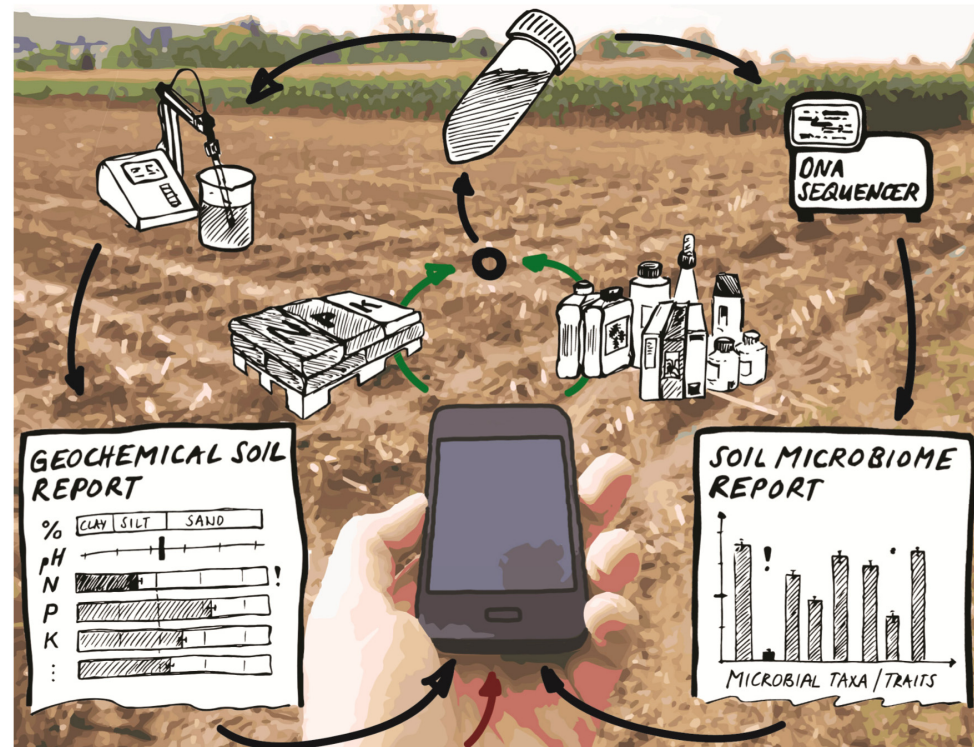
The Plant Microbiome at Work

« *Next-generation agriculture* »

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Conclusions

- The EU regulation 2019/1009 opens **new opportunities for innovative fertilising products**, including plant biostimulants.
- Biostimulant products are defined by **claims**, *i.e.* their **functions** on crops, which separate them from PPPs.
- Validation of the claims is achieved by a **standardization** approach, which is challenging.
- Avenues for including new microorganisms in the list of **Microbial Plant Biostimulants** are identified, but criteria bearing on both **biology** and **trade** need to be satisfied.

Thank you!
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