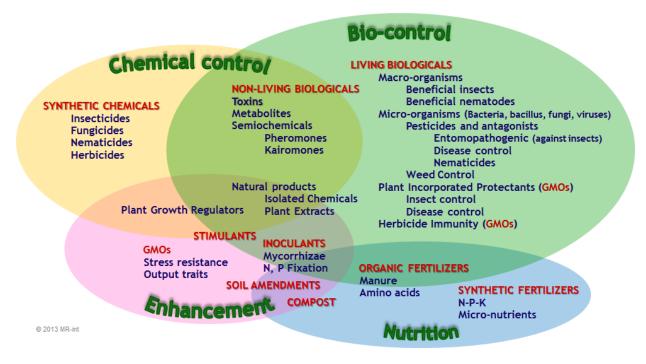


Challenges ahead for plant enhancement products

Plant enhancement products (PEPs) are better defined by what they are not: neither fertilizers nor pesticides. They help the plant growing better by fostering nutrient assimilation, by inducing resistance to biotic and abiotic stress, or by enabling other plant growth regulation effects.

As agricultural inputs they can be classified as in the following scheme:



Obviously, since different activities can be attributed to a given product and since products may show more than one effect, there are overlaps between these categories.

Many challenges must be met to develop and to put such products on the market:

- A. Understanding the underlying biological phenomenon
- B. Benefits for the growers or other stakeholders
- C. Product quality
- D. Application
- E. Regulatory requirements
- F. Marketing requirements
- G. Business attractiveness

Plant enhancement products can play an important role in modern productive and sustainable agriculture if regulatory barriers are not put at such a height that no one will be ready to invest, and if powerful marketing and distribution companies are willing to enter into this business segment.

A. Understanding the underlying biological phenomenon

The mode of action needs to be explained by which a substance or a micro-organism has an influence on the plant's metabolism. A mere description of the overall result is no explanation, in particular when multiple factors are engaged in the phenomenon; too often, the tautology "it works because it works" is the wrong argument of last resort.

If the biochemical pathway of an identified substance — natural or synthetic chemical — is elucidated then it is possible to understand the conditions under which a desirable effect can be obtained, or not. For example if a substance such as salicylic acid or harpin protein triggers a systemic acquired resistance mechanism then it is of high interest to know the intensity and the persistence of the plant response in order to determine treatment conditions and frequency.

When micro-organisms interact with plant roots it is either by inoculation (penetration into the plant tissues, endophyte) or by an external colonization. Plant growth promoting bacteria are described as enabling a better nutrient assimilation or to modulate phytohormone levels (phytoalexines, auxines) in the plant. Also, by a protection mechanism against pathogens¹, a micro-organism such as *Trichoderma* sp. relieves the plant from biotic stress, allowing the plant energy to be used for growth rather than for survival. But in this case and if there is no pathogen pressure the promise of growth improvement cannot be fulfilled.

All such explanations must be brought in simple but truthful form to the grower. Killing insects or weeds, or stopping disease symptoms is easier to communicate.

Critical questions a manufacturer should be able to answer:

- How is the product working?
- Which of its components does what?
- When is it working, when is it not?
- Is the functionality verifiable in the field?

B. Benefits for the growers or other stakeholders

For a grower, the benefits that he gains by using PEPs are different from those that he expects from the use of fertilizers or pesticides. In agronomic terms plant health and vigour are promoted. But this is not enough for the grower: he expects visible improvements and economic returns.

While the effectiveness of an herbicide is easy to verify this will not be the case with most of the PEPs. By sampling roots the nodules formed by nitrogen fixing bacteria, or the typical pattern of mycorrhizal inoculation can be verified. But a colonization in the ground around the roots is not observable with simple means.

In addition, spectacular effects are rarely observed when using PEPs. When insect populations are eradicated, or weeds disappears or don't grow at all, the grower knows that something is going on in favour of his crop. But when difficult to measure growth parameters are in cause the alleged effect will not look as convincing.

- production by the micro-organism of bacteriostatic (siderophore) or biocidal metabolites,
- promotion of systemic resistance by the plant itself,
- or, more simply, competition for space in the vicinity of the plant roots between a benign organism and a pathogen.

These control mechanisms are:

The grower is then confronted to one of these famous 2x2 matrices, as for example significance vs. visibility:



To get acceptance by the grower a PEP must deliver at least one of these benefits.

- ✓ Higher survival after transplantation
- ✓ Precocity (less time to first harvest)
- ✓ Shorter cultivation cycle
- ✓ Higher harvest yield expressed in Kg/Ha and/or average Kg/fruit, and less low grade produces
- ✓ Nice looking crop and produces
- ✓ Environmental friendliness, thus giving access to organic certification and demanding retail distribution channels

To demonstrate such benefits mere references to scientific literature, laboratory experiments, or small control trials in R&D greenhouses are not sufficient. Field trials are required in which comparisons will be made between crops treated or not with a PEP under the same high current production standards. These are costly multivariable trials that need to be conducted up to the harvest.

Significance means not only that the result of one treatment is statistically different from another one, but also that it will be meaningful to the grower in agronomic and economic terms.

Critical questions a manufacturer should be able to answer:

- What is the return on investment to the grower in using this PEP?
- What are the evidences on which the benefit claims are made?

 $^{^2 \}quad \text{A nice greening of plant leaves does not necessarily correlate with significant harvest yield increase or other economic benefits.} \\$

C. Product quality

The definition of a product quality begins with the declaration of what it is and how much of it does it contains. Then and only then features that are more or less attractive to the eye of the buyer can be described. Some PEP manufacturers seem not to feel obliged by such basic requirements.

PEPs are often offered as mixtures of various substances or micro-organisms, all being described as active. It may make good sense to offer mixtures if, at the same time of application, complementary effects are sought or if proven synergies result from the simultaneous actions of two components. But when more than a couple of components are

Critical questions a manufacturer should be able to answer:

- Is a complete product specification sheet available?
- If offered as mixture of active substances, what are the individual roles of each component?
- Are products with single components available that the grower can mix at the time of application, or apply at different times?

mixed together one can only wonder how such complex recipe could have been optimized with so many variables. This is where beliefs begin to take precedence over science and common sense. If only one of the components will show activity while the others remain shunted, than it is like offering a full menu to someone who desires to eat only one dish and let him waste the others.

D. Application

To be effective a product must be applied at the right place, at the right time, at the right dose, and in the right conditions.

Placement is linked with the nature of the product and may not be freely chosen. If for example an inoculant must come in contact with plant roots it is worthless to apply it by just depositing it on the soil surface through the irrigation system and to wait until it may [or not] migrate down to the roots.

OLD On Leaf Delivery.

This is made by foliar spray. Adjuvants may improve the spreading of the product on the surface, its stickiness or rain fastness, and protect it from sunlight.

Also, for a successful application of living micro-organisms an adequate level of humidity will be required that should last for at least a few hours, the time the micro-organism will take to wake up and to begin interacting with the plant.

OGD On Ground Delivery.

Dry granular products can be applied in furrow at seeding, or broadcasted at any time.

The irrigation system can be used (fertirrigation, fertigation) for highly mobile substances or colony forming micro-organisms.

ORD On Root Delivery.

Inoculants need contact with the roots to penetrate them. In this case application will be made in the planting hole or in furrow prior to transplanting or sowing. In nurseries the product can be mixed with the potting substrate.

OSD On Seed Delivery.

Seed treatment is a way of applying minimal product quantities and to avoid additional labour for the grower. Of course, the product must remain stable on the seed kernel up to sowing, and be biologically active upon seed germination.

In all cases compatibility needs to be known with other fertilizers and pesticides that will be applied to the given crop.

Critical questions a manufacturer should be able to answer:

- Under which conditions the product must be applied?
- What precautions must be taken to ensure maximal effectiveness?
- What is the dose rate dependency?

E. Regulatory requirements

If something is used should it be regulated?

If something is not formally authorized should it be used or prohibited?

While pesticides and fertilizers are regulated in a well-known way, the situation of PEPs is unclear. Sometimes the regulator assigns them to the pesticide category as it is the case of some plant growth regulators (e.g. gibbelleric acids) even if they do not help controlling pests, or as fertilizers (as in Switzerland "cultures of micro-organisms for their application on soils, seeds, or plants"). But in many countries a regulatory vacuum is open to manufacturers. In Spain, a tentative to establish a list of so called "other means of phytosanitary defence" was aborted not long after the law was published for lack of organization of the regional and central regulation authorities. In the USA the Environmental Protection Agency tends to register them either as "biopesticide" (e.g. citric acid) or to regulate them under the Toxic Substance Control Act (e.g. Rhizobium).

In Europe the Regulation (EC) No 1107/2009 in force since June 2011 has a very wide definition of what is a plant protection product; many PEPs will find themselves regulated in this category. Fertilizers and other products are under the authority of the member states who take different approaches, from very strict and costly in France to quite lax in Spain. But a new EU regulation on so-called bio-stimulants, the definition of which remains to be seen, is in the making, probably under the REACH umbrella.

To enable the development of safe and sustainable solutions it would be a good advice for regulators to ask for limited data when a product is used in small quantities, and to increase the requirements if it gains success and volume. To ask for all data before the first kilogram would be sold is a sure way to prevent the arising of valuable innovations. Also, international recognition of data packages or even of registration

Critical questions a manufacturer should be able to answer:

- What is the exact regulatory status that corresponds to this particular PEP in this particular country?
- What are the studies required to present a homologation dossier to the authorities?
- What requirements will be there in 1, 5, or more years?
- Are generic data available, from where, at which cost?

decisions could help. A corn plant in Iowa or in France is not better protected by a decision made by the US-EPA rather than by an EU-Standing Committee.

Depending on the particular case the registration of a PEP may cost between nothing up to hundreds of thousand dollars, and take almost no time up to several years.

³ Spain can be called a banana monarchy since it produces such fruits in the Canary Islands.

F. Marketing requirements

Having an effective and good quality product is not enough. Access must be found to the market and to the customers.

A grower knows that his production will not be possible without seeds, fertilizers, and pesticides. Seeds are sold on their intrinsic qualities and on the reputation of the manufacturer. Fertilizers are sold on their concentration, price, and logistic service. Pesticides are sold because the grower is rightly afraid of pests and knows how much he can lose. Comparison with competitive products are possible, among which generics where arbitrage is made between price, service, and quality.

But PEPs are not required agricultural inputs and the grower feels no penalty in not using them; therefore, it is much more challenging to convince a user. Being more used to think in terms of cash management rather than return on investment, missing an opportunity will not disturb him. And considering that the grower is exposed to too many "wonderful products", scepticismis rather of the order. Amazingly, similar challenges are met by seeds manufacturers: promoting a GMO with insect control or herbicide resistance is easier than a GMO with just yield enhancement traits.

A grower may make following objections in a more or less explicit manner:

- The product is unknown and its mode of action is not understandable;
- Products of the same type have been offered before and didn't work;
- Sometimes such products are effective, sometimes they aren't, too much risk;
- I've tested it and saw nothing;
- I know what I pay but not what I get;
- I don't believe you.

To overcome such critique an intensive communication needs to be put in place that includes numerous and frequent field demonstration sites.

Also the positive fame of the manufacturer will help: it is more straightforward for a Bayer or a Syngenta to bring a new solution to the market than for any starter company. The customer will listen and assume that the offer is a serious one.

Critical questions a manufacturer should be able to answer:

- How to present product features and benefits?
- What are the target markets?
- How are they organized?
- What support must be provided to the distributors?
- Who are other influencers who will help promote the PEP solution?
 - What do they need to do so?
- Are other players to involve upside (seed manufacturers) or downside (produce processors, retail distribution chains)?

Branding: once a product brand is created it will stick for a long while. And a company with high reputation is able to closely coach and monitor the activities of the distributors. This is the power of the brand.

G. Business attractiveness

A company interested to develop, produce and market PEPs is facing technical, regulatory and marketing challenges as described in this paper. To achieve success it has to be convinced of the product effectiveness and of its market potential.

Also, competitive advantages must be available, such as:

• Intellectual property position in the form of patents, micro-organism strain ownership, or unique production process and quality.

- But many PEPs are already generic commodities. This tends to discourage R&D based companies (see next point).
- A set of field trial results showing undisputable benefits. As PEPs are often specific products made in a particular way such results can only be attributed to that specific product. Generic copies will have to prove themselves as effective in the field (and not only in the chemical formula and impurities of five typical batches).
 Companies used to manage complex patent portfolios tend to forget the competitive edge of branding. But for example in the amino acid market there are a couple of brands that remain clear market leaders despite of dozens of similar offers; if not for results it will be for brand.
- Competitive positioning. This is no easy task since PEPS are usually not competing head to head against each other as do for example insecticides. Different crop management strategies will lead to the use of different products and methods: a new seed variety (genetically modified or not) may change the plant's treatment needs; a product having a different mode of action may render useless another one and may require further, different treatments. Market definition and segmentation is getting more complicated.
- Registration. A tedious and costly registration is a nice barrier to entry against potential
 competitors. This is why the industry is ambivalent when speaking of regulation. While it
 costs a lot it enables establishing a comfortable oligopoly for the happy few having made
 it. But on the other hand a lengthy and costly registration process will discourage business
 investors and innovators.
- Channel access. A small, "one product" company cannot hope to access the market fully, even with an excellent product. Alliances with solid marketing organizations will be needed once proof of concept and of marketability will have been made.

Any product development has a cost that, hopefully, will be offset by expected revenues. If the regulatory barrier is too high not many players will take the risk of making such investment even before the marketability of the product will have been demonstrated. This is probably one of the reasons why, aside of nitrogen fixing bacteria that have a proven sizeable market, PEPs remain mostly local products.

It is now a declared policy of officials in almost all countries or regions to foster the use of sustainable agricultural practices and of safe products that have no or a nonlasting impact on the environment. This declaration of intent should be reflected in the regulatory requirements and in procedures that are affordable for fledgling products. Rather than subventions this is the kind of support that the economy needs.

Critical questions a manufacturer should be able to answer:

- What are the unique selling propositions (USP) and competitive position on which a business can be planned?
- How to assess the market potential of the product or of the product family? How high is it?
- Are expected returns going to compensate the necessary investments?
- Will competition help building a new market (growing the pie), take a part of it (eating a larger slice), or change the rules of the game?
- Has the company the necessary marketing power?
 What alliances should be sought?



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