

Quality claims are essential for the biostimulants industry

On 17 March 2014, a group of consultants, led by Arcadia, presented a report on regulating biostimulants and fertilizer additives to the European Commission's Fertilisers Working Group. One of the principal items discussed from the report was the consultants' recommendation to modify the definition of biostimulants that had been agreed by the Fertilisers Working Group on 14 June 2012 and has been used by the stakeholders involved in the regulatory review –including DG Enterprise – since that time.

One of the central points of the recent discussion was whether the effects of biostimulants should be limited to “nutrient use efficiency” (combining the previous references to nutrient use and uptake” and abiotic stress tolerance. The justifications given for deleting the reference to quality can be summarized as follows:

1. The reference is vague
2. Quality effects could be confused with effects related to hormonal products authorised under the PPP framework

EBIC stresses that the reference to quality is not vague so much as it is general and in line with the spirit of the New Approach's specification of minimal product characteristics. The general reference to quality in the definition is complemented by specific product claims (and justification thereof) made by the producer. (See section 3 of this document)

With regard to the second point, the principle of dual-use and of claims-based definitions recognizes that a single substance could have multiple functions and that those functions might fall under different regulatory frameworks. The central issue is whether the functions for which a product is being sold have been properly authorized. (See section 4)

It should be noted that the impact of deleting “quality” from the definition of biostimulants would be devastating for the industry's development. (See section 2)

Finally, the inclusion of plant biostimulants in the future regulation on fertilizing materials and the subsequent modification of the definition of plant production products (PPPs) reflect wide agreement that the current definition of PPPs is too broad. This issue needs to be considered with a view to preparing the future, not preserving outdated paradigms.

1. Science supports enhanced quality as a result of good fertilization

Limiting interpretations of quality to effects produced by hormonal modes of action is extremely limited and overlooks common understandings of the word quality.

For instance, the International Fertilizer Industry Association (IFA) defines fertilizers as “any solid, liquid or gaseous substances containing one or more plant nutrients in known amount, that is applied to the soil, directly on the plant (foliage) or added to aqueous solutions (as in fertigation) to maintain soil fertility, **improve** crop development, yield and/or **crop quality**.” [emphasis added]

The examples of scientific literature studying the effect of fertilizers on crop quality are too numerous to list here. Needless to say, the contribution of plant nutrition to crop quality are multiple and well-documented. For example, nitrogen fertilization is often linked to increased protein content in wheat which contributes to better baking quality of bread, etc.

Other regulatory frameworks cited in the Arcadia study give precedents for such a reference, notably the feed additive definition: “Feed additives are products used in animal nutrition for purposes of **improving the quality of feed and the quality of food from animal origin, or to improve the animals’ performance and health**.” [emphasis added] If nutritional enhancement for animals is recognized as contributing to quality and health in ways that are independent from veterinary contributions, there is no reason that a parallel should not be articulated for qualitative benefits of nutritional enhancers for plants.

2. The economic impact of removing quality enhancement from the definition of biostimulants would be devastating to the sector

In order to evaluate the potential impact of eliminating the word “quality” from the biostimulants definition, EBIC conducted a survey among its members to evaluate the impact. Although the survey was only open for three days, 31 companies (2/3 EBIC’s current membership) responded. This sample represented at least 365 of the biostimulant-type¹ products currently on the market

According to the data gathered, the economic impact would be extensive, with at least 25% of products currently on the market being threatened. Based on previous EBIC estimates of the number of total biostimulant products currently being sold (600-1000), that would mean 150-250 products being withdrawn from the European market. Based on estimated number of products in the R&D pipeline, more than 200 products-in-development would also be endangered.

Furthermore, while farmers may appreciate improved nutrient use efficiency and abiotic stress tolerance, it is the resulting quality improvement that motivates them to use biostimulants because the return on their investment is related to the improved quality/yield of their crop and the premium they can earn as a result. Removing quality claims would decrease the attractiveness of biostimulants positioned only to support nutrient use efficiency and/or abiotic stress tolerance. According to the EBIC survey, **that could raise the threshold of endangered products over 50% of the total.**

Raw data and interpretations

Survey data indicated that at least 104 biostimulant products currently on the market are sold with claims focused solely on their ability to improve crop quality. In addition, at least 165 products make a quality claim combined with either nutrient use efficiency or abiotic stress tolerance (however, the design of the survey was such that we know this number has been significantly underreported).

¹ We use this term because of the lack of uniform definition and recognition of biostimulants from one EU country to another.

One member commented, “Quality is one of the most important parameters needed and expected by farmers when using biostimulants. Quality can be demonstrated by measurable parameters like Brix degree, Caliber, Color, Dry matter, Protein content, Zeleny, making the efficacy assessment possible.”

3. How can quality be conceptualized to help identify a product as a biostimulant?

EBIC members commented that quality is not just an outcome of nutrient use efficiency and/or abiotic stress tolerance. Strengthening cell walls, fruit setting and enhanced sugar content are examples. A number of factors make it difficult to indicate the specific mode of action of a biostimulants product, but it is nonetheless possible to demonstrate biostimulant effects:

- Because many (and an increasing number) of biostimulant products are complex, multicomponent products, it is extremely difficult to isolate the various modes of action from one another, but it is possible to observe that they are not related to plant protection actions and to isolate the impact of the plant biostimulant component from, for example, a fertilizer component. (The Consiglio per la Ricerca e la sperimentazione in Agricoltura – ENTECRA – in particular has done useful research into this methodology.)
- Research into modes of action is extremely complicated and costly, creating a barrier to the entry and operation of small and medium enterprises (SMEs).
- Taking the previous points into account, quality improvements provide measureable and objective proxies for demonstrating biostimulant effects, and these pragmatic proxies are much more accessible for SMEs.
- The need to provide extremely detailed research on modes of action seems antithetical to the Commission’s stated desire to establish minimal quality requirements and leave the market free to select the “best” products.
- Including an overly specific definition of quality attributes in the definition of biostimulants would, in effect, result in a positive list system, with all of the drawbacks that characterize the current system of fertilizer regulation under 2003/2003.
- Furthermore, overly specific quality attributes fail to take into account the crop-specific aspects of quality. For example, high-quality peas would have high sugar content and high starch content, whereas it would be the opposite for high-quality potatoes.
- Finally, concern over confusion with hormone-based plant protection products is in contradiction of the principle of dual-use, which states that the claimed effect and not the ingredients should determine the appropriate regulatory framework.

All of these points underscore the need for two-tier thinking about the concept of quality:

1. The general concept of quality in the definition of products and
2. The specific (science-based and justified) claim(s) made by the entity placing the product on the market at the time the registration dossier is prepared or updated.

This two-tiered approach can be modelled as indicated below. Biostimulant products can enhance sensory, technical or nutritional quality of the crop. Each type of quality enhancement can be expressed in more specific terms, depending on the product and the crop (see table below).

General categories of quality enhancements can be expressed in measurable characteristics

Sensory	Nutritional content	Technical
Appearance -- Size -- Form -- Color -- Defects	Minimizing the presence of unwanted elements such as heavy metals (by inhibiting their uptake)	Inherent tolerance to storage (excluding exogenous factors like fungicidal protection, etc.)
Taste	Protein	Tolerance to handling
Texture	Minerals (including micronutrients)	Persistence of other quality traits through transformation
	Vitamins	
	Nutraceuticals	
	Carbohydrates	

Some aspects of quality protection and enhancement fall outside the scope of biostimulants effects. These can be categorized as “sanitary” aspects of quality and include the control of and/or tolerance of pathogens (thus diminishing any negative effects on quality attributes) or reducing/eliminating toxicity due to pathogens, microtoxins or natural defenses.

4. The proposed regulatory process provides sufficient checks and balances to prevent systematic abuses of the quality claim.

The proposed process for placing biostimulants on the market should prevent widespread abuses of quality claims.

- The steps required for placing a fertilizer on the market under the future proposed regulation will be significantly easier than those for a biostimulant as the latter requires the submission of a complex dossier. Therefore, there would be no incentive to misrepresent a fertilizer-related quality improvement as being the result of a biostimulant effect.
- With regard to quality claims that are outside the natural scope of biostimulants (see section 3 above), the planned completeness check provides ample opportunity for the responsible agency to ensure that no inappropriate claims (i.e. related to PPP effects) are made without proper authorization.

5. Do the proposed definitions of biostimulants include effects in the soil (or other growing substrate) and not on plants?

The definition agreed by the Fertilisers Working Group in June 2012 and used by EBIC would accommodate products that do not directly act on plant processes (e.g. microbes that make nutrients more absorbable in the growing environment around the plant) because it states that the products “stimulate natural processes” with the specificity being provided by an explanation of which natural processes rather than by a reference to “plant processes”. This wording was carefully negotiated precisely to include products acting on the soil microbiome under the biostimulants umbrella.

- The proposed revisions from Arcadia would be problematic by excluding processes that are not directly tied to the plant and thus excluding microbes that make nutrients more affordable in the growing environment around the plant. The proposed modification is therefore problematic both from a commercial perspective and complicates the regulatory situation by fragmenting micro-organisms into multiple categories.
- The other modifications suggested by Arcadia do not seem problematic.