

Response to feedback on biostimulants

2 June 2014 Fertilisers Working Group

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With regard to Agenda point 6c:

Biostimulant products are diverse, making a standardized approach of list types impractical. Their diversity does not mean that the products and substances they contain are unknown, just that it is not practical to establish a positive list in advance. The approach proposed by the Commission for biostimulants is therefore meant to address issues related to quality and safety requirements in a different way from more standardized products, but nonetheless to address these points in a way that ensures adequate consumer and user protection while fostering innovation.

(c) Feedback on the COM proposal on plant biostimulants

- With regard to the inclusion of biostimulants in the future regulation on fertilizing materials and the inclusion of quality traits, fertilizers are widely acknowledged, both in general terms and through specific claims to promote plant growth, quality and vigor. For example, the International Fertilizer Industry Association (IFA) says that fertilizers are “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 inclusion of biostimulants in the future regulation on fertilizing materials is in line with this general definition.

The regulatory definition of feed additives says they 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].

In addition to effects that favour nutrient use efficiency, the effects of biostimulants help plants tolerate abiotic stress (by favouring plant vigor and resilience, not by acting on the stressor) and promote quality traits. The latter effect occurs in part by reducing the energy needed to recover from abiotic stress or increasing nutrient use efficiency, but also through other modes of action, not all of which have been fully elucidated. However, it is possible to identify – and exclude – modes of action that would fall into the realm of plant protection: protection of quality from attacks by pests and diseases, eliciting natural defences, etc. We agree with France that modifying the PPP definition can bring clarity with regard to the boundary between biostimulants and PPP effects. It is also possible to differentiate between effects due to mineral fertilizers and biostimulants that may include nutrients.

- We further emphasize that EBIC has recommended that the claims be examined as part of the completeness check to ensure that no inappropriate (e.g. PPP) claims are being made for biostimulant products. The procedure provides an additional mechanism for ensuring that the boundary is respected.
- EBIC disagrees with the position of Belgium that substances in Annex I of the PPP regulation cannot be incorporated into fertilizing materials, even if a fertilizing action can be justified by agronomic evidence. According to Belgium’s logic, neither urea nor copper salts (nor many

other substances) could be used as fertilizers because these have been included in the PPP listing.

- With regard to modifying the definition of PPP products, EBIC agrees that it would be simplest to add “or plant biostimulants” after “nutrients” and to leave the definition of plant biostimulants to the future regulation on fertilizing materials.
- EBIC agrees with Belgium and Denmark’s point that there are many reasons for exclusion from the list of PPP substances/products and such exclusion should not be automatic grounds for preventing the placing on the market of the substance/product for other purposes for which it is better fit.
- With regard to specific suggestions for amending the definition of biostimulants,
 - There is no problem referring to living micro-organisms;
 - “Main function” would be a helpful addition;
 - Tolerance to abiotic stress is a natural consequence of increased plant vigor and is very much related to fertilization and related processes and therefore should be retained in the definition of biostimulants. Biostimulants do not act on the stressors – they increase the general resilience of the plant.
 - “Independently of the nutrient content” was retained in the working definition at the request of FWG members and was meant to stress that there might be nutrients present, but that the main function of the product is not to provide the nutrients (e.g. amino acids or low levels of nutrients);
 - EBIC is not in favour of a single definition covering biostimulants and fertilizer additives. Biostimulants act on the plant and/or its microbiome whereas fertilizer additives affect the properties of a fertilizer product. The numerous differences between these two product categories were made clear by the recent Arcadia report.
 - Enhancing crop quality is an important effect of biostimulants, but not all products that affect crop quality are biostimulants. The effects of fertilizers on crop quality are widely documented and accepted. It is nonetheless possible to identify distinct biostimulant effects on quality.
 - EBIC has no problem with language to exclude water, carbon dioxide, etc. from the definition of biostimulants.
- Transparency about the real effect of products is critical for the proper functioning of the market. Grouping biostimulants with fertilizing materials is an accurate reflection of their effects on growth, development, vigor and resilience. [In contrast, grouping biostimulants with PPP products would wrongly lead people to believe that biostimulants act directly against aggressors and stressors.] In this light, we support Poland’s comment that the term “active substance” can be misleading if applied to biostimulants.
- EBIC disagrees with suggested language to specify that biostimulants are necessarily “organic materials”. Among other issues, there is significant ambiguity and confusion around the term “organic”.
- Defining biostimulants by reference to what they are not is not useful for user choice and ignores the known interactions of various product effects in cropping systems. It is also problematic if the definitions of those other products evolve.
- While EBIC is not opposed to the same registry being used for plant biostimulants and fertilizer additives, it is against the term “fertilizer additive” being used as an umbrella for both types of products. Plant biostimulants can be marketed and applied independently of fertilizers. It is unclear why a blanket term is necessary in order to include both product categories in the registry.
- With regard to ensuring safety and environmental protection, EBIC believes it is important to look at biostimulants registration as a process with multiple stages. Biostimulant substances are often first evaluated upstream of product registration, many of them through the REACH process, but possibly also through other regulatory frameworks such as food, feed additives and PPP registration. In addition, there are grounds for waiving testing

requirements to demonstrate safety for some substances and some micro-organisms on the basis of Qualified Presumption of Safety argumentation (originally developed for micro-organisms, EFSA has just issued guidelines for applying the principle to botanicals). Where cost-sharing arrangements are desirable, this would occur at the level of the substances, thus granting the right to any of the cost-sharing companies to cite the data in their product registration. Subsequent companies wanting to use that data would need to compensate the original owners of the data in an appropriate manner. Product registration would therefore, in many cases, not require new data to be produced, but would require appropriate data/information to be gathered into a coherent dossier. This system would provide a high level of protection while keeping costs manageable.

- Because many biostimulant substances are already subject to REACH, EBIC believes that ECHA would be the most qualified European agency to manage the future registry. This would also make sense because fertilizers fall under the remit of REACH and ECHA. Housing the registry at ECHA would help streamline processes and avoid regulatory duplication. Nonetheless, cooperation with EFSA could be possible where appropriate.