

**Following the enforcement of Regulation (EU) 2019/1009 in 2022, our EAR experts explore the likely impact for European companies wanting to launch new biostimulant products in the EU.**

**Here, biosolutions regulatory specialists Morgane Salaun and Concetta Di Paolo give their expert opinion on this important issue.**

The first big challenge for this new regulation (Regulation (EU) 2019/1009 of the European Parliament) is harmonization. The aim is to harmonise the conditions for the marketing of products. Of course it is an optional harmonisation as national routes will remain viable, but it is a great opportunity for companies in terms of eliminating trade barriers among member states.

Actually, it is not only a matter of opportunity in terms of enlarging market prospects but first and foremost an opportunity for the exploration of new constituent materials for fertilising products and also application methods and mode of use. Examples include the safe use of by-products and high purity materials, animal by-products or other agricultural residual products, or recycled bio-waste, beneficial microorganism, botanical extracts and other innovative sources.

The novelty is also in the fact that dual use or multiuse substances placed in a formulation will be defined for their function in that particular formulation and not only based on their own chemical or biological composition. Certainly, an active ingredient can have multiple uses, it can act as a biocide at certain concentrations or at determined rate of application but it can only show a genuine biostimulant effect if present in a particular formulation with certain concentration and if used in a certain manner.

This is the upcoming scenario in the agriculture sector, it is a completely new approach regulated through precise requirements demonstrated via harmonised standards. What will avoid the 'market flooding' is a sort of natural selection based on product effectiveness and high level of protection regarding health, safety, environment or other public interests.

The agricultural sector significantly impacts the environment, soil fertility and long-term crop productivity, due to the massive use of natural resources (e.g., water, soil, energy), so innovation needs to take into account the environment and human health. The new approach of the European regulation puts responsibility on manufacturers, they have to match a level of protection corresponding to the use they prescribe to the product under the conditions of use which can be reasonably foreseen. Essential requirements are designed to provide and ensure a high level of protection.

One of these essential requirements is traceability of the history of the product and this matters from both the regulator's and manufacturer's perspective. It enables unsafe, ineffective or non-compliant products to be traced through the distribution chain and identifies roles and responsibilities of the economic operator throughout the chain. Actually, traceability enables market surveillance authorities to trace products up to the factory gate and from factory to the end-user in certain cases. From a manufacturer's perspective traceability matters because it enables effective control of the production process and suppliers before the marketing of the products, and control of their distribution chain after the placing of the product on the market.

**In addition to the enforcement of the new EU regulation, India has also recently created official regulations for biostimulants, which could re-shape the competitive environment.**

Most likely it is going to be a mutual opportunity both sides, for both Indian and European companies, to the final outcome of a more sustainable agriculture which is evermore a global common objective.

The most influential voice in India on the theme of biostimulants is the voice of BASAI which is the Biological Agri Solutions Association of India. They played an important role in the definition of biostimulant and the consequent recognition of biostimulants under the FCO (Fertilizer Control Order) in August 2021.

Thanks to the push of this influential association and its CEO Vipin Saini, guidelines for the inclusion of biostimulants under schedule VI of the FCO has been developed, focusing on sources and product specification and with clear identification of analytical methods, calling for bioefficacy and contaminants limits, along the line of the European model.

Looking at this piece of legislation it is undeniable that the current Indian regulation for biostimulants bears many similarities to the European model. First of all, for “where” biostimulants are positioned, namely under fertilizer regulation, which is their natural collocation and clearly separated from plant protection products, so it has been excluded to collocate them under the Insecticides Act. Additionally, an important similarity to be considered between the European and Indian legislation is the one related to safety and safe use of plant biostimulants. Actually, the European FPR relies on REACH Regulation, it means basically that manufacturers, suppliers generate a full body of data, in terms of toxicity and eco-toxicity of substances and final mixtures of them. Currently, a similar regulation doesn't exist in India although India is currently processing a REACH like legislation, however in the Indian biostimulants regulation, acute toxicity tests and ecotoxicity are set out. A central biostimulant committee (CBC) has been instituted in India with the aim of advice the central government on the inclusion of new biostimulants and we can find that, somehow, it works similarly to European notified bodies.

The identified sources for a plant biostimulant product move from botanical extracts, including seaweed, to protein hydrolysates and amino acids, including cell free microbial products, humic and fulvic acids and their derivatives.

All these considerations related to similarities are an important anchor to enhance mutual business opportunities.

### **The biostimulant market in Europe is likely to grow and change over the next five years.**

Biostimulants are attracting more and more interest, all over the world and notably in Europe where the Green Deal and the Farm to Fork strategy have set ambitious goals towards sustainable agricultural development. The commitment for agriculture is to produce more, whilst reducing chemical inputs such as chemical Plant Protection Products and fertilizers. The aim is to build a sustainable food chain to feed a growing population on a warmer planet - plant biostimulants are part of the answer to this demand...

One of the principal expectations is to see how microbiomes can deliver sustainable and innovative solutions to build sustainable food systems, so, we expect more attention on this and maybe new micro-organisms or strains of micro-organisms, or additional processing methods to the component material category for such organisms under FPR.

Traditionally, agricultural application of beneficial microorganisms involves a few types of well-characterized microbes, such as mycorrhizal fungi or rhizobia bacteria, for which the mechanisms underlying their effects on plants are well understood. Currently FPR allows these strains based on their well-studied ability to facilitate such specific plant traits as phosphate solubilization, nitrogen fixation, and abiotic stress tolerance, although these need to be proved as effective for specific plant biostimulants formulation before placing it on the market.

In recent years, next-generation sequencing has revolutionized our understanding of microbial community composition and function, and together with improved culturing methodologies has greatly facilitated the use of biologicals in the field. Maybe the possibility to add new microorganisms or new strains to the positive list of allowed constituent material foreseen for a microbial plant biostimulant will become reality in the next few years?

It is undeniable that scientific progress moves faster than regulations and setting clear guidelines to address new available technologies allowing their routine use and the placing on market of innovative products could be the key. It seems that European Commission is on the right path, with the involvement of

stakeholders coming from industry and the expert group consultations – it shows they are opening up to technical progress to be clearly regulated and included in the guidelines via delegated acts to FPR.

**If you have any questions on this article, or the registration of biosolutions/biological products, please contact Eurofins Agroscience Regulatory; [regulatory@eurofins.com](mailto:regulatory@eurofins.com)**

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