Development of standards and guidance documents for biostimulants approval under European Fertilizer Regulation (EU) 2019/1009

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In recent years, the global market for biostimulants has been growing rapidly. Europe is currently the biggest market for biostimulants, with around 8.5 million hectares of area treated in 2016\(^1\). This has increased the need for a harmonized European Regulation for placing biostimulants on the market. Up to now, biostimulants have been regulated by national rules and in most cases, in the same category as fertilizers. The requirements for distribution of this product category range from a simple analysis of the composition and a conformity check with national regulations combined with an appropriate label (e.g. Germany) through to an extensive proof of the composition, efficacy and safety of the product (e.g. France).

On June 5th 2019, the new European Fertilizer Regulation (EU) 2019/1009 entered into force\(^5\) (Figure 1). It repeals the Regulation (EC) 2003/2003\(^3\), that mainly addresses mineral fertilizers. Regulation (EU) 2019/1009 defines six Product Function Categories (PFCs): Fertilizers, liming materials, soil improvers, growing media, inhibitors and plant biostimulants as well as blends of those PFCs. The European Biostimulants Industry Council (EBIC) proudly stated on its website, “The European Union thus becomes the first governing body in the world to recognize plant biostimulants as a distinct category of agricultural inputs”\(^4\). The new European Fertilizer Regulation will fully apply from the 16th July 2022. At that point, it will be possible to distribute CE-marked biostimulants across Europe according to harmonized rules. In the meantime, European standards and guidance documents have to be established for the implementation of Regulation (EU) 2019/1009. First draft proposals are expected in April of this year, however it will still take some time until the final versions will be available.

Once the new European regulation is in place, it will still be possible to bring biostimulants to the market under national regulations. Companies can then choose to market a biostimulant as CE-marked biostimulant or as national biostimulant.

![Figure 1: Regulation of biostimulants. In the past, biostimulants were solely regulated by national rules. With the publication of Regulation (EU) 2019/1009, in the Official Journal of the EU, biostimulants are now also part of a European Regulation. However, this regulation will only apply from 2022 and standards defining the implementation of this regulation still have to be developed. Bringing biostimulants on the market under national regulations will still be possible.](image-url)
So far, no guidance document for the implementation of the new Fertilizer Regulation has been published. Work to be done will be elaborate since biostimulants originate from a diverse set of biological and inorganic materials, defined by their function and not by their ingredients. Regulation (EU) 2019/1009 defines biostimulants as products that “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: nutrient use efficiency, tolerance to abiotic stress, quality traits, or availability of confined nutrients in the soil or rhizosphere” (Figure 2). Consequently, the functions will have to be justified when claimed on the label of a biostimulant.

![Biostimulants](image)

**Figure 2: Biostimulants as defined by Regulation (EU) 2019/1009.** The product can exhibit one of the indicated functions or can combine two or more of them.

Members of EBIC published an article, that proposes several principles to allow justification of label claims for biostimulants. The use of existing data (e.g. from published literature) is given great importance therein as a first step of the justification. However, in most cases new experimental data will also be necessary. Those could derive from controlled conditions of lab and growth chamber trials as well as from field trials.

Depending on the claim to be justified, one or the other type of trials will be more appropriate as field trials give better information on results that can be expected after use of the biostimulant by the farmer, but some claims will not be possible to justify in those “uncontrolled” conditions.

The standards to be developed to place biostimulants on the market under the new regulation should ensure that only products with proven positive effects on the crop and which comply with safety requirements for the user and the environment can be marketed. However, at the same time, a balance is needed so that the burden of requirements and costs do not overwhelm the manufacturer. Therefore, proposals such as combining crops in groups should be taken into account.

Eurofins Agroscience Services will soon become a member of Afaïa Association; it will allow us to actively participate in the development steps of the standards and guidance documents to place biostimulants on the market under Regulation (EU) 2019/1009.

Our team of experts will therefore be able to give biostimulant manufacturers the best advice for future projects. However, as the new fertilizer regulation does not yet apply and standard development for
the implementation is still at the very beginning, strategies for current project still have to rely on national rules.

For further questions and advice on your individual products, do not hesitate to contact our project manager for biostimulants **Morgane Salaun**.

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**References**