



European Biostimulants Industry Council

EBIC POSITION PAPER

Towards an Optimal Regulatory Framework for Biostimulants

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EXECUTIVE SUMMARY

→ **EBIC advocates:**

1. A definition of biostimulants that is consistent with the one already discussed and validated since 2012:

“A ‘Plant Biostimulant’ is a material that contains substance(s) and/or microorganisms whose function, when applied to plants or the rhizosphere, is to stimulate natural processes to benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and/or crop quality, independent of its nutrient content.”

2. The legitimate incorporation of dual-use components in biostimulant products with a reasonable regulatory burden in order to promote innovation.

3. Provisions for placing biostimulants on the market that will ensure:

- Data confidentiality and protection with negotiated access per REACH requirements;
- Equitable requirements for safety data requirements for all biostimulant components and products:
 - Equivalent procedural requirements, for substance-based products and microbial products, albeit with data requirements adapted to the specificities of each;
 - Re-utilisation of REACH registration for substances (or other appropriate registration/authorization processes);
 - An equivalent evaluation framework to REACH for microbial components (strains or consortia) that are either newly selected or not eligible for Qualified Presumption of Safety.
- **Proportional data requirements to demonstrate an acceptable human health and environmental risk assessment and proof-of-concept related to product claims** (that must be fulfilled by importers as well as EU producers);
- Final products should be subject to notification by the company placing them on the market, with sufficient data/evidence to satisfy safety endpoints and to demonstrate that

the biostimulant claims being made are founded (waivers, bridging and other mechanisms to be employed to keep costs to a minimum); and

- Recognition that **biostimulants are innovative products composed of different recipes and combinations**, associated with specific claims.

I BACKGROUND - Policy Rationale

→ Better and smarter policy-making in the EU

1. Fostering growth

The Commission's premise since the last months of 2014 has been that minimal regulation and low costs alone are sufficient to foster economic growth. EBIC supports the view, however, that reasonable costs and regulation need to be combined with measures to protect innovation and ensure fair competition.

2. Protecting and promoting innovation

Biostimulants are complex products formulated from simple components. However, as EBIC has noted before, biostimulants are generally not eligible for patent protection (although some aspects of the production process and products may be). Despite the fact that the European market is fragmented along national lines, the bulk of innovation in the biostimulants sector today happens in Europe because rules in most EU countries discourage copying products. A European-level regulation should further promote innovation in Europe and allow Europe keep its leadership position in the industry.

3. Avoiding counter-productive policies

A European-level regulation should avoid the following missteps that would actually undermine the EU's stated policies objectives:

- 3.1. Undermining innovation by commoditizing a potentially transformative agricultural technology;
- 3.2. Eroding employment by driving production away and eliciting imports into the EU; and
- 3.3. Unintentionally doubling the regulatory burden and thereby diminishing ability of the biostimulants sector to contribute to the realization of the bioeconomy.

4. Building the Circular Economy

Biostimulants are a Key Enabling Technology (KET) that can greatly enhance agricultural performance in the context of the Circular Economy. The biostimulants industry has the potential to be a catalyst for R&D in green innovation, boosting investment, and creating employment. Economic benefits also trickle down by increasing farmer profits and reducing public expenditures to address nutrient losses to the environment.

With this in mind, we call on decision-makers to agree a final text that enables the biostimulants industry to fulfil its potential as an engine for growth in the Circular Economy.

With the right regulatory framework in place, biostimulants can help unlock the potential of key EU priorities, such as delivering on jobs and growth, ensuring that the EU is at the forefront of green innovation, and growing the Circular Economy. Without the right regulatory framework, none of the cascading benefits that our KET brings to the Circular Economy can be realized.



Fundamental Principle: An optimal regulatory framework for biostimulants is one that encourages innovation, ensures fair competition, keeps production in the EU, does not add to the regulatory burden, and enables our technology to help power the Circular Economy.

II OUR POSITION - Towards an Optimal Regulatory Framework for Biostimulants

→ Definition and its boundaries

1. EBIC advocates a definition of biostimulants that is consistent with the one already discussed and validated since 2012

1.1. Definition validated by the DG Enterprise Fertilizers Working Group in June 2012: "A 'Plant Biostimulant' is a material that contains substance(s) and/or microorganisms whose function, when applied to plants or the rhizosphere, is to stimulate natural processes to benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and/or crop quality, independent of its nutrient content."

1.2. The principles of the definition as proposed by EBIC are non-negotiable, but we are open to refining the wording. The final definition should address the following issues that have arisen in biostimulant discussions:

- The need to acknowledge system effects arising from combining biostimulant components;
- Taking into account products that act on the plant indirectly by acting on the soil microbiome. The final text should clearly specify that plant nutrition processes in the soil and not just inside plants are included within the scope of biostimulants;
- Including positive effects on crop development, both yield increases and quality;
- Clarifying the language so that biostimulants can contain mineral elements (as long as their intended function is as a biostimulant); and
- Providing enough flexibility to accommodate substance-based and microbial products on equitable terms.



Fundamental Principle: An optimal regulatory framework for biostimulants is one that is consistent with the definition, discussed extensively within the Fertilizers Working Group and validated since 2012, that EBIC advocates: "A 'Plant

Biostimulant' is a material that contains substance(s) and/or microorganisms whose function, when applied to plants or the rhizosphere, is to stimulate natural processes to benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and/or crop quality, independent of its nutrient content."

→ **Dual-use components**

2. The legitimate incorporation of dual-use components in biostimulant products with a reasonable regulatory burden in order to promote innovation.

2.1. Explicit acknowledgement of the possibility to incorporate dual-use components in products with different functional uses should be made in the legislative text and supported by guidance documents.

→ **Key provisions for placing biostimulants on the market**

3. EBIC advocates a properly designed regulatory framework that is fit-for-purpose

3.1. Tenets that underpin the framework we advocate:

Final products should be subject to notification by the company placing them on the market, with sufficient data/evidence to satisfy safety endpoints and to demonstrate that the biostimulant claims being made are founded. Important data elements include a registered composition, product physical/chemical properties, and an acceptable human health and environmental risk assessment. Non-EU producers must also comply with these requirements. Waivers, bridging and other mechanisms should be employed to keep costs to a minimum.

A properly designed framework is better regulation (not overregulation) and is grounded in recognition of the following tenets:

- The entire family of fertilizing products is used in an integrated fashion, so it is therefore important for them to fall under the same regulatory architecture.
- However, there are important nuances among product functional categories that requires "different rooms under the same roof", with adapted regulatory solutions.
- A one-size-fits-all approach does not work because traditional fertilizers are well-known substances and formulations with lower thresholds for innovation. Nonetheless, innovation is key to the broader family of fertilizing products, so using the historical approach to regulating fertilizers, which has demonstrably failed to deliver innovation, should not be a model for other fertilizing products.
- We want a properly designed regulatory framework that is fit-for-purpose and allows regulators to know exactly what is in a product and the claims being made. However, any procedures for placing products on the market should be proportionate and should use existing regulatory instruments (e.g. REACH) as much as possible.
- Biostimulants are not commodity products. The value proposition of biostimulants is tied to different recipes and combinations, not based on components in isolation. In particular, the importance of strain-level characterization of micro-organisms and the influence of microbial consortia should be appropriately taken into account.
- A well-designed regulatory framework should lighten the bureaucratic/administrative load inherent in the existing committee process to update a list of ingredients and/or meeting the cumulative burden of a multitude of national requirements.

- Meeting essential requirements adapted to the specificities of biostimulants for safety and performance must be the bar for placing biostimulants on the market and respecting boundaries with other product regulations.

⦿ *Fundamental Principle: A one-size-fits-all regulatory model does not work. The Commission must improve on the historical approach to regulating fertilizers, which has demonstrably failed to deliver innovation and cannot be a model for regulating fertilizing materials in the future.*

⦿ *Fundamental Principle: An optimal regulatory framework will recognize the added value of biostimulants as innovative products composed of different recipes and combinations and will not commoditize them.*

⦿ *Fundamental Principle: Meeting essential requirements adapted to the specificities of biostimulants for safety and performance must be the bar for placing biostimulants on the market and respecting boundaries with other product regulations.*

3.2. The final legislative text must ensure data confidentiality and protection

Data protection should be provided for any data submitted related to products and/or their components, including microorganisms.

Any data sharing must occur within an appropriate data licensing agreement. Data sharing should only be obligatory for data related to testing on vertebrate animals. Companies sharing costs of data production should be allowed to practice market segmentation and to differentiate their labeling (without prejudice to legal requirements), as long as doing so is not misleading and does not circumvent any appropriate regulatory requirements.

No provision of data submission or conformity assessment should force innovating companies to subsidize their competitors. Provisions related to data submission and use should ensure fair competition.

Similarly, requirements for labelling should provide enough information to allow consumers to make informed decisions without facilitating reverse engineering and unfair competition.

We need a framework that takes into account the limits of intellectual property protection to foster innovation in a bio-based sector where other tools (such as trade secrets) play an important role. We need a framework that:

- Ensures fair competition;

- Dissuades low-cost producers (including in other jurisdictions) from copying innovative products; and
- Does not treat copycats better than innovators.

⦿ *Fundamental Principle: Data protection should be provided for any data submitted related to products and/or their components. Any data sharing must occur within an appropriate data licensing agreement. Data sharing should only be obligatory for data related to testing on vertebrate animals. Companies sharing costs of data production should be allowed to practice market segmentation and to differentiate their labeling (without prejudice to legal requirements), as long as doing so is not misleading and does not circumvent any appropriate regulatory requirements.*

3.3. Substance data requirements will be legislated under REACH

Many biostimulants substances will remain subject to REACH registry. This is a critical difference from biocides and plant protection products, which are explicitly exempted from REACH because their pre-existing registries are considered to meet the objectives of REACH. Therefore, the costs associated with registering components under REACH must be considered in the development of the regulatory framework.

⦿ *Fundamental Principle: An optimal regulatory framework for biostimulants must take into account that many components will already have been registered once under REACH, with all the costs this entails for industry.*

3.4. EBIC advocates biostimulant **product** (not component) data requirements specific to demonstrating biostimulant claims and acceptable risk to human health and the environment; non-EU producers must also fulfill these requirements

EBIC advocates a regulatory framework that allows regulators to know exactly what is in a product and the claims being made. This will dissuade companies from entering the market with products that are not effective biostimulants. Because it provides transparency, it should also satisfy Member States and MEPs who are concerned about protecting the food chain.

Due to synergies, neutralizing effects and system effects, the full effects of a complex biostimulant product cannot be extrapolated from its components. This is true for combinations of substances as well as microbial consortia. Essentially:

- Biostimulant claims can only be justified at the level of the combination;
- Effects are dependent on dose, rate, timing, placement and other contextual factors; and
- It is more accurate to assess potential risks for both humans and the environment at the product level because taking the intended use into account brings the evaluation closer to real conditions.

Member States will be more willing to accept products that have met EU risk assessment requirements, rather than products where the link between the product and the risk evaluation is looser. In the data requirements model that EBIC advocates, post-marketing surveillance will be clearly tied to a single producer/product.

A critical aspect of research and innovation in the biostimulants sector is the ability to identify and substantiate new claims for existing substances (rather than making old claims for novel substances, as is the case in sectors like plant protection). An optimal regulatory framework for biostimulants will recognize this.

Comparable products should have to face similar regulatory burdens and costs to be commercialized. Companies wishing to import biostimulants into the EU must face the same requirements as EU producers. Claims justification must be based on trials and tests conducted in the EU. Any certifications of production to EU standards must also be required of importing companies.


*Fundamental Principle: An optimal regulatory framework for biostimulants acknowledges **biostimulant claims can only be justified at the level of a specific product combination and composition**. The product composition and phys/chem properties must be part of the registration description (quality control, guaranteed composition).*


Fundamental Principle: An optimal regulatory framework for biostimulants stipulates that companies wishing to import biostimulants into the EU must face the same requirements as EU producers, both with regard to safety and performance data.


Fundamental Principle: An optimal regulatory framework for biostimulants recognizes that data protection should be provided for any data submitted related to products and/or their components.


Fundamental Principle: An optimal regulatory framework for biostimulants accepts that the legitimate incorporation of dual-use components in biostimulant products must be maintained, with a reasonable regulatory burden.