

EBIC POSITION PAPER

Acknowledging the Multiple Identities of Component Substances and Microorganisms Is Critical to Innovation in Biostimulants

EXECUTIVE SUMMARY

- “Dual-use substances and materials” are product components that can potentially be associated with multiple effects depending on the formulation and use of the final product. The presence of a single component cannot necessarily predict the effects of a formulated product. (This differs from blends where the components remain distinct from one another and retain their characteristics in a predictable fashion.)
- EBIC advocates using a functional use definition for determining whether products are identical or only contain similar components that might realistically have different effects and a different risk profile. A functional use definition is a holistic concept that includes:
 - Physico-chemical properties (i.e. formulation, concentration, etc.)
 - Mode of application (including placement, timing, frequency and rate/dosage, etc.)
 - Main effect(s) of the formulation (i.e. minor or indirect effects are not sufficient to categorize a product as dual-use).

Functional use definitions have two major strengths for regulating how products are placed on the market: 1) They are closest to how farmers perceive the product and how they express the benefits they seek in a product; 2) Functional use definitions make market surveillance and enforcement possible with regard to any unauthorised claims.

- Companies that make claims for products that have not been appropriately authorised or assessed as in conformity with applicable regulation, either on packaging or in marketing materials should be subject to appropriate sanctions from enforcement authorities.
- Failure to design the right approach to so-called dual-use substances could potentially create risks to health and safety as well as blurring the lines between product categories.

Keywords: dual-use substances, borderline substances, dual claims, dual-function products


I. INTRODUCTION

The members of the European Biostimulants Industry Council (EBIC) are committed to producing and commercializing biostimulants in a way that ensures:

- Biostimulants can be safely produced and used;
- Biostimulants on the market have demonstrated benefits for growers and crops;
- Users and consumers have access to sufficient, truthful and transparent information with regard to the use of biostimulants.

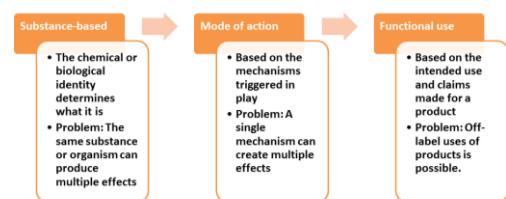
- In this light, any approach to the regulation of so-called “dual-use substances and materials¹” should have as its primary objective to create a free, competitive and fair market environment while ensuring product safety for users and consumers. Beyond the control of fraud, the evaluation of the relative merits/quality of specific products should be left to the market. Failure to design the right approach to so-called dual-use substances could potentially create risks to health and safety as well as blurring the lines between product categories, which could be detrimental for the use of many “traditional” biostimulant products such as seaweed extracts and hydrolysed proteins, which have been marketed and used safely and effectively for decades, but which can also be incorporated into many other product types, including other crop inputs.
- By “dual-use substances and materials”, we mean a product component that can potentially be associated with multiple effects depending on the formulation and use of the final product. The presence of a single component cannot necessarily predict the effects of a formulated product. (This differs from blends where the components remain distinct from one another and retain their characteristics in a predictable fashion.)
- Companies that make claims for products that have not been appropriately authorised or assessed as in conformity with applicable regulation, either on packaging or in marketing materials should be subject to appropriate sanctions from enforcement authorities. Only claims that are consistent with the regulatory framework through which the product was brought to market should be tolerated.

II. HOW SHOULD BIOSTIMULANT PRODUCTS BE DEFINED?


Fundamental Principle: A functional use definition corresponds best to how the market perceives products and the benefits that the farmer can expect from them. Drawbacks of functional use definitions can be countered through market surveillance and enforcement.

There are three principal ways to define a product:

1. Based on its composition;
2. Based on its mode of action;
3. Based on its functional use.



Each of these approaches has its strengths and weaknesses. The main problem with both composition-based and mode-of-action-based definitions is that multiple effects might be associated with that composition or mode of action. In order to counter that issue, the only option is to outlaw making certain claims, essentially shutting off potential avenues of innovation. The main issue related to functional use definitions is that there is the potential for companies to make claims for which they haven’t obtained appropriate authorisations. However, that problem can be countered by market surveillance and enforcement.

The main benefit of a functional use definition is that it corresponds best to how the market perceives the product and the benefits that the farmer can expect from it.

¹ For ease of reference, we use the term “substance” throughout this paper, but microorganisms may also have multiple potential uses.

To further strengthen the boundaries of a functional use definition, it should be holistic. Physico-chemical characteristics alone are not sufficient to define a product and its likely effect or risk profile. EBIC advocates using a functional use definition for determining whether products are identical or only contain similar components that might realistically have different effects and a different risk profile. A functional use definition is a holistic concept that includes:

- Physico-chemical properties (i.e. formulation, concentration, etc.)
- Mode of application (including placement, timing, frequency and rate/dosage, etc.)
- Main effect(s) of the formulation (i.e. minor or indirect effects are not sufficient to categorize a product as dual-use).

III. HOW SHOULD PRODUCTS CONTAINING DUAL-USE COMPONENTS BE REGULATED?

◎ *Fundamental Principle: Regulations applied to products containing dual-use substances should be proportional and favor consistency. This includes ensuring that data protection measures are not neutralized by the extension of other regulatory frameworks to biostimulants.*

The treatment of products incorporating “dual-use substances and materials” should reflect how other EU frameworks treat the same substance(s), as appropriate:

- Taking into account when “sufficient information is known about these substances that they are **considered to cause minimum risk because of their intrinsic properties**” as is the case for the substances listed in Annex IV of Reg (EC) 1907/2006;
- Considering if the substance is subject to additional requirements such as Reg (EC) 396/2005 on Maximum Residue Limits.

Regulation of all products should be done in a **proportional manner**: the least burdensome approach for achieving a regulatory objective should always be preferred over unnecessarily burdensome approaches (in terms of procedures, delays, costs).

Any approach should be designed to **favor consistency and coherency** and to minimize arbitrary decisions. This is particularly important when the substance is subjected to additional requirements under a regulation that was not originally intended for biostimulants. For example, there is no data protection clause under Reg (EC) 396/2005 which was originally designed for plant protection products (PPPs) because data protection is part of the product authorisation process for PPPs. When Reg (EC) 396/2005 is extended to other products, it is important that any relevant data protection measures (such as REACH) are not inadvertently invalidated by the processes under Reg (EC) 2005. This same principle should apply with regard to any other regulations extended to cover biostimulant components and products.

Data protection fosters innovation by ensuring fair conditions for all companies bringing products to market. Companies that invest in producing data required to meet regulatory requirements for bringing a product to market should be compensated by the user for any licensed data. Obligations to share data (for example, to minimize animal testing) should not allow companies to access another’s data unfairly because that would discourage innovation by unlawfully seizing and redistributing a company’s property.

Proportionality and consistency are especially **important for small and medium enterprises** that have little to no spare capacity to engage in lengthy and complicated bureaucratic procedures. Elegant, streamlined procedures make it possible to focus precious resources on innovation and business success while still ensuring health and safety for users and consumers.

“Dual-function products” -- In the case of two identical products – one a biostimulant and one with claims under a different regulatory definition -- the stricter of the two frameworks for risk assessment should be applied. Essentially what this means is that if a given formulation is intended to be applied to identical crops with identical timing, applications rates, etc., then it is reasonable to assume that the risk is also identical. However, it may still make sense to differentiate the regulatory pathway for other aspects of bringing the product to market, particularly demonstrating product claims to ensure that the most appropriate methodology is used. This is a different case than what EBIC generally means when it refers to dual-use substances or substances with multiple identities.

On the other hand, a change in crop, rate, timing, etc. may suffice to differentiate products and the applicable regulatory framework.

IV. DECISION-MAKING TOOL FOR DETERMINING THE REGULATORY PATHWAY OF A PRODUCT CONTAINING ONE OR MORE "DUAL-USE COMPONENTS"

PRODUCT • Physico-chemical properties (i.e. formulation, concentration, etc.) • Mode of application (including placement, timing, frequency and rate/dosage, etc.) • Main effects of the formulation	Examples	Data requirements	Permitted marketing claims
	Only biostimulant effects are claimed for the final product	<ul style="list-style-type: none"> Conformity assessment related to both safety and quality aspects of biostimulants and the other fertilising material(s) according to the provision of the future regulation on fertilising materials. 	<ul style="list-style-type: none"> Biostimulant effects only
	Claims for the final product include biostimulants effects and effects as another sort of fertilizer material (e.g. inorganic fertiliser)	<ul style="list-style-type: none"> Conformity assessment related to both safety and quality aspects of biostimulants and the other fertilising material(s) according to the provision of the future regulation on fertilising materials. 	<ul style="list-style-type: none"> Biostimulant effects Other fertilising material effects (in this case, supplying specific nutrients)
	Both biostimulant and PPP effects are claimed as main effects of the final product (a dual-function product)	<ul style="list-style-type: none"> Registration and authorisation of the PPP product under Reg (EC) 1107/2009 Conformity assessment related to biostimulant effects according to the provision of the future regulation on fertilising materials. 	<ul style="list-style-type: none"> Biostimulant effects PPP effects
	Only PPP effects are claimed for a final product that is known to also have biostimulants effects	<ul style="list-style-type: none"> Registration and authorisation of the PPP product under Reg (EC) 1107/2009 	<ul style="list-style-type: none"> PPP effects Should the producer ever want to claim biostimulant effects, the product would also need to undergo conformity assessment related to biostimulant effects according to the provision of the future regulation on fertilising materials.