

ACFI MEMBER BRIEF

For Internal Use Only

Sub.: Impact of Imposing Regulatory Restrictions on Biostimulants

Ref.: Optional Regulatory Framework for Biostimulants

Date: 24.11.17

Prepared by: Vipin Saini

Status: Draft

ACFI Note

on

Impact of Imposing Regulatory Restrictions on Biostimulants

Maintaining food production for a growing world population without compromising natural resources for future generations represents one of the greatest challenges for agricultural science, even compared with the green revolution in the 20th century. The intensification of agriculture has now reached a critical point whereby the negative impacts derived from this activity are now resulting in irreversible global climate change and loss in many ecosystem services. New approaches to help promote sustainable intensification are therefore required.

This paper will also briefly describe the legal and regulatory status of biostimulants, with a focus on the EU and the US, and outlines the drivers, opportunities and challenges of their market development.

Background of Concern

EXCERPTS

MINUTES OF 371st MEETING OF REGISTRATION COMMITTEE (RC) HELD ON 16.12.2016

The 371ST Meeting of Registration Committee (RC) was held under the Chairmanship of Dr. J.S. Sandhu, Deputy Director General (Crops Science) & Chairman of RC, Dr. P. K. Chakraborty, ADG (PP), ICAR, Dr. A.K. Sinha, Plant Protection Adviser and Mr. D.D.K. Sharma, Addl. Plant Protection Adviser & Secretary (CIB&RC) attended the meeting. Following officers from the Secretariat of CIB&RC were also present to assist the Committee:-

- 1. Dr. Sushil K. Khurana, Consultant (Pathology)
- 2. Dr. Shandhya Kulshreshtha, Consl(Pharma)
- 3. Dr. (Mrs.) Sarita Bhalla, Spl. Grade-I

- 4. Dr. Archana Sinha, JD(Chem)
- 5. Sh. Harish Chandra JD (Ento)
- 6. Mr. Dipankar Bhattacharya, DD(Chem)
- 7. Dr. Subhash Kumar, DD(WS)
- 8. Ms. Kamlesh Miglani, DD(Chem)
- 9. Sh. Hariom Miglani, Sr. Law Officer
- 10. Sh. Subhash Chand, DD(Chem)
- 11. Mr. Abhishek, AD (Chem) Pack.
- 12. Mr. G.P. Singh, AD(Chem)
- 13. Mr. R.B. Sharma, AD(Chem)
- 14. Mr. Niraj Kulshrestha, Law Officer

Agenda Item No. 2.1: Presentation of Dr. Sudhir Kumar Bhargava, Member of ICAR governing body on Plant Care Products.

Dr. Sudhir kumar Bhargawa, eminent Member of ICAR governing body made an exhaustive presentation on Bio-stimulant covering the following important information:

- a. Plant Biostimulant Definition
- **b.** Categories of Biostimulant
- **c.** Features of Biostimulant
- **d.** Mode of Action of Biostimulant
- e. Effects on crop productions
- f. Biological Market Vs Agro-chemical Market growth.
- g. Global Market drivers
- **h.** Attributes of growth in India
- i. Consequences and causes of counterfeit product under Biostimulant segment.
- j. Multinationals focus on bio-stimulant through merger and acquisitions
- k. Why Regulatory Framework needs.

It was presented and explained that how biostimulants are different from Pesticides or PGR through their Mode of Action. It was pointed out that due to absence of Regulatory System to control these biostimulants, the following problems are created and farmers stand at loss:

- **a.** Biostimulant Products are mixed with unregistered pesticides to make it more bio- efficacious.
- **b.** Promoted by unscrupulous dealers as "Bio Products", as they get high margins on such products.
- c. Can contain toxic impurities of the active ingredient (a.i.) whose Safety profile are not established

- **d.** Manufactured by companies with dubious credibility.
- **e.** No registration by the Central Insecticide Board & Registration Committee.
- **f.** Operate pretending that they are not covered under the Insecticides Act 1968.

The presentation and ground realities explained by Dr. Sudhir kumar Bhargawa was deliberated in detail and decided that the DAC&FW/Govt. of India may be requested to cover biostimulant under the Insecticides Act, 1968 or may be requested to add biostimulant in the domain of Pesticides Management Bill 2008 (PMB 2008) to save the farmers from unscrupulous modus operandi of these bio- stimulant suppliers. Dr Bhargawa was requested to submit a detailed formal proposal in this regard.

Note: Till date, no mention on Biostimulants have been observed in subsequent RC held thereafter.

In a world increasingly concerned with the environmental impact of the chemicals included in plant protection products and fertilizers, there is a growing awareness of the potential of natural agents to fulfill their role.

Biostimulants are organic and work to protect a crop by stimulating natural processes, thereby improving nutrient uptake and efficiency. These products can be applied at any stage of growth, even flowering, to increase crop yields.

Introduction to Plant Biostimulants

Plant biostimulants represent an emerging class of agricultural inputs. Microbial plant biostimulants, an important category of this emerging class of agricultural inputs, promote plant growth, enhances / benefits nutrients uptake and activate plant systemic response against biotic and abiotic stress. Among microbial plant biostimulant are included *Trichoderma* versatile strains and plant growth promoting rhizobacteria. Such microbial plant biostimulants represent one of the solutions for the negative impacts associated with the high residues agricultural systems. Plant growth and development stimulation by microbial biostimulants could compensate delay in the early stage of development. Both plant pathogens biocontrol activities, related to direct competition on plant residues niche and systemic activation of the plant defense mechanisms, reduce the risk of soil-born plant pathogens. Enhancement of nutrient bioavailability and increase nutrients uptake balance nitrogen (and other nutrients) temporary immobilization, usually result from higher carbon inputs into soils.

Development of sustainable and environmentally friendly systems which address the question of feeding the growing world population is the biggest challenges for agriculture today. As the area of arable land goes on decreasing, the only way to achieve this objective is by increasing the crop yield and protecting what we produce.

Materials of biological origin that enhance plant growth when applied to the soil are called Biostimulants.

Biostimulants, often used in plural form, is a broad term that literally means a group of ingredients that stimulate life. This could also be interpreted as a group of compounds that promotes favorable plant responses. This is neither a plant nutrient nor a pesticide, but has a positive impact on plant health.

They are neither fertilizers meant to solve a severe nutrient deficiency of plants, but are mixtures of microorganisms, trace elements, enzymes, plant hormones, and seaweed extracts. They increase availability of nutrients, water-holding capacity, increase antioxidants, enhance metabolism and increase chlorophyll production.

They are gaining importance also for their possible use in organic and sustainable agriculture, to avoid excessive fertilizer applications. In recent years, they are gaining importance due to their ability to increase the nutrient uptake, growth and development of the plants, and to improve the quality, productivity and environmental impact.

Plants meet their maximum, healthy potential due to stimulation by the applied Biostimulants. They are easy to apply and <u>can be mixed and applied with pesticides and fertilizers</u>. They can enhance plant chlorophyll content also.

They appear as a versatile descriptor of any substance which is beneficial to plants without being nutrients, pesticides, or soil improvers. They have the capacity to modify physiological processes of plants in a way that provides potential benefits to growth, development and/or stress response. Bio stimulants benefit plant productivity by interacting with plant signaling processes thereby reducing negative plant response to stress. The term bio stimulant is also used in scientific literature to describe physiological effects on other organisms than plants, including microbes, animals and humans. The various qualities required for a material to be considered as a bio stimulant are:

- 1. Ability to modify the physiology of plants, making them more efficient for using limited resources of their environment
- 2. Ability to protect plants against harmful agents, which can be reactive oxygen species induced by stressful environments, or pathogens or pests.

Bio stimulants exhibit diverse physiological nature. The various type of physiological functions they perform include the protection of photosynthetic machinery against photo damage, or the initiation of lateral roots. These functions are supported by cellular mechanisms. These functions may finally translate into economic and environmental benefits like higher crop yield, savings of fertilisers, increased quality and profitability of crop products, enhanced ecosystem services, etc.

The amount of economic and environmental benefits depends also on the existing agricultural and environmental policies, both in terms of objectives and assessment endpoints. Scientific, technical and regulatory nature offer challenges for the development of bio stimulants.

The complexity of the physiological effects of bio stimulants is the main scientific challenge whereas the formulation and blending of bio stimulants with other fertilizing / plant protection product materials poses the technical challenge. Regulatory challenges cover the categorization and premarket assessment of bio stimulants, and challenges to intellectual property rights.

Customization of extraction processes are required to maintain a precise ratio of each ingredient in complex natural mixtures thus assuring the quality and consistency of the bio stimulants.

The various factors which distinguish biostimulants from traditional crop inputs are:

i. They operate through different mechanisms than fertilizers, regardless of the presence of nutrients in the products

- ii. They differ from crop protection products because they act only on the plant's vigour and do not have any direct actions against pests or disease
- iii. Bio stimulation is thus complementary to crop nutrition and crop protection.

The importance of Bio stimulants in greenhouse and outdoor crop production is increasing manifold recently.

Plant growth is promoted by Nutrients by the provision of chemical elements used by metabolic processes for the synthesis of biomolecules and for biomass production whereas it is promoted by Pesticides by reducing the detrimental effects of pathogens and pests on plant integrity and functionality.

In order to make this distinction as clear as possible, nutrients and pesticides are explicitly excluded from the definition of biostimulants. Many applications of bio stimulants are due to their ability to influence hormonal activity. Stress tolerance is one another important benefit of biostimulants.

Biostimulants affect the physiology of plants at the cellular level, organ level and at the whole-plant level. The physiological effects depend on applied dose formulation, target and environmental conditions. Biostimulants are applied alongside fertilizers in low concentrations to the crop or soil or applied as part of a seed treatment. This necessitates the formulator to consider the mode of application so that it could be ensured that the formulation fits into the existing regime. The chlorophyll content of leafy vegetables are increased due to application of bio stimulant, the color and visual appearance of edible leaves also improves, thus enhancing the attractiveness for consumers The formulations of bio stimulants are generally proprietary compositions based on seaweed extracts, complex organic materials, plant hormone-like compounds, amino-acids, and humic acids. Some of the bio stimulants like chitosan may have pesticidal effects also.

It has direct pesticidal effects on fungal pathogens. In such a case, the primary aim of the application should take priority over side-effects. As another example, amino –acids mixtures provide the plant with an additional nitrogen source, but this nutritional effect is not the aim of the application. The gene-regulation and hormonal effects promoting plant growth should be considered as a priority for the categorization of a substance under the class of biostimulants. Bio stimulants act in synergy with plant nutrients. Combinations of humic acid plus nitrogen have been reported to increase root growth, increase metabolism and increase chlorophyll content of leaves .Increase in production of anti oxidants is also reported due to foliar applications of bio stimulants.

Some significant advantages of using biostimulants include:

- a. Organic growth enhancer.
- b. Help keep disease and stress down to a minimum."
- c. Micro nutrition
- d. production of bigger, deeper roots
- e. Loosening and mellowing of the soil
- f. Increasing nutrient and water intake
- g. soil conditioner
- of India h. Neutralize both acid and alkaline soils &; regulate the pH value of soil."
- i. Natural chelator for metal ions under alkaline conditions and promotes their uptake by the roots
- j. Increase germination and viability of seeds.
- k. Enhance plant's natural resistance against disease and pests

The major ingredients of the common commercial biostimulants are Plant hormones, humic substances, Manure and/or sea kelp extracts. The chemistry of these basic biostimulant ingredients is extremely diverse in nature, origin, synthesis, function, and role in plant-soil ecosystem. Biostimulants are available in a wide variety of formulations based on their ingredients.

Biostimulants might also be called phyto-chemicals, which are chemicals that occur naturally in plants. All families of phyto-chemicals have some distinct desirable characteristics as far as their actions on plants are concerned. The inherent limitations of singular phyto-chemicals could be best overcome by utilizing a precise combination of three families of phyto-chemicals.

A Biostimulant is an organic material that, when applied in small quantities, enhances plant growth and development. They complement the various fertilizers and products used for plant protection by enabling plants to make optimal use of these conventional inputs.

Biostimulants have been widely classified as:

- 1. Humic substances
- 2. Complex organic materials
- 3. Beneficial chemical elements
- 4. Inorganic salts
- 5. Seaweed extracts
- 6. Chitin and chitosan derivatives
- 7. Antitranspirants
- **8.** Free amino acids
- **9.** Other N-containing substances.

The "organic" substances in use have often a dual purpose – there is often no clear borderline between plant protection and fertilization

Solutions need to be found for the **borderline to Plant Protection Product** (**PPP**) without excluding substances with multiple actions e.g. seaweed extract: wherein the component laminarin was purified, concentrated and registered as PPP. However, full seaweed extract has no significant effect in plant protection; it should therefore not be excluded from the authorization as plant biostimulant under the fertilizer legislation, although it contains by its nature laminarin.

<u>Due to the low financial return, it is not possible to invest in high registration costs for most organic substances.</u> If data requirements are high and the registration process – as actually designed – is adapted very much to synthetic substances, this will lead to very high costs and even higher imponderability's for the registration of organic substances.

The low financial return is the main reason why most "organic" substances are produced by SME - due to limited attractiveness of these substances for investors. However, the public interest in these substances is high, therefore an adapted, feasible registration should be made available. To avoid that substances for historical uses vanish from the market, safe historical use of substances traditionally used in organic farming shall be considered in the registration process.

Beyond the registration procedures, the following measures should be taken to facilitate the registration of traditional used substances, support for research assessing the use and characteristics of substances traditionally used in organic farming e.g. under a Jevak Kheti Campaign of the GOI.

A plant biostimulant is any substance or microorganism applied to plants with the aim to enhance nutrition efficiency, abiotic stress tolerance and/or crop quality traits, regardless of its nutrients content. By extension, plant biostimulants also designate commercial products containing mixtures of such sub-stances and/or microorganisms. The definition proposed by this article is supported by arguments related to the scientific knowledge about the nature, modes of action and types of effects of biostimulants on crop and horticultural

<u>plants.</u> Furthermore, the proposed definition aims at contributing to the acceptance of biostimulants by future regulations, especially in the EU, drawing the lines between biostimulants and fertilizers, pesticides or biocontrol agents. Many biostimulants improve nutrition and they do so regardless of their nutrients contents.

Definition of and discussion on Biostimulants in the context of the revision of the EU fertilizer legislation

Definitions proposed by Arcadia:

Plant biostimulant

"A plant biostimulant is any substance or microorganism, in the form in which it is supplied to the user, applied to plants, seeds or the root environment with the intention to stimulate natural processes of plants benefiting nutrient use efficiency and/or tolerance to abiotic stress, regardless of its nutrient content, or any combination of such substances and/or microorganisms intended for this use."

Proposal to change the definition of Plant biostimulants:

A plant biostimulant is any microorganism or substance based on natural resources, in the form in which it is supplied to the user, applied to plants, seeds or the root environment soil and any other substrate with the intention to stimulate natural processes of plants to benefit their nutrient use efficiency and/or their tolerance to abiotic stress, regardless of its nutrients content, or any combination of such substances and/or microorganisms intended for this use.

Justification: "Root environment" is a vague definition, whereas "soil and any other substrate" clearly addresses the substrate the plant is growing in. The limitation to "abiotic" stress would cause some difficulties, as it is not always clear if the main source of stress for a plant lies in biotic or abiotic factors. If the definition would be limited to abiotic stress, many substances used today would disappear from the market.

Biofertilisers, which we propose as a subcategory of biostimulants, increase nutrient use efficiency and open new routes of nutrients acquisition by plants. In this sense, microbial biostimulants include mycorrhizal and non-mycorrhizal fungi, bacterial endosymbionts (like Rhizobium) and Plant Growth-Promoting Rhizobacteria. Thus, microorganisms applied to plants can have dual function of biocontrol agent and of biostimulant, and the claimed agricultural effect will be instrumental in their regulatory categorization. The present review gives an overview of the definition and concept of plant biostimulants, as well as the main categories.

Glossary of 'biosolutions' contributing to Sustainable Plant Productions

Biostimulant: A plant biostimulant is any substance or microorganism applied to plants with the aim to enhance nutrition efficiency, abiotic stress tolerance and/or crop quality traits, regardless of its nutrients content. By extension, plant biostimulants also designate commercial products containing mixtures of such substances and/or microorganisms.

Biofertiliser: A biofertiliser is any bacterial or fungal inoculant applied to plants with the aim to increase the availability of nutrients and their utilization by plants, regardless of the nutrient content of the inoculant itself. Biofertilisers may also be defined as microbial biostimulants improving plant nutrition efficiency.

Biocontrol: The control of one organism by another. Biocontrol agents used in plant productions are living organisms protecting plants against their enemies, i.e. reducing the population of pests or diseases to acceptable levels. Modes of action may include competition, antibiosis, parasitism and also Induced Systemic Resistance which is mediated by the plant.

Regulation of Plant Biostimulants

The regulatory situation of biostimulants is very complex today, in the absence of any specific and harmonized framework in either the EU or the USA. One of the main reasons for this situation is the lack of formal definition and acceptance of the concept by regulatory bodies.

In Europe today, biostimulants are placed on themarket by following either of two routes: one is the national regulations on fertilizers, the other one is the European pesticides law, which combines both supranational and national provisions for introducing plant protection products on the market. In Europe, the current situation is that the EC regulation No 1107/2009 on plant protection products ('PPPs') is applicable to all categories of biostimulants, considering the very broad definition of PPPs. Indeed, Article 2 of this regulation reads: 'This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

(b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient.'

As any biostimulant is intended to influence the life processes of plants by other ways than as a nutrient, it may be regarded as a « plant protection product » from a strict regulatory view point. Synthetic and natural substances (including botanicals and basic substances as mentioned before), and microorganisms, are all covered by this regulation. All plant growth regulators and herbicide safeners have been registered under this PPP regulation until now and these are substances that interact with the physiology of the plant, even though they do not protect the plant against pests or diseases. Due to the lengthy and costly procedures to place a PPP on the European market, taking into consideration that many companies developing biostimulants are SMEs and that improved plant nutrition and growth are the main scope of biostimulants, an alternative route has been chosen, namely the 'fertilizers route' in which case national legislation is applied. Why not the European law on EC fertilizers (regulation (EC) No 2003/2003) ? Because the definition of fertilizers laid down by this regulation is very restrictive and cannot include biostimulants.

Indeed, Article 2 reads: For the purposes of this Regulation the following definitions shall apply:

- (a) 'Fertilizer' means material, the main function of which is to provide nutrients for plants.
- (b) 'Primary nutrient' means the elements nitrogen, phosphorus and potassium only.
- (c) 'Secondary nutrient' means the elements calcium, magnesium, sodium and sulphur.
- (d) 'Micro-nutrients' means the elements boron, cobalt, copper, iron,manganese, molybdenum and zinc essential for plant growth inquantities that are small compared with those of primary and secondary nutrients.'

Any fertilizer must provide nutrient as its main function. This is clearly not the case of biostimulants, which by definition promoteplant growth by other means than by providing nutrients. Annex Iof the (EC) No 2003/2003 regulation on EC fertilizers lists types of fertilizers, which are all inorganic materials providing macro- and micronutrients, but also chelating and complexing agents intended to optimize the delivery of micronutrients to plants, allowing chelated and complexed micronutrients to be placed on the mar-ket by the way of this regulation. It was later considered that other compounds used as fertilizers additives, i.e. nitrification and urease inhibitors, should also be granted market access via this regulation. This led to a breakthrough in the European fertilizer regulation, which was amended by the (EC) No 1107/2008 regulation in order to introduce materials which are not providers of nutrients (fertilizers sensu stricto) but additives of fertilizers enhancing fertilizers performance. Many biostimulants may be considered as enhancers of fertilizers performance and this regulatory advance seemed to pave the way to the inclusion of biostimulants into the EU fertilizers law. However, this option is not realistic as amending regulations is a laborious procedure which cannot be followed for all

biostimulants. When the national fertilizers laws are used for introducing biostimulants on the European market (mainly those enhancing nutrition and growth, e.g. humic acids, seaweed extracts and protein hydrolysates), marked differences exist between member states in terms of data requirements for efficacy, toxicity and ecotoxicity assessment.

To complete this overview, it is worth to mention that legal provisions exist within the EU to promote « mutual recognition » between member states (Regulation (EC) No 764/2008), i.e. 'fast tracks' exist for the placing on the market of members states when an authorization has been granted in one of them. However, based on interviews with representatives of stakeholders and competent authorities, It is realistic to think that this system is not efficient enough and is not expected to develop in the future. Taking into consideration the need for harmonization of legislation on biostimulants, but also of other categories of fertilizing materials and additives, – i.e. nutrients performance enhancers, organic and organo-mineral fertilizers, soil improvers, growing media, liming materials – the European Commission and its Fertilisers Working Group representing competentauthoritities of member states and stakeholders has initiated an ambitious reform of its fertilisers regulation.

The situation in the USA is to some extent similar to the European situation: no approved definition of biostimulants, no harmonization between the 50 states, use of fertilizers laws for the placing on the market of certain biostimulants at the state level, and work in progress between stakeholders, representatives of regulatory bodies and federal agencies to improve the legal certainty surrounding biostimulants. The role of the American Association of Plant Food Control Officials has already been underlined, especially regarding the definitions and formal recognition of categories of fertilizers (AAPFCO, 2012). The future will indicate how the federal agencies EPA and USDA will regulate biostimulant products.

A plausible scenario today seems that some of the biostimulants could fall under EPA jurisdiction, while the others would be registered as fertilizers or soil amendments at the state level. Furthermore, USDA, via its Natural Resources Conservation Service (NRCS) Agency, could acknowledge the capacity of certain biostimulants to reduce nutrient run off by including biostimulant products in a list of soil health-promoting practices.

We understand, the new EU fertilizer legislation aims to cover products historically used for decades in organic farming as seaweed extract. However, the whole process for registration presented and also the definition is adapted too much to synthetic substances.

Biostimulants can be used as a tool to complement the use of chemical inputs, by involving non-living-based products, or living-based products containing beneficial rhizosphere microbiome, such as plant growth-promoting rhizobacteria (PGPR). Pest management research has also made major advances in the development of efficient biocontrol methods. Elicitors and semiochemicals are considered to be some of the most promising tools for inducing plant resistance to various diseases and enhancing natural predation, respectively. Several products are already on the market. This review discusses current methods for exploiting and applying biostimulant and biocontrol products in contemporary agricultural systems.

The role of biostimulants and bioeffectors as alleviators of abiotic stress in crop plants

(This review of information is intended to provide a broad overview of known effects of biostimulants and their ability to improve tolerance to abiotic stresses).

The use of bioeffectors, formally known as plant biostimulants, has become common practice in agriculture and provides number of benefits in stimulating growth and protecting against stress. Inoculation or application of extracts from algae or other plants have beneficial effects on growth and stress adaptation. Algal extracts, protein hydrolysates, humic and fulvic acids, and other compounded mixtures have properties beyond basic nutrition, often enhancing growth and stress tolerance. Non-pathogenic bacteria capable of colonizing roots and the rhizosphere also have a number of positive effects. These effects include higher yield, enhanced nutrient

uptake and utilization, increased photosynthetic activity, and resistance to both biotic and abiotic stresses. While most biostimulants may also demonstrate numerous and diverse effects on plant growth, **this review focuses on the bioprotective effects against abiotic stress**. Agricultural biostimulants may contribute to make agriculture more sustainable and resilient and offer an alternative to synthetic protectants which have increasingly falling out of favour with consumers. An extensive review of the literature shows a clear role for a diverse number of biostimulants that have protective effects against abiotic stress but also reveals the urgent need to address the underlying mechanisms responsible for these effects.

Challenges

- I. Variant definitions
 - At every corner of the world, urea is urea, mancozeb is mancozeb, copper sulphate is copper sulphate, atrazine is atrazine, glyphosate is glyphosate etc.
 - In other words, there is a common language and a common word to describe a given product or molecule! What about biostimulants? The answer is NO! A rapid look at the legislation in various countries shows that the approach is different.
- II. Although a legal definition for fertilizers and plant protection products exists, an equivalent legislation for plant biostimulants remains to be defined. There are guidelines on efficacy evaluation for the use and registration of these products, but little has been done towards developing a qualitative method for discriminating among the myriad of plant biostimulants increasingly released into the market. How can one certify whether a product is a biostimulant or not? To answer this question and establish a guideline to access biostimulant activities with simple protocols, it is worthwhile using both reproducible plant models and suitable biological markers.
- III. One of the main constraints for practical use in agricultural systems of microbial plant biostimulants is the development of a bio-product compatible with the existing application technologies and equipment.
- IV. A standard protocol to evaluate the effects of biostimulants on plant physiology is still lacking.
- V. It is important to have a reference protocol with both a standard plant and period of treatment to identify whether a biostimulant is efficient or not and could replicate consistent results under field condition as a second step. The standard protocol for biostimulants should be both technically accessible and economically viable.

List of Annexures

- Annexure 1. Plant biostimulants: Definition, Concept, Main Categories and Regulation
- **Annexure 2.** EBIC POSITION PAPER Towards an Optimal Regulatory Framework for Biostimulants
- **Annexure 3.** IFOAM EU position paper on the Commission proposal for a new fertiliser regulation
- Annexure 4. BIOSTIMULANT MARKET- OVERVIEW