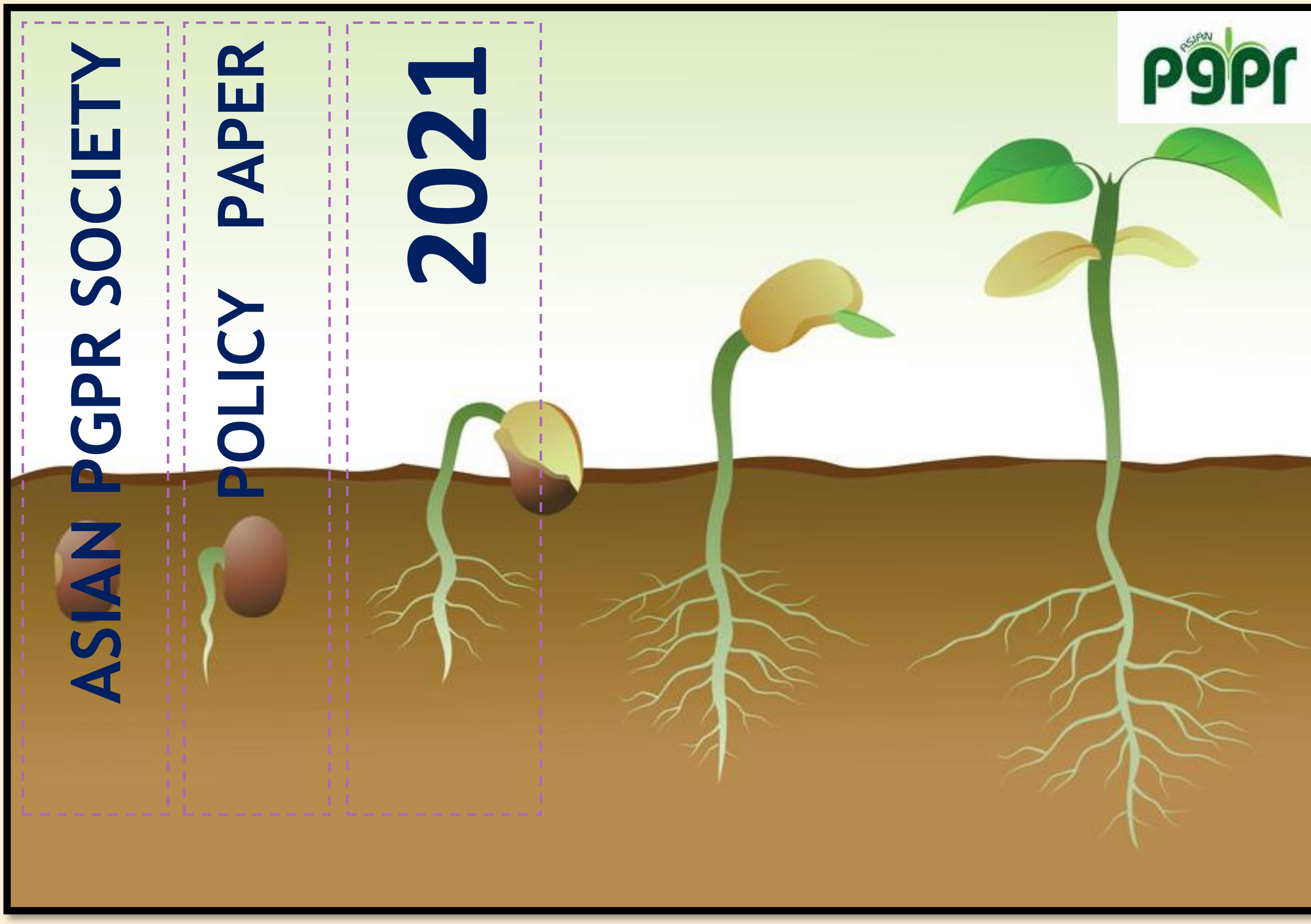

Regulations for Plant Growth-Promoting Microorganisms

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Regulation of Plant Growth-Promoting Microorganisms

Background

The major challenges facing the developing countries in Asia are in ensuring food and nutritional security to all, improvement of soil health, and environmental quality. high fertilizer usage in an imbalanced way has brought in sustainability concerns that require adoption of remedial measures and alternative interventions to improve soil, plant and environmental health. The hotspots of N fertilizer application have shifted from the USA and Western Europe in the 1960s to eastern Asia in the early 21st century and there is hence an urgent need to reduce and optimize fertilizer use. Agriculture is a major source of livelihood in rural areas and, small and fragmented land holdings are a common feature in Asia. Small land holder and marginal farmers with less than two hectares of land account for as high as 82% of all farmers in India and number almost 126 million. Higher inputs cost, reduced ground water availability, erratic weather conditions have all been reducing the factor productivity and driving down the farm profits making agriculture unviable for the small holder farmers. Hence a robust system based on indigenous and traditional knowledge coupled with modern practices are important to rejuvenate agriculture and increase productivity while preserving the quality of the resource base. Improvement of soil health by increasing the recycling of organic wastes, crop rotations with legumes and use of plant growth-promoting microorganisms as inoculants (biofertilizers) for promoting nutrient availability to crops and protection from pests and diseases (biopesticides) have all been a critical part of the package of practices to sustainably promote crop production.

History of Microbial Inoculants

Beneficial plant-microbe relations result in increased availability of plant-available nutrients through nitrogen fixation, mineralization from organic sources or dissolution from inorganic fixed forms of phosphates, silicates, potash, iron etc. Microbes afford disease resistance by improving plant immunity through various mechanisms including the production of siderophores and antibiotics, insect pest control through infestation and production of toxic molecules and offering tolerance to adverse soil and climatic conditions through the production of various biomolecules.

Microbial inoculants have been used for more than 125 years beginning with the inoculation of legume crops with rhizobia; the first patent of *Rhizobium* was granted in the USA in 1896. Subsequently, commercial production of rhizobial inoculants started in 1905 in Canada, 1914 in Australia and Sweden, and 1934 in India to name a few examples. Quality control legislation in USA in 1912, use of fermenters for mass cultivation of rhizobia from 1927 in USA, mass production of biofertilizers in India from 1956, Indian Standards Institution quality marking from 1977 for *Rhizobium* and 1979 for *Azotobacter*, along with similar concurrent efforts in many countries have all led to increased production and distribution of microbial cultures in more than 30+ countries worldwide. High quality peat-based inoculants worldwide led to a large market share for rhizobia followed later for other plant growth-promoting rhizobacteria (PGPR) like *Azotobacter* and *Azospirillum* (mostly in lignite and charcoal carriers). In many countries these inoculants were marketed under functional categories as phosphate, silica, potassium and zinc solubilizing bacteria. In India in the post-green revolution period beginning with 1990 there has been widespread production and use of biofertilizers (rhizobia and non-symbiotic plant growth promoting bacteria) for most cultivated crops, particularly in the southern and western parts of India. Inoculants have been developed and used for almost all crops including many horticultural crops. They include P solubilizing fungi, mycorrhiza, blue-green algae for rice and *Acetobacter* for sugarcane. The advent of liquid inoculants, granules, high-count dry inoculants, etc., addressed the concerns about the poor quality and low shelf life of carrier-based preparations. To regulate Biofertilizer production, the Ministry of Agriculture, Government of India brought Biofertilizers under Fertiliser Control Order in 2006. However, despite all these promising developments in Biofertilizer Research and Development worldwide and useful regulations, and many success stories of usage, there have always been continuing concerns on product quality not only in developing countries but also in developed countries. A recent development has been the categorization of plant growth-promoting microorganisms as microbial bio-stimulants in Europe (which includes four biofertilizers), in USA and Canada (biofertilizers and some biopesticides).

Principle stages in Bioinoculant development

1. Isolation of competent Microbes
2. Screening studies for specific abilities
3. Testing under *in vitro* conditions
4. Green house / small-scale trials
5. Field trials
6. Inoculum standardization & Quality control
7. Commercial production of bioinoculants

Markets

As societies become increasingly ecologically conscious, there has been a worldwide upsurge of interest in organic farming and the consequent switch from fertilizers and agrochemicals to organic manures, biofertilizers and biopesticides. As of 2015, India had the most organic producers followed by Uganda and Mexico. In 2018, India was 9th in terms of land under organic agriculture with 3.56 million ha under organic certification of which half was cultivated and half was through wild harvest collection. The recent spurt in consumer demand for organically farmed products has thus led to tremendous growth in the industry for plant growth-promoting microbial inoculants (biofertilizers and biopesticides). Of the 3 *Agricultural Biologicals*, the global market is nearly 50% for biopesticides, 30% for biostimulants (non-microbial) and 20% for biofertilizers (microbial biostimulants). The global market size for biofertilizers was valued at USD 1.34 billion in 2018 and is projected to reach USD 3.15 billion by the end of 2026 at a CAGR of 11.3%. Of these, N fixers constitute the majority (83%) followed by P solubilizes (12%). As per another estimate the market may be around 2.7 billion USD growing at a CAGR of 12.8%. North America and Europe constitute about 55% of the revenue share. Indo-Pacific region presents the great opportunities for future expansion. The microbial preparations are predominantly bacteria (68%) and fungi (16%). These are predominantly liquid formulations (65%) whose demand is intensifying owing to ease of application, convenience in the use of the product and to avoid any spoilage or wastage of the product due to contamination. However, dry formulations are also gaining traction. Their utilization for production of fruits and vegetables will remain high in the future.

The experience of some Asian countries like India in microbial inoculants goes back more than a century. In India the biofertilizers (now classified under microbial biostimulants in EU and North America) industry grew from about 1000 tonnes per annuum in 1990 to ~20,000 tonnes per annum in 2010-11. During 2015-16, the production jumped to ~95,000 tonnes and in 2017-18 to ~1,20,000 tonnes per annum. The potential requirement of biofertilizers in India with 50% area coverage was estimated by the Ministry of Agriculture, Government of India at 2,35,000 tonnes in 2001.

The key market drivers for plant growth promoting microorganisms in the future will be in Europe (marketed as microbial biostimulants) due to its increasing demand for organic produce and in China and India (biofertilizers) in pursuit of their policy to reduce fertilizer consumption and improving the soil health. The demand for biopesticides in the future is expected to be the highest in South America. Such a global demand for Agricultural Biologicals is a very promising opportunity, which is even greater when we look at the immense potential of Asian countries particularly India to manufacture biologicals (vaccines, inoculants, enzymes, pharmaceuticals etc.) and supply them to the world. Correspondingly our responsibility is also greater.

Policy Initiatives

The Government of India has taken several policy measures to promote organic farming, natural farming, biofertilizers and biopesticides. Under the *"Paramparagat Krishi Vikas Yojana"* for Soil Health Management under the National Mission of Sustainable Agriculture (NMSA), organic farming is promoted through adoption of organic villages by cluster approach and participatory guarantee scheme certification. Farmers' trainings, discussions, soil sample testing, planting of nitrogen-fixing green leaf manure legumes, support for production of traditional microbial biostimulant inputs (Panchagavya, Beejamruth and Jeevamruth), botanical extracts production units (Neem cake, Neem oil), liquid biofertilizer consortia (Nitrogen fixing/Phosphate Solubilizing/Potassium mobilizing Cultures), liquid biopesticides, Phosphate

Rich Organic Manure, Vermicompost etc., are being provided. The government is giving continuing back-end subsidy for the setting up of biofertilizer production units. Recently, the Government of India organised the Vaishwik Bharatiya Vaigyanik Summit (VAIBHAV), a global summit of leading overseas and resident Indian scientists and academicians for on-line discussions in October 2020 to deliberate on areas of collaboration for cutting edge research.

In the theme on `Microbial Resources for Sustainable Agriculture' in which some of us (M.S. Reddy, D.L.N. Rao) participated, one of the major resolutions brought was, that, in the coming scenario of adverse climatic changes, microbes in view of their resilience and adaptation (and India being a mega-diversity hotspot) provide rich opportunities for scientific advancements. Climate-smart technologies and translation to farmers needs by entrepreneurship set up through Indian initiatives for global good are needed. The most pertinent recommendation in the context of the present policy paper was to set up a centre of excellence in Biofertilizer Technology. Therefore, in the background of the very encouraging scenario of governmental support for sustainable farming technologies, the various issues concerning quality biofertilizer production need to be addressed and upgraded to bring at par with global standards to promote `Make in India' for Global markets which also gives strong support to other policy dimensions of Government of India.

Asian PGPR Society

We at the Asian PGPR Society are a group of more than 1500 extremely active group of enthusiastic scientists, academicians, agricultural entrepreneurs, research scholars and progressive farmers who are focused on and constantly deliberating on all aspects of microbiology and in particular plant growth-promoting microorganisms aimed at improving crop yields, crop nutrition, mitigating adverse effects of abiotic and biotic stresses and improving soil health. Looking at the common challenges facing all Asian countries, of improving yields and farmer income, reducing the cost of cultivation, assuring livelihood and nutritional security, our group has organized a brainstorming session in November 2020 to get inputs from academia, research and industry to identify the main drivers and challenges faced in improving biofertilizers (plant growth promoting microorganisms) in agriculture.

The objectives of the exercise were to:

1. Discuss the current state of regulations on biofertilizers (plant growth-promoting microorganisms) in India.
2. Ascertain what additional groups of microorganisms can be brought under Biofertilizers including a few Biopesticides.
3. Suggest improvements in critical quality parameters to improve the efficacy of biofertilizer performance.

The discussions and the other inputs are summarized in this white paper. The objective is to communicate to the Governments in Asia the various policy-related suggestions on Biofertilizers and their regulation. We have made further suggestions on nomenclature, manufacture, usage, biosafety and marketing of biofertilizers which when adopted uniformly across the region by the countries would go a long way in assuring the quality of these crucial but hitherto neglected inputs in agriculture which have a huge potential. There are immense opportunities that await the world. So far, we have no unified markets in the Asia region and our suggestions if adopted uniformly across Asia will facilitate smoother marketing now and particularly in the future should a common market like EU come into existence among SAARC or Indo-Pacific countries. Hence our suggestions to all in the concerned Governments, Academicians, Professional societies, NGO's, Think-tanks, Industrialists and Entrepreneurs for helping in translating into action our policy suggestions on Plant Growth Promoting Microorganisms (Biofertilizers) to strengthen the foundations of sustainable agriculture and create an ecologically sound planet.

PGPM (Biofertilizers, Biopesticides)/Microbial Biostimulants

In a large majority of countries like India plant growth-promoting microorganisms (PGPM) have been categorised as `Biofertilizers' when registered under fertiliser legislations and as `Biopesticides' when regulated under the plant protection category. In Europe and USA, Biofertilizers and some Biopesticides are categorised as Microbial Plant Biostimulants since they are by nature more similar to fertilising products than to most categories of plant protection products. They act in addition to fertilisers, optimising the efficiency of those fertilisers and reducing the nutrient application rates, act on the plant's metabolism, or enrich the soil microbiome, increase plant production and improve soil health but differ from crop protection products because they do not have any direct actions against pests or diseases.

‘Biofertilizer’ refers to preparations of plant growth-promoting microorganisms containing nitrogen fixing bacteria, phosphate solubilising bacteria and fungi, mycorrhiza etc., used to solubilize/mobilize nutrients to improve plant nutrition and promote plant growth. PGPM (Biofertilizers) are currently included in microbial plant biostimulants in Europe and USA. PGPM induce changes in the physiology of plants-invoking immune responses, improving root proliferation, improving photosynthesis and nutrient uptake. Microbial Plant biostimulants in Europe are included under fertiliser regulations and specifically as ‘a product stimulating 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:

(a) Nutrient use efficiency

(b) Tolerance to abiotic stress

(c) Quality traits

(d) Availability of confined nutrients in soil or rhizosphere

Biostimulants are however excluded from the scope of regulations on plant protection products. The above definition does not mention biotic stress specifically although it is well known that microbial biostimulants confer a degree of resistance to biotic stresses too. There is a lack of reference to phyllosphere, and humification and degradation of organic compounds in soil which was initially proposed. The EU definition does not specifically mention the products capacity to increase yields even though it is implied. The organisms approved so far in the EU legislation on plant microbial biostimulants are only four: *Azotobacter* spp., Mycorrhizal fungi, *Rhizobium* spp. and *Azospirillum* spp. This means that only these four will be presently regulated, while more innovative products (for example, consortia of microorganisms) are omitted, and manufacturers will not be allowed to market them. It is a serious restriction, and it may be noted that fortunately we have an approved NPK consortium in the FCO.

The description of biostimulants in the 2018 Farm Bill of USA is similar to that of EU bill and only adds crop quality and yield thus fully bringing it in line with the observed effects of biofertilizers/plant growth-promoting microorganisms as: “a substance or micro-organism that, when applied to seeds, plants, or the rhizosphere, stimulates natural processes to enhance or benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, or crop quality and yield.”. Here microbial biostimulants broadly specify: *Rhizobium*, PGPR, Mycorrhizae, *Trichoderma*, other beneficial fungi. This brings within the ambit of microbial plant biostimulants, organisms such as *Trichoderma*, *Bacillus* and *Pseudomonas* (allowed so long as a plant protection claim is not made on their product label). Biostimulants can also include, or much more complex “natural” communities derived from organic matter processing. Biostimulants are regulated as Microbial Supplements in Canada under the Fertilizers Act. Many products offer both crop fertilization and crop protection traits. Under the current rules in Canada, manufacturers have to choose whether their product will be regulated through the Fertilizers Act or the Pest Control Products Act. Both properties cannot be claimed on the label. A need to develop a process that would allow for dual registration on one label needs to be developed. It is essential to distinguish between the two uses only in so far as the requirements and rigor of pathogenicity tests are concerned.

As afore mentioned, the list of organisms considered as microbial plant biostimulants varies among various countries, some include only biofertilizers and some include also some biopesticides with or without label claim. In India the biofertilizers and biopesticides are distinctly defined and regulated. Further the understanding of their definition varies in different countries. EU and USA define them only by their physiological effects on plants and not on composition, whereas some countries like India define them by their inherent functionality. Also, to be noted is that the recent draft Plant Bio-stimulants Order of Government of India, although includes microorganisms in the definition but does not list any of the 10 microbial preparations currently classified as Biofertilizers under the FCO. In the context of the FCO itself, considering the overall mechanism of their action into consideration, there is also a case for India to include some of the Biopesticides (*Pseudomonas*, *Bacillus*, *Trichoderma*) into the FCO under Biofertilizers much like what has been done in USA and Canada for these organisms since they are also known to improve nutrient use efficiency. Given their long history of safe usage this would not vitiate the regulation of the products as long as there is no label claim of plant protection and the organisms used in production are certified to have no pathogenic or toxic effects by the culture collection.

Quality Standards

The quality standards of biofertilizers/plant growth-promoting microorganisms globally as well as in Asia varies from country to country. Since regional groupings are striving to unify or facilitate markets, those conforming to the highest standards should be certified by a common recognizable symbol of quality marking that qualifies for export world-wide. The SAARC/Indo-Pacific Region countries may work out a mechanism to incentivize quality manufacturers by distinguishing labels.

The quality specifications of the microbial inoculants in countries of the Indo-Pacific region vary from 5 x 10^7 cell/g (India) to 1-2 x 10^8 cells/g (Thailand, China) to 1 x 10^9 cells/g (Australia) for carrier-based inoculants. For liquid inoculants it varies from 1 x 10^8 cells/ml (India) to 2 x10^8 cells/ml (China) to 5 x10^9 cells/ml (Australia) The legislation in Brazil for soybean rhizobia also requires 1 x 10^9 viable cells/g until the 6 months expiration date and absence of contaminants at 1 x 10^{-5}/g (same as the contamination standard in India). This 50-fold variation in viable cells across various continents and countries is not acceptable for any other product in say the food or pharma industry and needs to be uniformly rationalized across the region. In India the ISI standard for carrier-based inoculants for *Rhizobium* when first notified in 1977 was 10^8 cells/g at manufacture and 10^7 cells/g at the end of the six months expiry period. The standards were the same for *Azospirillum*. For *Azotobacter* it was 10^7 cells/g at manufacture and 10^6 cells/g at the end of the expiry period. Later it was made uniform for all bacterial inoculants at 5 x 10^7 cell/g for solid carrier-based and 1 x10^8 cell/ml for liquid inoculants. The tolerance limits in India are 20% for carrier based and as high as 50% for liquid biofertilizers- The *viable count shall be not less than 1 x 10^7 cell/g for carrier based and not less than 5 x 10^7 cell/ml for liquid formulations during the entire period of shelf life*. Also, in NPK consortia the counts are lower for individual members in solid carrier-based inoculants, 1 x 10^7 cell/g even though the total is 5 x 10^7 cell/g. Why the count of individual members is lower is not made clear in the order. Taking inoculant quality standards in Australia, USA, Canada, Brazil and EU as examples, fresh standards are proposed in this paper.

Efficacy

At the present moment there is no requirement under FCO Biofertilizer regulations to specify in quantitative terms any agronomic benefits or physiological effects as required for microbial biostimulants under the EU regulations. It is natural that there can be never a guaranteed specific level of efficacy under all conditions, as many factors influence the performance of biofertilizers in the field (spatial variability in soil properties, soil organic matter, soil available nutrients, soil microbiome diversity, crop variety, its physiological response under varying soil and climatic conditions etc.). However for Indian manufacturers making inoculants in India for marketing domestically as biofertilizers or biopesticides and in EU/USA as Microbial biostimulants, some data on "agronomically observable " yield increment trends over years or at different locations compared to uninoculated plots in field trials will need to be generated to make a bio stimulant claim (not necessarily statistically significant) because of the nature of the effects induced by the biostimulant and the inherent variability in soils and crops. For validating claims on (a) Nutrient use efficiency (b) Tolerance to abiotic stress (c) Quality traits and (d) Availability of confined nutrients in soil or rhizosphere, not all the above traits can be demonstrated from field trials or in a single year. Data generated under controlled green-house conditions are admissible for some of the above traits if it is from a manufacturer's own certified/accredited R&D facility or a research institute, university etc. The criteria are a demonstration of consistent physiological processes at laboratory level producing stable effects- Enhance the productivity consistently, improve metabolism and assimilation, improve water use efficiency, tolerance to stress, improved root architecture. The use of a microbial biostimulant also has to be consistent with integrated nutrient management, integrated pest management, organic farming and cultivation practice.

In the Indian context, many plant growth promoting microorganisms (biofertilizers) are marketed not only as pure cultures in carriers but by addition of growth effectors, waste materials, other microbial extracts or botanical extracts, organo-mineral or chemical fertilizers, humic substances (humic acid and fulvic acid) etc., claimed at improving the product efficacy. The labels should specify such additives and improved efficacy shall clearly be supported by rigorous R&D studies published in peer reviewed journals. Same applies for consortia tailored for a specific crop or recommended for application at specific growth stage or timed release etc., which shall be backed by published results. Some biofertilizer preparations mixed with fertilizers are marketed without any rationale, in fact added fertilizer nitrogen delays the onset of nodulation of legumes by *Rhizobium* inoculants and even in case of PGPM delays their ability to promote nodulation by native rhizobia.

Labeling

As per EU regulations, in a Microbial Plant Biostimulant product label, all intentionally added micro-organisms shall be indicated. Where the micro-organism has several strains, the intentionally added strains shall be indicated. The actual concentration(s) of micro-organisms (colony forming units per gram-cfu/g) may deviate by no more than 15% from the declared value(s). The label shall contain the following phrase: ‘Micro-organisms may have the potential to provoke sensitizing reactions’. However currently in India there is no requirement to disclose the strain by its genomic identity. Conscious of the opportunistic nature of many microbes in inducing pathogenicity in immune compromised, neo-natal and sometimes even healthy individuals it is proposed that all the Biofertilizer packet labels should specifically list all the organisms present in the composition and declare that they do not contain any pathogenic strains.

Biosafety

Safety requirements for preparations consisting of a microorganism or a consortium of microorganisms in EU legislation on microbial biostimulants, specify limits for Salmonella, *E. coli*, *Listeria*, *Vibrio*, *Shigella*, *Staphylococcus*, enterococcaceae, anaerobes, yeasts and moulds. For biofertilizers in India there have not been such requirements. However, when pure cultures of a defined agriculturally useful microorganism with long history of safe usage or a consortium of such organisms, are cultivated in sterilized media in GLP certified laboratories, there may not be a necessity for such stringent tests. However, given that many species of *Enterobacter*, *Klebsiella*, *Serratia*, of the *Burkholderia cepacia c*omplex, *Pseudomonas aeruginosa*, among others, isolated from soils have the capacity of promoting plant growth, they may not be permitted as inoculants without studies to determine their taxonomic position and biosafety level. Safety requirements for all biostimulants in EU prescribe heavy metal contaminant limits for Cd, Cr VI, Total Cr, Pb, Hg, Ni, As, Cu, Zn which may not be necessary when microbes are cultivated in synthetically defined medium.

Akin to European Union’s CE Marking as an administrative measure to indicate conformity with health, safety, and environmental protection standards for products sold within the European Economic Area, it is proposed that the countries of the **SA**ARC/**I**ndo-**P**acific Region may work out a mechanism to assure biofertilizer (plant growth promoting microorganisms-PGPM) safety by SA EcoMark and IP EcoMark at regional level and separately certified in each country by relevant body concerned, e.g., in India by BIS/India Organic etc.

Considering the aerial transmission of fungal spores and well-known adverse respiratory effects, it is urged that utmost precautionary step be followed both in the manufacture of such inoculants as well as their aerial spraying in agriculture. To limit the adverse effects while using them for hastening the decomposition of leftover cereal straws in the fields at harvest, it is advocated to mix such decomposing cultures with well-rotted compost and applied on soil which would provide additional synergistic benefits on soil health besides rapid decomposition.

Other Biofertilizers

There should be a window for inclusion of new plant growth promoting microorganisms under the category of Biofertilizers depending on historical data of safe production and use. Biofertilizers not currently included in the FCO in India or in other countries regulatory bodies, e.g., blue-green algae, cultures for compost acceleration, bacterial plant endophytes, soil health improving inoculants can be considered. Biofertilizers like blue green algae, *Streptomyces* (when not labeled as biopesticide), *Arthrobacter* can be produced and sold generically, when included in FCO. There are a number of other mycorrhizal organisms (both ecto-and endo-) whose efficacy as plant inoculants is not so well known or researched under Asian conditions as rigorously as *Glomus* (*Funneliformis*) or *Gigaspora* have been. Their inclusion among microbial inoculants may be considered by relevant standards and regulatory authorities in India only after generating experimental information on their effects on plants and soil carbon sequestration when used as sole or mixed inoculants for crop plants through field experiments conducted in India.

RECOMMENDATIONS

We propose the following set of suggestions to all stakeholders involved in regulation of plant growth promoting microorganisms as biofertilizers. This set of recommendations pertains to biofertilizers only.

1. Biofertilizers should contain only pure cultures of bacteria, fungi, blue green algae or actinomycetes or their consortia.
2. The name of the microorganism in the biofertilizer be mentioned on the packet along with the cell load in cfu/g or cfu/ml at the time of manufacture of each batch and lot and at expiry. In the case of a consortium, the names of all the organisms and their titre values to be mentioned.
3. The information that should be supplied for registration should go beyond the identity and give details as follows:
   a. Function of the microbial strain in the biofertilizer preparation
   b. Identity at species level; disclosure of sub-species and strain information may be required depending on the nature of the microorganism.
   c. Ecological origin of the isolate (accession number of culture collection where deposited or sourced from).
   d. Detailed information on the molecular identity of the organism to support the taxonomic identity (16S rRNA or 18S rRNA identity sequence as the case may be or any other).
   e. Relationship to known pathogens (phylogenetic tree) for clear differentiation of the organism from any closely related pathogenic and/or toxigenic species and strains.
4. The cultures which are included in the biofertilizer should have the gene sequence deposited in a gene bank and the culture be deposited at any two nationally recognized microbial culture repositories, one of them preferably a Budapest treaty recognized depositary. In case of India, one of the repositories be the National Bureau of Agriculturally Important Microorganisms, Mau, U.P.
5. Many plant growth promoting microorganisms now marketed as phosphate, potassium and zinc solubilizes, also have a biocontrol ability (e.g., *Bacillus* spp. and *Pseudomonas* spp.). In view of the identity disclosure as per no.3 above, regulatory authorities would need to permit their inclusion in the list, as long as there is no label claim for them as biocontrol agents.
6. To further harness the potential of indigenous microbial isolates for the larger benefit of the farming community, a Biofertilizer (PGPM) Registry be maintained by National Biodiversity Authority and the National Bureau of Agriculturally Important Microorganisms, Mau, U.P.
7. The Biofertilizer producers should be required to make additional disclosures in the product literature about bio-efficacy of the product in support of various label claims on yield and other functional characteristics.
8. Given their long history of safe usage some currently listed biopesticide organisms (*Pseudomonas*, *Bacillus*, *Trichoderma* strains certified as non-toxigenic, non-pathogenic by the culture collection from where sourced) could be brought under FCO as Biofertilizers without a significant impact on the regulatory guidelines of these products.
9. As a first step, the minimum cell load for all bacterial biofertilizers should be increased to 1 $\times 10^{8}$ cells/g of carrier material for solid inoculants and 1 $\times 10^{9}$ cells/ml for liquid inoculants of each organism whether in single culture or as a consortium. There need be no fear of the

capability of Indian inoculants industry to meet these higher standards as these are already being adhered to for export markets. Rather it would help weed out manufacturers producing poor quality products.

10. The tolerance limit be reduced to 15% only, i.e., 0.85 x 10^8 cells/g of carrier for solid inoculants and 0.85 x 10^9 cells/ml for liquid inoculants.
11. New Biofertilizer categories for photosynthetic N fixers-cyanobacteria (blue green algae), organic decomposing (*Trichoderma*), bioremediation of pesticides, hazardous chemicals or industrial wastes (*Arthrobacter*), soil health promoting (*Arthrobacter*, *Streptomyces*) cultures need to be recognized and standards developed.
12. Only a positive list has been included above. If some strains of PGPM species included in biofertilizer formulations are known to be potential or opportunistic pathogens for mammals, then in addition to the general information at 3 (e) above, specific information on the biosafety level of the particular strain would need to be provided by the manufacturers.
13. Ensuring the quality in the production process carries importance even during the production phase to maintain worker safety, reduce contamination in the product, production ecosystem and its environment along with the safety to the health of the end users, the farmers. Hence, the producers should be mandated to follow good laboratory Practices (GLP) and Good Manufacturing Practices (GMP) with a set of demonstrated procedures. It should be made compulsory to specify that all inoculant producers are certified by relevant national/international organizations and strictly follow standard GLP and GMP practices.
14. It is advocated to mix crop residues decomposing cultures with well-rotted compost and applied on soil to not only hasten decomposition but provide additional benefits to soil health.
15. Since the members of Asian PGPR Society and also other professional societies like Association of Microbiologists of India (AMI) and Indian Phytopathological Society (IPS) have a rich and varied experience both nationally and globally in the field of Biofertilizers, and a critical stake in promoting the use of plant growth promoting microorganisms, it is submitted that they may be invited by the governments and regulatory agencies for consultations along with industry representatives when formulating fresh guidelines.

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