



Review article

Arbuscular Mycorrhizal inoculants and its regulatory landscape[☆]Maunata Ghorui^a, Shouvik Chowdhury^a, Prakash Balu^b, Sashidhar Burla^{c,*}^a Symbiotic Sciences Pvt. Ltd., Plot no 575, Pace City-II, Sector 37, Gurugram, Haryana, 122001, India^b Department of Biotechnology, School of Life Sciences, Vels Institute of Science, Technology and Advanced Studies (VISTAS), Pallavaram, Chennai, 600 117, India^c ATGC Biotech Pvt. Ltd., Sy. No. 494, 495 & 496, ATGC Agri Biotech Innovation Square, TSIC Kolthur Biotech Park, Genome Valley, Shamirpet Mandal, Hyderabad, Telangana 500078, India

ARTICLE INFO

Keywords:

Arbuscular mycorrhizal (AM) inoculants
Regulations
Regulatory
Soil
Quality
Plants

ABSTRACT

One of the most prominent means for sustainable agriculture and ecosystem management are Arbuscular Mycorrhizal (AM) inoculants. These inoculants establish beneficial symbiotic relationships with land plant roots, offering a wide range of benefits, from enhanced nutrient absorption to improved resilience against environmental stressors. However, several currently available commercial AM inoculants face challenges such as inconsistency in field applications, ecological risks associated with non-native strains, and the absence of universal regulations. Currently, regulations for AM inoculants vary globally, with some regions leading efforts to standardize and ensure quality control. Proposed regulatory frameworks aim to establish parameters for composition, safety, and efficacy. Nevertheless, challenges persist in terms of scientific data, standardization, testing under real conditions, and the ecological impact of these inoculants. To address these challenges and unlock the full potential of AM inoculants, increased research funding, public-private partnerships, monitoring, awareness, and ecosystem impact studies are recommended. Future regulations have the potential to improve product quality, soil health, and crop productivity while reducing reliance on chemical inputs and benefiting the environment. However, addressing issues related to compliance, standardization, education, certification, monitoring, and cost is essential for realizing these benefits. Global harmonization and collaborative efforts are vital to maximize their impact on agriculture and ecosystem management, leading to healthier soils, increased crop yields, and a more sustainable agricultural industry.

1. Introduction

1.1. An insight into AM inoculants

Arbuscular mycorrhizal (AM) inoculants, also referred to as mycorrhizal inoculants or mycorrhizal biofertilizers, are formulations containing AM spores, mycelium, and/or propagules. By integrating beneficial soil microorganisms called AM fungi into agricultural

[☆] AM Inoculants and its Regulatory Landscape

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<https://doi.org/10.1016/j.heliyon.2024.e30359>

Received 13 November 2023; Received in revised form 23 April 2024; Accepted 24 April 2024

Available online 25 April 2024

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and horticultural ecosystems, these inoculants promote plant growth, plant health, and nutrient absorption [1]. AMF can be used to establish symbiotic relationships with more than 70-90 % of the land plant species [2], which can have significant implications for agricultural and forest ecosystem sustainability. Few reports clearly show that there has been a rise in the usage of AMF inoculants in agriculture [3,4], several companies are now concentrating on enhancing the production of AMF inoculum for agricultural use. These AM inoculants have emerged as viable biofertilizers in all farming and agriculture sectors [5,6]. The primary objective of these inoculants is to increase AMF spore density in soils and function as “biofertilizers,” thereby facilitating the efficient use of existing soil nutrient pools by the crops [6,7].

1.2. Significance of AM symbiosis

The symbiotic relationship between plants and AMF offers a multitude of advantages in agriculture. AMF plays a crucial role in increasing the absorption of vital minerals by plants, especially phosphorus, copper, and zinc [4]. This is particularly significant in nutrient-deficient soils, where efficient mineral uptake can substantially enhance plant growth and health [8]. The partnership between plants and AMF not only leads to improved crop nutrition and quality but also encompasses aspects such as nutrient uptake, plant growth promotion, disease suppression, and soil health enhancement [5]. Understanding the role of AMF in crop production is essential for optimizing agricultural practices and increasing crop yields [9]. This symbiosis also results in increased biomass and yields for plants in both agricultural and natural ecosystems, as AMF facilitates nutrient assimilation [10]. AMF contributes to drought resistance by enhancing water absorption and osmotic regulation in plants, enabling them to maintain physiological functions during water scarcity [11]. In the context of soil salinity, AMF plays a critical role in helping plants tolerate this stressor, mitigating its adverse effects on plant growth and health [12]. AMF symbiosis has also been shown to boost the production of secondary metabolites in traditional Chinese plants [13], medicinal plants [14], aromatic plants [15] which often have beneficial effects on plant health, defense against pests and pathogens, and potential human health benefits [13]. AMF also offers protective effects against soil contamination from heavy metals and other pollutants, while also enhancing soil physiochemical characteristics like nutrient cycling and organic matter decomposition, thereby promoting overall soil health [16]. This symbiosis induces systemic resistance in plants, increasing their resilience to pathogen infections and reducing the severity of plant diseases [17]. AMF can also safeguard plants from nematodes and specific root diseases by enhancing plant defence mechanisms and mitigating the harmful effects of root-parasitic nematodes [18]. AMF can enhance nitrogen fixation in leguminous plants, leading to increased nitrogen availability in the soil and improved nitrogen nutrition for associated plants [19].

The symbiotic relationship between plants and AMF offers several significant benefits to ecosystems. AMF plays a vital role in soil structuring, promoting soil aggregation and enhancing its structure, leading to increased soil stability and reduced erosion [20]. This partnership contributes to carbon sequestration in the soil, aiding in the mitigation of climate change and the storage of atmospheric carbon dioxide [21]. A recent estimate indicates that global plant communities allocate a substantial amount of carbon, equivalent to 3.93 GtCO₂eq per year, to AMF [22]. This allocation represents a significant portion of anthropogenic CO₂ emissions in 2021, emphasizing the role of AMF in carbon sequestration. Moreover, AMF assists in reducing nutrient leaching from the soil, particularly essential nutrients like phosphorus, enhancing nutrient use efficiency by plants and preserving valuable nutrients in the ecosystem [23]. The presence of AMF in the soil fosters interactions and cooperation among diverse microbial communities, promoting a more diverse and productive soil ecosystem [24]. AMF acts as a catalyst for microbial activity, enhancing nutrient cycling and organic matter decomposition. AMF can help reduce greenhouse gas emissions, specifically nitrous oxide (N₂O), a potent greenhouse gas, from soils. They indirectly limit N₂O release, a byproduct of microbial denitrification, by facilitating efficient nutrient assimilation by plants [25]. Furthermore, the utilization of AMF biotechnology has the potential to significantly enhance the outcomes of land restoration efforts on degraded lands [26]. AMF establishes a common mycorrhizal network (CMN) connecting plants within the same ecosystem that enables the transfer of nutrients between plants, facilitating nutrient allocation, improving plant yield, and enhancing soil properties

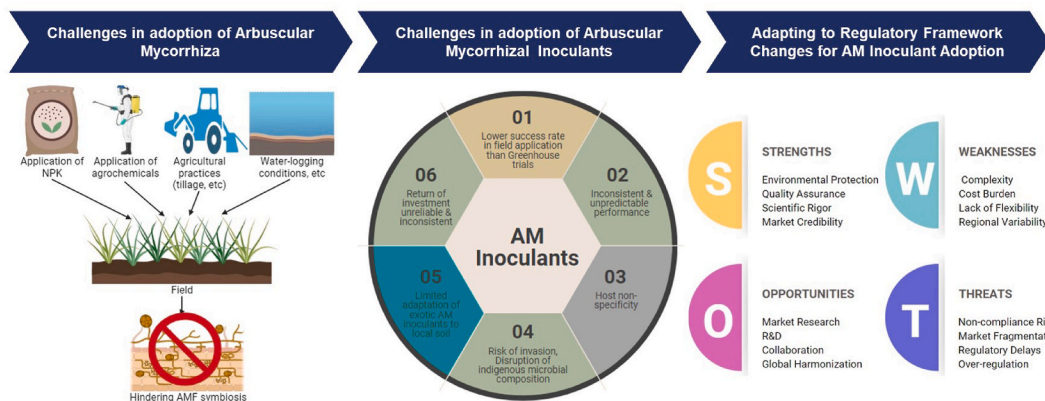


Fig. 1. The existing obstacles to widespread adoption of Arbuscular mycorrhizal inoculants in sustainable agriculture, along with strategies for encouraging their incorporation.

[27].

1.3. The existing setbacks and constrictions for AM inoculants

1.3.1. Challenges confronted by AMF

Fig. 1 and Table 1 illustrates the present challenges hindering the acceptance of Arbuscular Mycorrhizal inoculants and suggests methods to promote their utilization in sustainable agricultural methods. The application of high levels of phosphorus (P) fertilizers in soil has been found to inhibit mycorrhizal symbiosis allowing them to absorb sufficient phosphorus without sharing carbohydrates with AMF [28–31]. High-P soils result in reduced production and exudation of strigolactone by plants, reducing the extent of AMF symbiosis in plant roots [32–34]. High P fertilization reduces soluble carbohydrate supply in plant roots, which, in turn, decreases appressoria formation and fresh infection [28,32]. The colonization of AMF, particularly arbuscule formation and active P transfer to plants, is diminished in high soil P conditions [35]. In such cases, AMF's ability to exchange phosphate for carbon from plants is compromised, affecting the cooperative nature of the symbiosis [36]. Additionally, the presence of functional plant and fungal Pi:H⁺ symporter (PT) genes responsible for P uptake in extraradical mycelia is hindered in high P soils, leading to a shift towards AMF's parasitic nature [37–39]. The impact of nitrogen (N) fertilizers on AM colonization varies depending on the application level. Low to medium levels of nitrogen fertilization increase AM colonization, sporulation, plant growth, and root formation, whereas higher levels of nitrogen fertilizer reduce AM colonization in plants [40,41]. When potassium (K) concentration exceeds the optimum level, root exudation decreases, leading to the accumulation of soluble carbohydrates in the root cortex, which hampers the signalling for AMF

Table 1
A compendium table of AM inoculants and its regulatory framework.

Aspect	Information
Beneficial Effects of AM Inoculants	<ul style="list-style-type: none"> • Increased mineral absorption • Enhanced crop yields • Heightened resistance to drought and soil salinity • Improved soil health • Decreased reliance on chemical fertilizers
Challenges in adoption of AM inoculants	<ul style="list-style-type: none"> • Lack of technical knowledge among farmers • Inconsistent field application • Ecological ramifications due to non-native AMF strains • Limited adaptability of exotic strains to local soils • Variable return on investment
Current Global Regulatory Landscape	Varied regulatory frameworks exist globally, with notable standardization efforts in countries such as India, Japan, the European Union, and specific U.S. states.
Challenges in adopting Current Regulations	<ul style="list-style-type: none"> • Scientific data gaps • Standardization issues • Costing • Efficacy testing under realistic field conditions • Product stability • Accounting for variability in AMF strains • Evaluating potential ecosystem impacts • Difficulty in commercialization at global level
Expectations from New Regulatory Objectives	<ul style="list-style-type: none"> • Improve soil health, decrease dependence on chemical inputs, and confer environmental benefits. • Emphasis on quality control, efficacy, safety • Augment adoption in agriculture • Support research and innovation • Prevention of misleading claims • Promotion of sustainable agricultural practices • Facilitation of international trade
Strategic Recommendations	<ul style="list-style-type: none"> • Uniform global regulations. • Standardized terminologies and definitions world-wide. For instance, globally AMF can be classified as 'Microbial-based Plant Biostimulants' • Uniform registration requirements and product testing parameters. • Report on toxicology, ecotoxicology, environmental fate, and plant residues on application of AM inoculants. • Similar product packaging label testifying the key parameters like inoculum composition (biological and physico-chemical properties), mode of action, absence of contamination, carrier material specifications, detailing manufacturing, quality control, and analytical methods, providing information on toxicology, ecotoxicology, environmental fate, and plant residues, demonstrating the agronomic efficacy supporting specified claims. • Increased funding for research, comprehensive research on potential ecosystem impacts, fostering public-private collaborations, rigorous monitoring and compliance mechanisms, extensive awareness and training initiatives of farmers and stakeholders.
Foreseen Challenges in Future Regulations	<ul style="list-style-type: none"> • Ensuring widespread compliance • Addressing standardization intricacies • Providing sustained research support • Fostering educational initiatives • Instituting robust certification processes • Establishing effective monitoring systems • Managing associated costs.

colonization [41].

The use of agrochemicals, including both systemic and non-systemic fungicides, has varying effects on mycorrhizal fungi. Most fungicides negatively impact AMF spore germination, colonization, hyphal growth, sporulation, and phosphatase activity [42,43]. The effects of fungicides on mycorrhizal fungi are often dose-dependent, with some fungicides inducing effects at lower doses [42,44]. Azoxystrobin, flutolanil, fenpropimorph, and penicuron are examples of fungicides that can impact AMF differently depending on their concentrations [44].

Tillage practices can physically damage AMF spores and disrupt hyphal networks in soil, reducing root colonization [45]. Soil disturbances during tillage can also disrupt extra-radical mycelium networks, hampering AM-mediated nutrient and water uptake and glomalin-related soil aggregate formation [46]. Reduced tillage, on the other hand, tends to improve soil aggregation, increase soil organic carbon content, moisture retention, and reduce erosion, ultimately promoting AMF colonization [47,48]. Other agricultural practices, such as long fallow periods and crop rotation with non-mycorrhizal crops, can significantly affect AMF communities, propagule density, and activity [27,49]. Waterlogged conditions in paddy cultivation can hinder AMF activity. Overall, these agricultural practices play a crucial role in shaping the interactions between plants and mycorrhizal fungi, impacting nutrient uptake and soil health. All these factors are responsible for hindering the adoption of AM inoculants for sustainable agriculture.

1.3.2. Challenges encountered by AM inoculants

Despite having several known advantages of these potent inoculants in agriculture [10,50,51], there are still substantial knowledge voids regarding their efficacy and optimal application practices. Field applications typically have lower success rates than greenhouse experiments [7,52–56]. Some studies have shown that these inoculants can increase plant growth and yield [57,58], whereas others have shown that fungal inoculation has no significant effect on plant performance [59,60]. Some studies have also discovered that the successful introduction of AM fungal inoculants is frequently inconsistent and unpredictable, with high rates of inoculant establishment failure [7,55,61,62].

Due to their host non-specificity and risk of invasion, AM fungal inoculants have ecological consequences [63–65]. When a specific isolate is introduced into an established AMF community, it can have a substantial effect on species richness by displacing native AMF species [66–71]. Consequently, the introduction of a commercial isolate has the potential to alter the composition and diversity of microbial communities.

Over the past few decades, companies all over the world have manufactured and commercialized AM inoculants, either with single AMF species or consortia that may include plant-growth promoting rhizobacteria (PGPR) or other symbiotic and/or other bio-control fungi [4]. Priority effects in ecological terms describe the influence of the order and timing of species' arrivals in a specific habitat on subsequent community development [72,73]. Priority effects [73,74] have prevented large-scale inoculant application from gaining attention due to restricted growth, *in vitro* multiplication of only a few species, and excessive competition with native existing AMF. Despite demonstrating their efficacy in practice, the adoption of these commercial AM inoculants in agriculture has been slow, primarily due to concerns about the quality and efficacy of the products under specific local conditions where native AMF species are predominant over non-native ones [75–79]. Some commercial inoculants fail to infect the host plants because of the limited adaptation of exotic AM inoculants to local soil conditions, such as nutrient concentrations and other environmental factors [80,81]. Furthermore, the ecological repercussions of soil inoculation with exotic AMF strains include concerns about the potential hazards involved, as they may influence the soil microbial community and disrupt the indigenous microbial composition and structure [20,82]. In addition, the manufacturers' return on investment is unreliable and inconsistent [83]. Additional impediments to the acceptance of AM inoculants include unpredictable efficacy outcomes, difficulties in identifying and tracking inoculated strains in the field, a limited understanding of microorganism-plant interconnections, production technology challenges, and adherence to marketing standards. Moreover, the practices of farmers, encompassing fertilization, soil management, and application methods, hinder the proliferation of AMF and, consequently, the widespread adoption of AM inoculants [84]. Other significant factors contributing to the limited adoption are the lack of technical knowledge among agricultural advisors and farmers regarding application methods and increased reliance on mineral fertilizers. These aspects exert a substantial influence on practical implementation of AM inoculants.

2. Regulatory framework for AM inoculants

Regulation plays a crucial role in ensuring the quality, safety, and efficacy of AM inoculants. Proper regulation is essential to address potential risks, ensure product effectiveness, and foster consumer confidence in using these products. The regulations ensure consistent product quality, composition, viability, and effectiveness across different batches and manufacturers. This involves standardizing production processes, testing for viable propagules, and accurate labelling of product constituents [85]. Furthermore, regulatory oversight aids in assessing the efficacy and performance of AM inoculants under various environmental conditions and crop systems. Field trials and data on parameters like root colonization rates, nutrient uptake, and crop yield enhancements are crucial for these evaluations [50]. The regulations also serve to prevent misleading claims regarding the benefits of AM inoculants. Manufacturers are required to provide scientific evidence to support their product claims, discouraging exaggerated or unsupported marketing strategies [50,52]. Additionally, regulatory frameworks can promote sustainable agriculture by encouraging the use of AM inoculants, reducing reliance on chemical fertilizers, and improving soil health while minimizing environmental impacts [51]. Ensuring product safety is another essential role of regulation. It involves evaluating potential hazards associated with introducing non-native AMF strains and assessing any adverse effect on soil microorganisms and ecosystems [20]. By requiring safety assessments, regulators can mitigate risks and prevent unintended ecological consequences of AM inoculant applications. Global harmonization of regulations facilitates international trade in AM inoculants by providing common standards. This simplifies product distribution to multiple

countries, increasing availability and accessibility worldwide. Furthermore, regulatory oversight encourages research and development in the field of AM inoculants as companies strive to meet regulatory requirements and demonstrate product efficacy [86]. Governments and industry stakeholders can promote the responsible use of AM inoculants, leading to increased agricultural productivity and environmental sustainability, by instituting well-designed regulatory frameworks.

3. Strengths, weaknesses, opportunities, and threats (SWOT) analysis for global standardized regulatory framework of AM inoculants

Strengths: One of the significant strengths of regulatory requirements in the context of AM inoculants is their positive impact on environmental protection. These regulations act as a shield, ensuring that AM inoculants adhere to safety and environmental standards, thus safeguarding ecosystems from potential harm. Furthermore, regulatory mandates bolster quality assurance, fostering product consistency and enhancing the effectiveness and reliability of AM inoculants. These requirements are deeply rooted in scientific rigor, underpinned by extensive research, and serve as a cornerstone for the development of AM products with a robust knowledge base. Moreover, compliance with these regulations can enhance the market credibility and trustworthiness of manufacturers and suppliers, instilling confidence among farmers and facilitating trade among countries.

Weaknesses: The complexity of regulatory requirements can pose a challenge, particularly for new players. Navigating the intricacies of these regulations demands significant resources, which may act as a barrier to entry for emerging enterprises in the AM inoculant market. Additionally, the cost burden associated with compliance can be onerous, potentially discouraging innovation and market growth. Regulatory inflexibility is another drawback, as regulations may struggle to keep pace with advancements in AMF research and technology. Regional variability in regulations across different countries and regions can present hurdles for businesses with international operations.

Opportunities: Regulatory frameworks can spur market growth as awareness of the benefits of AMF increases, driving demand for safe and effective AM inoculants. Furthermore, these mandates can encourage investment in research and development, fostering the creation of more efficient and environmentally friendly AM inoculants. Collaboration between regulators and the industry holds promise for more effective and efficient regulatory frameworks. Additionally, efforts to harmonize regulations globally can mitigate barriers to international trade, offering broader market access.

Threats: Divergent regulations across different regions can lead to market fragmentation, complicating expansion efforts for businesses operating internationally. Lengthy regulatory processes can delay product launches, inhibiting market entry and innovation. There's also the potential threat of overregulation, where excessive regulatory constraints could stifle industry growth and innovation, diminishing competitiveness in the AM inoculant market.

4. Regulatory framework

4.1. Country-wise or region-wise

There is a lack of universal regulations on marketing AM inoculants. Table 2 presents the details of regulations of the major contributors playing a significant local in framing compliance and regulations for AM Inoculants.

4.1.1. India

As per Biofertilizers and Organic Fertilizers - The Fertilizer (Inorganic, Organic or Mixed) (Control) Order 1985, AM inoculant has been classified as 'Mycorrhizal biofertilizers' under the broader classification of Biostimulants with specific requirements outlined [87]. The specifications include a minimum of 10 viable spores per gram in the finished product, the pH level of the product within the range of 5.0–7.0 and the inoculum potential of 1200 Inoculum Potential (IP) per gram of the finished product using the Most Probable Number (MPN) method with a 10-fold dilution. Additionally, the order provides comprehensive guidelines for conducting the tests in a manner that aims to establish a standardized procedure.

4.1.2. Japan

In 1990, The Ministry of Agriculture, Forestry and Fisheries (MAFF) [88] of the Japanese government promoted the technologies that would reduce the usage of agrochemicals. The ordinance mandates that AM products must carry a quality guarantee label on their product containers and should include specific information like the name and contact details of the manufacturer or producer providing transparency and accountability; the raw materials used in the product, as well as the carrier material employed, such as peat or zeolite; the symbiotic efficiency of the AMF expressed as colonization percentage by the inoculum in a specific test plant under standardized conditions; any relevant information about crops for which the inoculum may be ineffective, such as species belonging to the Brassicaceae and Chenopodiaceae families, or in soils rich in available phosphate; clear instructions on the appropriate application rate; instructions on proper storage conditions, such as temperature and humidity to maintain the viability of the AMF; and expiration date to ensure that consumers use the inoculum within its shelf life. As part of this regulation, a standard bioassay protocol was introduced, which mandated testing and labelling guidelines for AM products. Ongoing research in Japan has demonstrated the effectiveness and reliability of domestic AMF producers, confirming that the introduced quality control measures were successful [89]. In 1996, Saito and Marumoto [90] highlighted the introduction of "The Soil Productivity Improvement Act" which established quality control mechanisms to regulate AM inoculants. In 2021, the MAFF introduced the 'Green Food System Strategy,' aiming to achieve a 30 % reduction in chemical fertilizer usage by 2050. The strategy focuses on promoting crop root development using biofertilizer

Table 2

Major contributors playing a significant role in the regulatory framework concerning Arbuscular Mycorrhizal Fungi (AMF).

	India	Japan	Indonesia	Thailand	Philippine	The European Union
Legal Terminology	Mycorrhizal Biofertilizer	Soil Conditioner	Biological fertilizers	Biological fertilizers	Microbial Inoculant	Microbial Plant Stimulant CMC-7 under PFC6(A) falling under PFC 6(A)
Ministry	Ministry of Agriculture and Farmers Welfare	The Ministry of Agriculture, Forestry and Fisheries (MAFF)	Ministry of Agriculture (MOA)	Department of Agriculture (DOA)	Bureau of Agriculture and Fisheries Standards (BAFS)	European Parliament and of the Council 1
Order	Fertilizer (Inorganic, Organic or Mixed) (Control) Fifth Amendment Order, 2021	The Soil Productivity Improvement Act	Law No. 22 of 2019 Regulation of the MOA No. January 2019	Fertilizer Act B.E. 2550 (2007)	The PNS/BAFS 183:2020	EU fertilizing product Regulation 2019/1009
Year of enactment	July 2021		2019	2009	2020	July 2022
Spore count	10 viable spores per gram			25 spores per gram	solid base inoculants- 10 spores per gram root inoculant-2300 Infective Propagules per gram by MPN	
pH	5.0-7.0				4.5-8.0	In liquid form, pH suitable for both the microorganisms it contains and for plants
Inoculum Potential	1200 Inoculum Potential (IP) per gram by MPN using 10-fold dilution					
Moisture content by weight					solid inoculants- <10 %, root inoculants- 15-20 % for Nematode	
Contamination/ Pathogens						<i>Salmonella</i> spp- Absence in 25 g or 25 ml <i>Escherichia coli</i> - Absence in 1 g or 1 ml <i>Listeria monocytogenes</i> - Absence in 25 g or 25 ml <i>Vibrio</i> spp-Absence in 25 g or 25 ml, <i>Shigella</i> spp-Absence in 25 g or 25 ml, <i>Staphylococcus aureus</i> -Absence in 25 g or 25 ml, <i>Enterococcaceae</i> -10 CFU/g, <i>Anaerobic plate count</i> -10 ⁵ CFU/g or ml
Heavy metals						Cadmium (Cd)-1,5 Hexavalent chromium (Cr VI)-2 Lead (Pb)-120 Mercury (Hg)-1 Nickel (Ni)-50 Inorganic arsenic (As)- 40 Copper (Cu)-600 Zinc (Zn)-1500 Different testing methodologies based on method pf production (in vivo or
Testing methodologies Provided	Yes					(continued on next page)

Table 2 (continued)

	India	Japan	Indonesia	Thailand	Philippine	The European Union
Acceptable Deviation from stated Product Registration	Manufacturers to provide chemistry details, bio-efficacy trial results, toxicity data, and heavy metal analysis. A regulatory body will oversee industry operations, ensuring quality control and safe substance usage.	Following the EU's Fertilizer Regulation amendment, a Japanese industry group has formed to engage with authorities, aiming to standardize biostimulants through enhanced communication efforts.	Testing conducted by an approved testing agency for: a. Quality assurance (based on minimum technical requirements from the relevant MOA decree in 2019) b. Confirming effectiveness. Certificates and testing reports for quality or effectiveness are valid for 12 months, and their submission is a requirement for registration. Registrations: Application to include a detailed description of the fertilizer, proposed labelling in Indonesian, authorized mark certificate, effectiveness test report, quality certificate or testing report, and a stamped statement confirming document completeness and accuracy. Approved applications undergo technical verification by the director general of the Agricultural Infrastructure and Facilities Department,	The Fertilizer Act B.E. 2518, amended by the Fertilizer Act (No. 2) B.E. 2550, outlines the definitions and procedures for registrations, obtaining licenses for the manufacturing, exporting, importing, and transit of various types of fertilizers.	<10 %	<i>in vitro</i> and product type (spores only or with roots). Molecular characterization <15 % The manufacturer creates technical documentation, engages a notified body to assess the design's adequacy, obtains the EU type examination certificate, manufactures the fertilizing product, prepares the EU declaration of conformity, and acquires the CE trademark.

microorganisms. However, specific guidelines for the development and utilization of biofertilizers are not outlined. The Japanese government currently approves only a limited number of biofertilizers, with VA mycorrhiza being the exception. Notably, VA mycorrhiza is referred as *ordinance-designated 'soil conditioner'* by ordinance in Japan. Despite this, the production of VA mycorrhiza has dwindled from 25 tons per year in 2011 to a mere 5 tons per year in 2020 [89].

4.1.3. Indonesia

Fertilizers in Indonesia are primarily governed by Law No. 22 of 2019, which focuses on the Sustainable Agricultural Cultivation System. According to these laws, fertilizers distributed in Indonesia must be registered to meet specific quality standards and appropriately labelled. Additionally, adherence to Regulation of the Ministry of Agriculture (MOA) No. January 2019 concerning the Registration of Organic Fertilizers, Biological Fertilizers, and Soil Improvement is crucial. It mandates a quality test by an MOA-approved institution for registration. The regulation defines '*Biological fertilizers*' as *active biological products containing microbes that enhance fertilization efficiency, soil fertility, and soil health*. The procurement of biological fertilizers meeting minimum technical requirements can be domestic or imported. Testing for biological fertilizers involves two types: one for quality assurance, based on minimum technical requirements from the relevant MOA decree in 2019, and another to confirm effectiveness. Both tests must be

conducted by an approved testing agency. Certificates and testing reports for quality or effectiveness are valid for 12 months, and their submission is a requirement for registration [90].

4.1.4. Thailand

In Thailand, the importation and use of fertilizers are regulated by the Department of Agriculture (DOA) under the Fertilizer Act B. E. 2550 (2007). A 2009 DOA notification on 'biological fertilizer' certification and procedures categorizes biological fertilizers into four main types: Nitrogen-fixing rhizobium bacterial fertilizer, Arbuscular mycorrhiza fertilizer with at least 25 spores per gram, Dissolved phosphate biological fertilizer and Dissolved potassium biological fertilizer [90].

4.1.5. Vietnam

In recent years, there has been a concerted effort by state authorities at all levels in Vietnam to promote the development and usage of biological fertilizers. To address this, the Ministry of Agriculture and Rural Development (MARD) has issued additional guidelines to various entities, including committees, agencies, companies, and associations, to enhance the development and utilization of biological fertilizers in Vietnam. The regulatory framework for fertilizers in Vietnam is primarily governed by four instruments: Law on Cultivation No. 31/2018/QH14, Decree No. 84/2019/ND-CP issued by the Government on November 14, 2019, focusing on fertilizer management, National Technical Regulation on Fertilizer Quality, QVCN 01-189:2019/BNNPTNT, Decision No. 4756/QD-BNN-BVTV of the MARD dated December 12, 2019, addressing plant protection procedures under the ministry's management [90].

4.1.6. Philippine

The Bureau of Agriculture and Fisheries Standards (BAFS), guided by the Technical Working Group, established, and adopted the Philippine National Standard (PNS) for Organic Soil Amendments (OSA) in 2016. The PNS/BAFS 183:2020 (ICS 65.080) of 'Organic Soil Amendments' standard cancels and replaces PNS/BAFS 183:2016. This standard refers AMF as Vesicular Arbuscular Mycorrhizal (VAM) Fungi classifying it as '*microbial inoculant*' which is defined as *biologically-active product containing optimum population of one or a combination of active strains of bacteria, algae, and fungi that are useful in different biological activities, such as, but not limited to: N₂-fixation, decomposition of organic residues, and enhancement of nutrient availability*. The PNS/BAFS 183:2020 standard mandates a guaranteed analysis for fungal strains, necessitating a minimum count. The minimum criteria for VAM Fungi in solid base inoculants should be 10 spores per gram and root inoculant should be a minimum of 2300 Infective Propagules (IP) per gram by include a most probable number (MPN) without nematode contamination. The pH range is specified between 4.5 and 8.0. Additionally, the minimum moisture content by weight should be below 10 % for solid inoculants and within the range of 15–20 % for root inoculants [91].

For registrations, a certificate of analysis must be submitted from an FPA-recognized lab with two 200 g/200 ml samples from the same batch. One sample undergoes confirmation analysis, with the applicant covering the cost. The second sample is retained by FPA for testing a month before the labelled expiry date, and pathogen testing is conducted. Laboratory results must indicate each component at a minimum of 90 % of the stated value. For microbial inoculants, the actual microorganism concentration must align with the label's count and meet the PNS/BAFS 183:2016 standard. Regarding product information, include brand/trade name, type of product (biostimulants), confirmed guaranteed analysis from FPA-recognized labs, packaging details, country of origin (for imports), manufacturer and supplier names (for imports), trader details (for imports), company information, raw materials list, target crops, FPA-accredited researcher's name (conducting efficacy test), and cost components/prices. Note that superlative or supernatural names like "Miracle," "Super," "Best," and "Demon" are not allowed for brand names [92].

4.1.7. The European Union

In Europe, prior to 2022, biostimulants and other fertilizing products were regulated at national level, and marketing processes varied across Member States. Many countries lack detailed registration procedures and accessible, searchable databases for plant biostimulants [93]. The challenge of mutual recognition for AMF in the EU arises from divergent regulatory frameworks, varying classifications across member states, and a lack of common standards. The absence of standardized criteria for assessing AMF efficacy, safety, and quality contributed to disparities in regulatory requirements. Administrative hurdles, including diverse procedures and documentation requirements, further impeded manufacturers seeking authorization for AMF products.

However, with the introduction of the New Regulation (EU) 2019/1009 [94], effective from July 2022, a clear definition of biostimulants was established based on their functions, distinguishing them from Plant Protection Products. *Plant biostimulants were defined as a product that stimulates plant nutritional processes to improve characteristics such as nutrient use efficiency, abiotic stress tolerance, qualitative characteristics, and nutrient availability in the soil*. This new regulation has enabled biostimulants to obtain an EU-type certificate wherein the manufacturer can affix the CE mark, enabling access to the entire EU market. European Academy of Regulation (EAR) offers comprehensive support for biostimulants market access, including conducting market access studies, developing regulatory strategies, performing literature searches, analysing data gaps, providing support for data generation (study monitoring, labelling preparation), preparing dossiers, and offering post-submission assistance [95]. This step provides farmers with the confidence that registered AM inoculants meet established quality standards and delivers expected benefits to plants and the environment.

Furthermore, "Mycorrhizal fungi" has been classified as a type of 'Microorganisms' under CMC-7 (Component Material Category) within the broader category of '*Microbial Plant Stimulant*' falling under PFC 6(A) (Product Function Category) for EU fertilizing products. An EU fertilizing product falling under PFC 6(A) is allowed to contain microorganisms, including dead or empty-cell microorganisms and non-harmful residual elements from the media used in their production without any processing other than drying or freeze-drying consisting of the following microorganisms and may include various types, such as *Azotobacter* spp., Mycorrhizal fungi, *Rhizobium* spp., and *Azospirillum* spp [95,96].

The new regulation has established the following significant conditions [97].

- **Regulations on EU manufactured fertilizing products:** The EU fertilizing products should have free movement within the internal market. If a component material, derived according to Regulation (EC) No 1069/2009, reaches a manufacturing chain point beyond posing any significant risk, it should be exempt from unnecessary regulatory burdens.
- **Regulations on third-country EU fertilizing products:** To ensure compliance of third-country EU fertilizing products, importers must confirm conformity with this Regulation, conduct appropriate assessments, and make documentation available for inspection by national authorities.
- **Conformity assessment** procedures, adapted from Decision No 768/2008/EC, should be chosen in proportion to the risk level.
- **Manufacturers** should opt for more stringent procedures without jeopardizing compliance. The system should prevent risks to human, animal, or plant health, safety, or the environment during proper storage and intended use. Manufacturers and importers must take corrective measures for non-compliance and inform authorities of risks promptly.
- **Importers** must verify conformity before placing fertilizing products on the market, ensuring compliance with Article 15 procedures, and notifying authorities of any risks. Importers placing an EU fertilizing product on the market, if suspecting non-compliance with the Regulation, must promptly take corrective actions, withdraw, or recall the product. In case of potential risks to human, animal, or plant health, safety, or the environment, importers must immediately notify the relevant national authorities, providing details of non-compliance and corrective measures taken.
- **Distributors**, before market availability, must ensure proper documentation, compliance with Article 6(7) or Article 8(4), and adherence to manufacturer and importer requirements. If a distributor believes the product is non-compliant, they must refrain from making it available until conformity is ensured. Moreover, if a fertilizing product poses risks, distributors must inform manufacturers, importers, and market surveillance authorities promptly.
- **Market surveillance authorities:** If market surveillance authorities have grounds to suspect a product risk, they must evaluate it according to Regulation requirements.
- **Economic operators:** The economic operators must cooperate, and if non-compliance is found, corrective actions must be taken within a reasonable timeframe. The relevant notified body should be informed, and measures shall follow Regulation (EC) No 765/2008, Article 21.

The New EU regulations has laid down the following guidelines for microbial plant biostimulants [97].

i. Pathogen limit:

Micro-organisms/Their Toxins, Metabolites	Number of units	Number of sample units above defined limit	Limit
<i>Salmonella</i> spp.	5	0	Absence in 25 g or 25 ml
<i>Escherichia coli</i>	5	0	Absence in 1 g or 1 ml
<i>Listeria monocytogenes</i>	5	0	Absence in 25 g or 25 ml
<i>Vibrio</i> spp.	5	0	Absence in 25 g or 25 ml
<i>Shigella</i> spp.	5	0	Absence in 25 g or 25 ml
<i>Staphylococcus aureus</i>	5	0	Absence in 25 g or 25 ml
<i>Enterococcaceae</i>	5	0	2 CFU/g
Anaerobic Plate Count	5	0	2×10^5 CFU/g or ml
Yeast and Mould Count	5	2	2×10^3 CFU/g or ml

ii. Safety limit:

Elements	mg/kg dry matter
Cadmium (Cd)	1,5
Hexavalent chromium (Cr VI)	2
Lead (Pb)	120
Mercury (Hg)	1
Nickel (Ni)	50
Inorganic arsenic (As)	40
Copper (Cu)	600
Zinc (Zn)	1500
Phosphonates shall not exceed	0,5 % by mass

- iii. In liquid form, it must possess an optimal pH suitable for both the microorganisms it contains and for plants.
- iv. All intentionally introduced microorganisms must be disclosed.
- v. The concentration should be stated as the quantity of active units per volume or weight, such as colony forming units per gram (cfu/g).
- vi. The label must include the following statement: 'Micro-organisms may have the potential to provoke sensitising reactions'.
- vii. The actual concentration(s) of micro-organisms may deviate by no more than 15 % from the declared value(s).

4.1.8. The United States

In the United States, plant biostimulants fall outside the categories of fertilizers [98] or pesticides, serving as enhancers of natural plant processes. Unlike conventional fertilizers and agrochemicals, these products do not have consistent global regulatory oversight, leading to uncertainty for developers and thus hindering commercialization and adoption [99]. They are not currently regulated by the federal government under a specific regulatory framework. Unlike chemical fertilizers and pesticides, AM inoculants do not fall under the purview of federal agencies such as the Environmental Protection Agency (EPA) or the United States Department of Agriculture (USDA). Until recently, the United States lacked specific regulations for biostimulants [100]. However, some states started regulations for the marketing of biostimulants [100]. In Canada, AM inoculants are registered under 'fertilizers: registered supplements,' without a distinct category for microbial plant biostimulants (Canadian Food Inspection Agency, 2020). California requires AM inoculants to be registered with the California Department of Food and Agriculture (CDFA) before they can be sold in the state. The registration process in California may involve submitting data on the product's quality, efficacy, and safety, like the requirements in the EU. Due to the lack of federal regulation, there is currently no standardized evaluation process for AM inoculants at the national level in the US. As a result, the quality and effectiveness of AM inoculants in the US market may vary between different products and manufacturers.

On December 20, 2018, the 'Agriculture Improvement Act of 2018', signed by President Donald Trump, became law. This act commonly known as the '2018 Farm Bill', was tasked with defining plant biostimulants and making recommendations on their review, approval, availability, and uniform labelling for agricultural producers. The 2018 farm bill defined *plant biostimulants as 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, crop quality or yield* [101].

In 2019, the EPA published draft guidance, and the USDA submitted a report to Congress identifying potential regulatory, non-regulatory, and legislative recommendations for efficient and uniform national labelling of plant biostimulant products [100].

In 2020, the Association of American Plant Food Control Officials (AAPFCO) established a Biostimulant Committee, supported by regulators and industry, to develop a biostimulant definition, label, and model bill. The Committee was considering the USDA's proposed Biostimulant Alternative Definition 2, stating that "A *plant biostimulant is a substance (s), microorganism (s), or mixtures thereof, that when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant's natural nutrition processes independently of the biostimulant's nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, and consequent growth, development, quality or yield.*" [100]

During the 2021 AAPFCO Annual Summer Meeting, the committee launched Working Groups, involving representatives from the Biological Products Industry Alliance (BPIA) and the Biostimulant Council (TFI and Biostimulant Coalition). These groups were working on a Non-Plant Food Ingredient Model Bill, covering aspects such as definition, registration, unlawful acts, compliance audits, and labelling, with an initial draft expected by December 2021 [102,103].

In 2022, AAPFCO officially adopted the term "plant biostimulants" on August 2, 2022. Some states have their regulations for AM inoculants. The USDA collaborated with the Environmental Protection Agency (EPA) and various stakeholders, organizing meetings, and forming working groups on regulatory issues, state interactions, and product certification. The regulatory landscape at both the federal and state levels involve overlapping authorities, and currently, there is no recognized independent classification for plant biostimulants [102,103]. The current status to sell their mycorrhizal products in the United States and Canada, manufacturers need to obtain approval from 53 regulatory agencies representing all 50 states, the District of Columbia, Puerto Rico, and Canada [104]. A lack of a clear, unified, science-based regulatory pathway for plant biostimulants in the U.S. prevents developers from registering products based on intended use, composition, and specific benefits. The Biostimulant Industry Workgroup (BIW) composed of Biological Products Industry Alliance (BPIA), The Fertilizer Institute (TFI) and Biostimulant Council has proposed science-based criteria to validate claims made by plant biostimulant products. The goal is to enhance the credibility of individual products and the entire category. These recommendations aim to stay current with scientific advancements, developments in International Standards Organization (ISO), and relevant regulatory guidance from entities such as the EPA, USDA, AAPFCO, as well as international organizations like the Organization for Economic Cooperation and Development (OECD) and the Food and Agriculture Organization (FAO) of the United Nations [102,103].

The 'United States Biostimulant Industry Recommended Guidelines to Support Efficacy, Composition, and Safety of Plant Biostimulant Products' has provided a 'Decision tree for assessing the human health and environmental safety of microorganisms as plant biostimulant guaranteed substances' and the 'Guidance on Identifying the Risk Group Classification based on World Health Organization (WHO) Classification of Infective Microorganisms by Risk Group (2004) which classifies the agents in that country by risk group based on pathogenicity of the organism, modes of transmission and host range of the organism. Additionally, it provides the US EPA/OECD Guidelines for Assessing Microbial Safety [105].

4.1.9. Africa

Unfortunately, most African countries lack the necessary regulatory framework to facilitate the development of biofertilizers. The Plant Protection & Regulatory Services department within the Ministry of Food and Agriculture (MoFA) is currently working on

creating a regulatory framework for fertilizer quality control, which will encompass biofertilizers [106]. Additionally, the MoFA, in collaboration with COMPRO II, is in the process of formulating and implementing registration guidelines [107]. Standard Operating Procedures (SOPs) for testing biofertilizers, covering aspects such as sampling, laboratory, greenhouse, field safety, and quality procedures, have been developed. The validation of these procedures is underway at Kwame Nkrumah University of Science and Technology [106]. Kenyan biofertilizer specifications for Mycorrhiza is similar to that of Indian specifications [106].

4.1.10. Brazil

In Brazil, under Lei 6.894/1980 (LEI ORDINÁRIA), biostimulants are classified as Inoculant (a substance containing microorganisms with favourable actions for plant development) or Stimulant/Biofertilizer (a product containing an active ingredient capable of directly or indirectly improving plant development). The Decree n° 10.375, published on May 26, 2020, simplifies the registration process for biofertilizers and biopesticides. Although mycorrhiza is not explicitly mentioned, based on the definitions, AMF would fall under the biostimulant category [100].

4.1.11. Mexico

The current Mexican legislation published in 2004 does not explicitly mention biostimulants. However, they could potentially be categorized as Microbial Inoculants for seed treatments or direct soil application or classified as Non-Synthetic Fertilizers or Non-Synthetic Plant Growth Regulators (PGR) [100].

4.1.12. Chile

In 2021, Chile enacted Law No. 21.349, followed by Resolution 6725 in 2022, to define and regulate biostimulants. According to Law 21–349, biostimulants are substances or mixtures, including microorganisms, applied to seeds, plants, or the rhizosphere. Their purpose is to stimulate natural plant nutrition processes, enhancing nutrient utilization efficiency, abiotic stress tolerance, quality attributes, and the availability of immobilized nutrients in the soil or rhizosphere. Registration is granted upon submission to the Unique National Register [100].

4.2. Current challenges

The projected market size for Mycorrhizal inoculants is USD 1.87 billion by 2029 [108]. However, the absence of a clear regulatory framework and the adoption of a standardized global approach for AM inoculants pose numerous challenges and limitations. These factors have the potential to hinder the progress and commercialization of these products in the field of agriculture.

4.2.1. Ambiguous categorization

Globally, the AM inoculant faces challenges in classification, as various countries use different names and definitions, creating inconsistencies in legal frameworks. A potential solution is to consider them as ‘Plant Biostimulants’ or specifically categorize them as ‘Microbial based Plant Biostimulants’. Notably, only few Asian countries have established clear specifications for AMF, while most nations have not explicitly designated Mycorrhiza as biostimulants or assigned them to any specific category.

4.2.2. Oversight

There is an absence of a clearly defined and legally recognized pathway for the sale of plant biostimulant products, including making claims about associated benefits, and a lack of a legal definition. For instance, in the United States, although the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines plant regulators, numerous plant biostimulant products are excluded from the statutory definition of pesticides [109]. The presence of diverse regulatory definitions between countries and the absence of mandatory quality control criteria are a contributing factor for their non-acceptance. This challenges the producer and distributor to maintain the quality standards [110]. This situation raises concerns regarding farmer protection and presents a formidable obstacle for a market that could play a crucial role in the future of sustainable agriculture. Additionally, existing regulations may not mandate comprehensive efficacy testing of AM inoculants across various environmental conditions. This means that the performance of these products under diverse scenarios, including different soil types, climates, and crop varieties, may not be adequately assessed. Furthermore, as AMF are living organisms, ensuring their stability and viability during the production, storage, and transportation of inoculants can be challenging. Issues related to poor shelf-life or inconsistent viability can compromise their effectiveness in the field.

4.2.3. Lack of standardization in production process

AMF being living microorganisms, makes it difficult to standardize their production and quality. This can result in disparities in the efficacy of AM inoculants, creating difficulties for regulatory agencies in ensuring the safety and effectiveness of these products. The commercialization of a variety of microbial inoculants on a global scale has not met expectations. EU has laid down the guidelines for production processes which can be adopted by various countries.

4.2.4. Lack of research and quality control

While regulatory evaluations tend to focus on short-term effects, the long-term performance and persistence of AM inoculants in agricultural ecosystems require more extensive and prolonged research efforts. Achieving consistent and high-quality production of AM inoculants by manufacturers can be challenging, with potential variations in quality control measures. The ecological consequences of introducing non-native AM strains through commercial inoculants remain incompletely understood, raising concerns about

potential unintended impacts on native AM populations and soil microbial communities. The variability in effectiveness among different AM species or strains under varying environmental conditions also needs to be studied.

4.2.5. Cost

Cost is also a factor to consider, as some AM inoculants or their production can be time taking and thus, relatively expensive, limiting their adoption, particularly among small-scale farmers or in regions with limited financial resources.

Addressing these multifaceted challenges requires a collaborative effort involving researchers, regulatory agencies, and industry stakeholders. This collaboration can lead to the development of robust and standardized regulations for AM inoculants world-wide, considering factors such as efficacy, safety, and environmental impacts. Furthermore, increasing funding for research and conducting long-term studies can enhance our understanding of AM Inoculant and contribute to their responsible and effective use in agriculture.

5. Standardization efforts for framing global standardized regulations

5.1. ISO/TC 134 – fertilizers, soil conditioners, and beneficial substances

The International Organization for Standardization (ISO) is a non-governmental independent global association of 164 national standards bodies, each representing its respective country or region. Through collaboration with experts worldwide, ISO develops voluntary, consensus-based International Standards to address global challenges and support innovation. ISO 8157:2015 was developed by the Technical Committee ISO/TC 134, which focuses on fertilizers, soil conditioners, and beneficial substances. These substances aim to enhance plant nourishment and improve soil properties for efficient agricultural use. The extension to cover beneficial substances reflects growing global interest in biostimulants. Two dedicated Working Groups developed ISO standards for beneficial substances (including biostimulants) and microorganisms. The third edition of ISO 8157:2015, developed in Sep-2022, categorizes AMF as 'plant biostimulants' [111]. The standard discusses a proposal for the term "Plant biostimulant," defined as *product that contains substance(s), microorganism(s), or mixtures thereof, that, when applied to seeds, plants, the rhizosphere, soil or other growth media, act to support a plant's natural nutrition processes independently of the biostimulant's nutrient content. The plant biostimulant thereby improves nutrient availability, uptake or use efficiency, tolerance to abiotic stress, availability of confined nutrients in the soil or rhizosphere, and consequent growth, development, quality or yield.* This harmonization if achieved at the global level will standardize characterization, efficacy, and safety, facilitating international trade of biostimulants [112].

5.2. CEN/TC 455 – plant biostimulants

The European Committee for Standardization (CEN) formulates European standards (ENs) applicable across the entire European single market. It comprises of national standards agencies from 34 countries and a network of numerous technical experts from various sectors. CEN is mandated by the European Commission to create standards supporting the implementation of the fertilizing products regulation. To address this, CEN has established Technical Committee CEN/TC 455 on Plant Biostimulants. In France and select nations, Association Française de Normalisation (AFNOR) develops solutions based on voluntary standards and plays a role in standardization activities for the common good and acts as the secretariat for CEN/TC 455 Plant Biostimulants [113].

EN standards will be incorporated in EU legislation after the validation of the standards by CEN which will occur in two phases: first, the creation of a Technical Specification (TS), which is an EN without a ring-test and has been completed in April 2022. Subsequently, the second phase involves the development of a Harmonized EN standard (hEN) by April 2024, which includes a ring-test and citation into the Journal of the European Union (JOEU) [114].

CEN/TS 17722:2022 outlines the scope, normative references, and terms and definitions. It provides methods for the quantification of mycorrhiza, including general guidelines and specific procedures for preparing various types of formulations. Enumeration methods are detailed, encompassing spore isolation, counting procedures, and bioassays. The document also addresses molecular characterization and identification of mycorrhiza isolates, outlining steps for spore cleaning, DNA extraction, PCR preparation, gel electrophoresis, and sequencing [115].

5.3. BIS

BIS (Bureau of Indian Standards) has established a Soil Quality and Fertilizers Sectional Committee, FAD 7 (ICS No. 65.080; Doc No.: FAD 7(16503)C, dedicated to outlining requirements and sampling/test methods for AM inoculants across various genera like *Glomus*, *Acaulospora*, *Gigaspora*, *Racocetra*, etc. This committee specifies the criteria for mycorrhizal inoculum, covering aspects such as maximum moisture content, pH levels, minimum total viable propagule count, infectivity potential, and infection points in test roots per gram. The guidelines extend to sampling and testing methodologies. Additionally, the document provides comprehensive information on product packing, marking, storage procedures, and includes specifications for BIS certification markings [116].

6. Future scenarios of regulations governing AMF

The future of regulations governing AMF inoculants offers an opportunity to address key challenges and optimize the utilization of these beneficial microorganisms in agriculture, fostering sustainable agriculture and environmental preservation. These impending

regulatory objectives prioritize several critical areas to maximize the benefits of AMF while mitigating potential risks.

- **Environmental stewardship:** These regulations aim to promote soil health and reduce dependence on chemical inputs by encouraging the use of AMF as natural soil enhancers. By facilitating nutrient uptake and enhancing plant resilience, AMF can significantly contribute to sustainable agricultural practices.
- **Quality Control:** There will be a heightened focus on implementing stringent quality control measures to ensure the efficacy and safety of AMF products. By establishing robust standards, regulators seek to instill confidence among farmers and consumers regarding the reliability and effectiveness of AMF-based solutions.
- **Wider adoption through research:** The regulations will seek to drive widespread adoption of AMF technologies in agriculture through support for research, innovation, and collaborative partnerships. By fostering collaborations and investing in research, regulators aim to accelerate the development and deployment of AMF technologies globally.
- **Ensuring Environmental and Human Safety Through Comprehensive Research:** there will be a focus on conducting comprehensive studies to assess the environmental impact and safety of AMF inoculants, informing regulatory decisions, and ensuring responsible use. This entails research into toxicology, ecotoxicology, environmental fate, and plant residues associated with AMF application. Such studies will play a crucial role in shaping regulatory policies and safeguarding environmental and human health.
- **Promoting transparency through clear labelling:** There will be an emphasis on preventing misleading claims and promoting sustainable agricultural practices through clear guidelines and standards. Standardized product packaging labels will provide farmers with essential information about AMF products, empowering them to make informed decisions and contribute to sustainable farming practices.
- **Global standardization of AMF regulations:** These regulations will streamline regulatory processes and promote uniformity in AMF-related regulations worldwide, advocating for standardized terminologies and definitions to categorize AMF products globally.
- **Facilitating international trade:** The regulations will prioritize facilitating international trade of AMF products by advocating for uniform global regulations and standardized testing parameters. By harmonizing regulatory frameworks across regions, regulators will streamline market access and promote fair trade practices.

6.1. Addressing obstacles in implementing future regulatory measures

The introduction of new regulations for the commercial AMF industry brings forth a range of complex challenges that must be effectively navigated to ensure the success of these regulations. One critical challenge involves the need to ensure that manufacturers and distributors comply with the new rules. To achieve this, robust enforcement mechanisms must be established to prevent the sale of substandard or ineffective AM inoculants in the market. Both policy makers and competent authorities can be recommended to develop monitoring programs and capacity (for laboratory staff) to carry on the necessary controls. Another challenge is the standardization and harmonization of regulations on a global scale. This task is made difficult by the diversity of regional practices and policies. A dearth of scientific data on the efficacy and safety of AM inoculants poses another challenge, making it difficult for regulatory agencies to develop evidence-based regulations applicable to all AM inoculants, which can vary widely in composition, production methods, and efficacy. The international nature of AM inoculant trade further complicates matters, as it challenges regulatory agencies to enforce country-specific regulations. This challenge can be facilitated by coordinating efforts under international frameworks such as the World Trade Organization (WTO) which referred conventions like the 'Codex Alimentarius' for food standards, 'International Plant Protection Convention (IPPC)' for protecting world's plants, agricultural products and natural resources from pests, and many others. Furthermore, sustained investment in research and development is crucial. This investment will help identify effective AMF strains, understand their interactions with various plant species, and optimize product formulations. Long-term monitoring of AM inoculants' performance across different agricultural systems and environments is vital. This monitoring will validate their effectiveness and assess their environmental impacts. Environmental concerns must also be addressed. The introduction of non-native AMF strains through commercial inoculants may have unintended ecological consequences. Robust monitoring and research are imperative to mitigate potential risks to native AMF populations and ecosystem dynamics. To prevent resistance from developing in AMF populations, strategies like rotating AM inoculant products or using diverse AMF strains may be required. Adequate funding and support for AM research are therefore imperative. Educating farmers and agricultural stakeholders about the benefits and proper usage of AM inoculants represents an additional challenge. Raising awareness regarding the significance of mycorrhizal symbiosis and the role of AMF in sustainable agriculture can promote their adoption. Educating farmers and advisors on the integration of AMF into fertilizer or soil management practices and reducing application of mineral fertilisers is crucial. To ensure that only approved and effective products enter the market, reliable certification and testing facilities must be established to assess the quality, viability, and efficacy of AM inoculants. Additionally, the cost of compliance with new regulations may pose challenges, particularly for small and medium-sized AM inoculant manufacturers. This financial burden could potentially hinder their operations. To address this, financial support from public authorities within a framework aimed at promoting the transition toward sustainable agriculture can be instrumental. The affordability of AM inoculants for small-scale farmers is another concern, as high costs may impede their widespread adoption. Measures to reduce production expenses and provide financial support may be necessary. Effective communication and collaboration among regulatory agencies, researchers, manufacturers, farmers, and consumers are essential for the successful implementation and continuous improvement of regulations. Addressing these multifaceted challenges will necessitate a collaborative and coordinated

effort among diverse stakeholders committed to advancing sustainable agriculture practices through the responsible use of AM inoculants.

7. Conclusion

AM inoculants revives or expands the symbiotic relationships between AM fungi and plant roots, offering benefits such as enhanced mineral absorption, increased yields, drought and salinity resistance, secondary metabolite production, and protection against diseases. Despite their potential, challenges like inconsistent field applications, ecological consequences, lack of universal regulations impede their widespread use and trade facilitation. Other challenges include scientific data gaps, standardization issues, and the impact on ecosystems. Addressing these challenges requires increased funding, public-private partnerships, compliance monitoring, awareness programs, and research on ecosystem impacts. Establishing a transparent, reliable, and uniform regulatory framework is essential for introducing these products to the market and instilling confidence among manufacturers, end-users, and environmental stakeholders. A study on the impact of AM inoculants on human toxicology, environmental fate, ecotoxicology must be conducted. Looking ahead, enabling the acceptance of safe and efficient AM inoculants, and ensuring their accessibility to end-users will be crucial for maintaining a sufficient, healthy, and cost-effective food supply while promoting sustainability. Addressing global consistency in classifications, naming conventions, labelling, standards, and jurisdiction is imperative to achieve these objectives. Upgrading regulations in the commercial AMF industry can yield numerous benefits. Stringent standards will enhance AM inoculant quality, ensuring consistency and efficacy. This will instil confidence in farmers, driving greater adoption and promoting sustainable agriculture. The ripple effects will extend to agribusiness, research, and environmental impact. Regulatory harmonization will facilitate global collaboration, creating market opportunities. These regulations also encourage research, innovation, and soil health, with potential environmental benefits by reducing reliance on chemicals. Mandating scientific data submission will ensure safety and efficacy, promoting transparency in the AM inoculant industry. Thus, improved regulations will elevate quality, foster sustainability, and deliver substantial environmental advantages.

Funding

Not applicable.

Institutional review board statement

Not applicable.

Informed consent statement

Not applicable.

Data availability statement

Data is readily accessible in the public domain, given that this article concentrates on regulatory issues concerning mycorrhizal inoculants in the agricultural ecosystems worldwide.

CRedit authorship contribution statement

Maunata Ghorui: Writing – original draft, Data curation, Conceptualization. **Shouvik Chowdhury:** Writing – original draft, Formal analysis, Data curation. **Prakash Balu:** Writing – original draft, Validation, Formal analysis, Data curation. **Sashidhar Burla:** Writing – review & editing, Validation, Supervision, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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