Milestone report

An established functional legislation and regulatory system in at least one target country

Project

Institutionalization of quality assurance mechanism and dissemination of top quality commercial products to increase crop yields and improve food security of smallholder farmers in sub-Saharan Africa – COMPRO-II

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To obtain the original document of the registration guidelines in each project country, please contact the competent regulatory body in the country of interest. The drafts in this milestone reports give the reader an overall picture of the regulatory framework, but the official documents should be obtained from the competent regulatory body in each country for citation or official use.

Project Website: www.compro2.org

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Introduction

In COMPRO-I (2009-2011), over 100 commercial agricultural products, including microbial inoculants (e.g. bio-fertilizers and bio-pesticides) and specialty fertilizers (such as seed and foliar applied fertilizers) were evaluated for quality and efficacy in Ethiopia, Kenya, and Nigeria. Results showed that only few products (<10%) were of high quality and had a potential economic benefit to farmers (Jefwa et al. 2014). Therefore, there was an overdue need to assess the underlying issues so that appropriate solutions could be developed. In fact, the quality of agricultural inputs is of utmost importance to protect farmers, retailers, wholesalers and importers, and to minimize health and environmental hazards.

At the end of COMPRO-I, a scoping exercise was conducted to determine the causes associated with the proliferation of poor quality agricultural inputs in the marketplace. Lack or inadequate regulatory system to ensure quality, efficacy, and safety of agricultural inputs as well as proper product labelling were identified as part of the main issues. Absence of an effective regulatory framework may create a conducive environment to counterfeiting, product adulteration, and proliferation of sub-standard products among others. Such a situation generally results in poor performance of the products in the marketplace, and consequently low demand and market growth. It is also related to poor crop yields, food insecurity, loss of income, and trust in the private sector. This could partially substantiate the minimum rate of adoption of novel technologies by smallholder farmers in sub-Saharan Africa (Chianu et al. 2011). Hence, interventions were required to improve the situation. The scoping exercise demonstrated that the status of the regulatory systems for agricultural inputs was variable across participating countries (Ethiopia, Ghana, Kenya, Nigeria, Tanzania, and Uganda). Hence, Objective 3 of COMPRO-II (i.e. establishment and institutionalization of quality control and regulatory mechanisms) did engage the appropriate key stakeholders to develop and implement country-specific action plans to streamline the regulatory system in each of the project countries. The discussions were led by the competent regulatory bodies in each country and facilitated by the African Agricultural Technology Foundation (AATF) and backstopped by the International Institute of Tropical Agriculture (IITA).

This milestone report focuses on the establishment of functional legislation and regulatory systems, which is one of the five milestones under Objective 3. The other four milestones are related to: (i) availability of knowledgeable personnel and improved laboratory capacity, (ii) laboratory approval/accreditation in each of the two regional hubs for quality control (i.e. East and West Africa respectively), (iii) institutionalization of quality control system by relevant institutes as a customer-paid service to conduct routine assessment of quality, and (iv) product registration through the national regulatory agencies for legal sale. The five milestones are interrelated to ensure functional regulatory systems. Hence, in this report, reference to these other milestones will be made when applicable, but details will be provided in the specific milestones reports respectively.

It is worth mentioning that COMPRO-II was implemented when the Alliance for a Green Revolution in Africa (AGRA) was developing fertilizer policies in most of the project countries. Hence, COMPRO-II did focus on microbial inoculants, particularly bio-fertilizers, and bio-pesticides at less extent. The regulatory systems for bio-pesticides were quite advanced compared to bio-fertilizers in most project countries. The first step for implementation of activities under this milestone was the validation of the scoping exercise by the relevant competent regulatory bodies in the project countries, followed by the development of action plans to address the identified gaps in each country. The implementation of the action plans resulted in registration guidelines for bio-fertilizers in all the project countries, quality standards for selected bio-fertilizers, and standard operating procedures (SOPs) for quality control. This report focuses mainly on the registration guidelines, whereas details on the quality standards and SOPs will be provided under the milestone on institutionalized quality control system to conduct routine assessment of quality.

1 Summary of the COMPRO-II scoping exercise

During COMPRO-I (2009-2011), one of the main constraints to scaling up effective technologies identified in Ethiopia, Kenya, and Nigeria was the regulatory environment affecting the legal sale and distribution of such products in the market place. Quality control procedures and efficacy testing were insufficient and not clearly-understood by key stakeholders to ensure effective promotion of the technologies. The institutionalization of

quality control and implementation of adequate regulatory frameworks for commercial microbial inoculants therefore carried the most weight in the COMPRO-II vision of success. Hence, the scoping exercise focused on legislation and regulations of such products for improved crop yield, food security, and livelihood in sub-Saharan Africa. The following recommendations were made to improve the situation in each of the project countries:

1. Kenya: (i) streamlining operations in the departments within the Ministry; (ii) advocacy for the enactment of the draft Bill on Fertilizers and Soil Conditioners in parliament; and (iii) enhancing the capacity of regulatory bodies for product quality control and market monitoring.
2. Tanzania, Ethiopia, and Nigeria: (i) defining the roles of institutions; (ii) enhancing human and infrastructural capacity; and (iii) facilitating the sustainability of the quality control procedures and processes.
3. Ghana and Uganda: (i) trigger and accelerate the law enactment processes through national institutions, including parliamentary committees responsible for policy and legislative instruments development, by supporting relevant lead institutions and stakeholders to organize workshops and conferences aimed at creating public awareness and advocacy; (ii) promote processes to facilitate implementation of regulatory frameworks, (iii) support human and infrastructural capacity development to enhance implementation of quality control and other protocols, and establish an accreditation system for bio-fertilizers and chemical agro-inputs at national, regional and international levels; (iv) promote stakeholders' interactions to strengthen policy linkages and networking among stakeholders from private and public sectors; and (v) promote the establishment of an effective collaboration with national regulatory agencies to implement sustainable regulation and customer-paid certification procedures for the importation and commercialization of new products.

COMPRO-II (2012-2017) aimed from the very beginning at increasing the awareness of key stakeholders and facilitating, implementing, or strengthening the regulatory framework for bio-fertilizers and related agro-inputs based on country-specific needs, keeping in mind the need for harmonized requirements to protect the consumers, while facilitating trans-boundary trade. In fact, an adequate regulatory framework in the context of sub-Saharan Africa as well as elsewhere should be able to protect (smallholder) farmers against fraud while facilitating

their access to quality, innovative, profitable technologies in a timely fashion for food security and improved income.

2 Establishment of functional regulatory systems

2.1 Stakeholder engagement

Sub-agreements were signed between IITA and the competent regulatory bodies in the six project countries to ensure smooth implementation of the activities related to this milestone. The participating regulatory bodies were:

a) Plant Health Regulatory Department (PHRD) of the Ministry of Agriculture and nature resources in Ethiopia under the sub-agreement with the Ethiopian Institute of Agricultural Research
b) The Plant Protection Regulatory Services Directorate (PPRSD) of the Ministry of Food and Agriculture in Ghana
c) The Kenya Standing Technical Committee on Import and Export (KSTCIE) whose secretariat is Kenya Plant Health Inspectorate Service (KEPHIS) under the Ministry of Agriculture Livestock and Fisheries (MOALF)
d) The National Agency of Food and Drug Administration and Control (NAFDAC) in Nigeria
e) The Tanzania Fertilizer Regulatory Authority (TFRA), and
f) The Department of Crop Protection (DCP) of the Ministry of Agricultural, Animal Industry and Fisheries in Uganda, in collaboration with the Agricultural Chemicals Board (ACB) under the sub-agreement with Makerere University.

In addition to these regulatory bodies, engaged key-stakeholders included, but not limited to, the representatives of the ministry of agriculture, bureau of standards, private sector (industry/product proponents), national agricultural research system, and experts in agricultural microbiology in each project country. The diversity of stakeholders allowed effective discussions to set up quality standards that could be met by product proponents. These stakeholders were therefore involved in the consultation and sensitization workshops to discuss and promote the registration guidelines, the quality standards, and SOPs.

2.2 Validation of the scoping exercise

The first main activity was the workshop conducted in November 2012 to validate the scoping exercise by the project team together with the participating regulatory bodies. The

main finds are summarized in Table 1 below. As a result of the discussion it was agreed that in most cases bio-fertilizers were already defined in the Fertilizers Acts or regulations even when the term was not directly used as such. For instance, the definition of a 'fertilizer supplement' in the Fertilizers Act of Tanzania (2009) covers bio-fertilizers i.e. *any substance or mixture of substances, other than a fertilizer, that is manufactured, sold or represented for use in the improvement of the physical conditions of soils or to aid plant growth or crop yields*. Conversely, 'fertilizer' is defined as *a substance or mixture of substances, containing one or more of nitrogen, phosphorus, potassium or other elements represented for use as a course of plant nutrients.* The critical need was therefore to develop registration guidelines, quality standards, and SOPs specific to bio-fertilizers so that the requirements are very clear to both the regulatory bodies and the product proponents. This was very crucial to the industry for development of timely business plans and also for a levelled playing field.

Table 1

Status of the bio-fertilizers regulatory framework in the project countries by end of 2012

Regulatory Mechanisms	Ghana	Tanzania	Ethiopia	Kenya	Uganda	Nigeria
Fertilizer Act	In place	In place	In place	In place	Draft	In place
Institutional Framework	PPRSD	TFRA	PHRD	DVS[a] & KSTCIE	ACB	NAFDAC
Quality standards	None	None	None	None	None	None
Registration Guidelines	None	None	None	None	None	None
Laboratory Capacity (material resources)	Limited	Limited	Limited	Limited	Limited	Limited
Laboratory Capacity (human resources)	Limited	Limited	Limited	Limited	Limited	Limited

[a]*DVS = Department of Veterinary Services*

Based on the validation of the scoping exercise, the project did focus on addressing the current gaps to streamline the regulatory system for bio-fertilizers in each of the project

country. The country-specific action plans therefore did focus on the development of the registration guidelines, quality standards for common microbial inoculants, and strengthening the laboratory capacity (i.e. human and material capacity in the participating laboratories).

2.3 Registration guidelines

Registration guidelines are meant to ensure that regulatory bodies and product proponents have the same understanding of the regulatory requirements before a product could be registered for legal sale in a given country. They also ensure a levelled playing field as all interested product proponents are well informed about the process and go through the same process. As a result of the consultation process, registration guidelines were developed in the six project countries (Annexes 1-6), and have effectively been implemented in all the countries but Ethiopia. The consultation and sensitization is ongoing in Ethiopia to ensure effective implementation early 2016. The main content of the registration guidelines is outlined in the subsections below, while country-specific details are found in the various annexes.

2.3.1 Pre-submission

Product proponents may prepare comprehensive applications for product registration when they have a better understanding of the details in the registration guidelines. Hence, pre-submission meeting could be useful to seek for clarification as applicable. The regulatory systems developed by the various regulatory bodies in collaboration with AATF and IITA in the six project countries include provisions for pre-submission meeting. In most of the cases a pre-submission meeting is requested by the product proponent.

2.3.2 Application procedure

2.3.2.1 Administrative requirements

Checklists have been developed to ensure that applicants could compile all the necessary items required for the registration process. In addition to the letter of intention, an application form has to be filled out. The signing authority (i.e. authorized representatives) and a local agent when applicable have to be designated.

2.3.2.2 Efficacy data requirements

Submission for product registration should include efficacy data. The registration guidelines define the type of data required and how they should be generated. A summary of the evidence of the product performance should be submitted alongside the supporting documents. All the label claims related to the performance of the products should be supported by appropriate data. In the absence of label claims, data related to yield should be used to support product efficacy. Interestingly, given the challenge of food security in sub-Saharan Africa (SSA), only products that could significantly contribute to yield increase, and found profitable will be eligible for registration. When generating efficacy data, the products should be tested in the appropriate conditions i.e. products intended for field used should be tested in the field, while products limited for use in controlled environment should be tested in controlled environment.

2.3.2.3 Quality requirements

In addition to efficacy data, a product proponent is required to demonstrate that his/her product contains the active ingredient claimed in the product label and in sufficient amount based on prescribed quality standards. The product should not contain any contaminant beyond the tolerance limit, whereas it should be free of any pathogenic contaminant. Details of the quality standards and SOPs for quality control are included in the milestone on institutionalization of quality control system by relevant institutes as a customer-paid service to conduct routine assessment of quality. Quality requirements are applicable to both product registration and routine marketplace monitoring intended to significantly reduce the proliferation of poor quality products in the marketplace.

2.3.2.4 Safety requirements

A rationale to support the safety of the overall product and each ingredient in the formulation is required before the registration of the product. It should be demonstrated that the product is safe to plants, animals, humans, and the environment when used as directed. Scientific evidence are required to show the safety of each ingredient based on literature review, research and development data, and/or material safety data sheet (MSDS) when applicable. The rationale should also include details of the quality assurance and quality control measures in the manufacturing plant.

2.3.2.5 Labelling requirements

The labelling requirements include the type of information that should be found on the product label or accompanying documents considered as integral part of the label. The product label must include the mandatory items, while product proponents may add optional items when applicable. This may ensure proper use of the product based on the directions for use and adequate handling based on the cautionary statements. Mandatory items mainly include: (i) product name, (ii) guarantee analysis for the active ingredients listed in the product label, (iii) directions for use, (iv) registration number, (v) batch number, (vi) manufacturing date, (vii) expiry date or product shelf-life or sell by date , (viii) contact information of the manufacturer or product proponent, (ix) net weight using the International System (IS) of measure units, (x) cautionary statements, (xi) storage conditions, and (xii) handling conditions.

2.3.3 Registration decision

The registration guidelines list the type of decisions that could be taken after a comprehensive analysis of quality, efficacy, and safety data as well as the registration label (i.e. draft label that will later include the registration number once the content is approved). Three scenarios are possible depending on the situation:

- Full registration when all the conditions are met
- Conditional registration when the registration is restricted pending additional information [note: this is expected when the safety and the quality of the product are demonstrated and the product is proper labelled, but additional efficacy data are still required. The conditional registration will generally be amended to full registration once the product performance is supported by sufficient efficacy data]
- Denial of registration [note: this is expected when the safety, quality, or efficacy of the product cannot be demonstrated out of any reasonable doubt]

When a product is accepted for registration it will be given a lifetime registration number and a certificate of registration will also be provided to the product proponent. The registration number will be included on the product label at a visible location so as to ensure that consumers, competent inspectors, and interested stakeholders could easily distinguish registered products from non-registered ones. The status of registration will be regularly reviewed basing on continued compliance to registration requirements with possibilities of revocation and/or suspension of registration.

2.4 Capacity building

With the development of the registration guidelines, it was necessary to build the capacity of the national partners for effective enforcement of the regulatory system for bio-fertilizers. One laboratory with minimum expertise in the area of soil microbiology and/or bio-fertilizers was selected in collaboration with the competent regulatory body in each project country. In the context of institutionalization of quality control for bio-fertilizer products, those laboratories will require formal approval from the competent authority in each project country as detailed in the milestone on laboratory approval/accreditation for quality control. The capacity of the selected laboratories was improved to ensure that they could be able to implement the SOPs for quality control. Inspectors involved in marketplace monitoring have also been trained in Ghana, Kenya, Nigeria, and Tanzania, and those in Ethiopia and Uganda will be trained early 2016.

Details of the capacity building will be provided in the milestone on availability of knowledgeable personal and improved laboratory capacity. Selected project countries have started implementing the registration guidelines as shown in the milestone on product registration through the national regulatory agencies. Sensitization workshops were also organized in Kenya and Tanzania to create awareness of key stakeholders (mainly policy makers and product proponents) on the improved regulatory systems of bio-fertilizers. In a nutshell, this milestone has successfully been completed and the overall achievement is summarized in Table 2. Countries like Ethiopia, Kenya and Tanzania also plan to retroactively apply the requirements in the registration guidelines on products in the marketplace including locally manufactured products; marketplace assessment has already been initiated.

Table 2

Status of the bio-fertilizers regulatory framework in the project countries after ≈4 years of COMPRO-II

Regulatory Mechanisms	Ghana	Tanzania	Ethiopia	Kenya	Uganda	Nigeria

Fertilizer Act				In place		
Institutional Framework	PPRSD	TFRA	PHRD	DVS & KSTCIE	ACB	NAFDAC
Quality standards				In place		
Registration Guidelines				In place		
Laboratory Capacity (material resources)				Improved		
Laboratory Capacity (human resources)				Improved		

Concluding remarks

Effective implementation of the regulatory system for bio-fertilizers will contribute to maintaining high quality products in the marketplace, while significantly reducing the proliferation of poor quality products. It is expected that use of high quality products will result in yield improvement and consequently contribute to enhancing food security in the project countries. However, given the existence of porous borders in most regions of SSA and lack of similar regulatory systems in other countries, there will be a need of continuous awareness creation in the project countries to ensure that they have a better understanding of bio-fertilizers registered following the registration guidelines developed by COMPRO-II versus bio-fertilizers that will have not got similar scientific scrutiny. Equally important, harmonization of the regulatory systems for bio-fertilizers as well as other agricultural inputs of interest would be crucial to minimize farmers' exposure to sub-standard products.

Evaluation of bio-fertilizers (similar to other agricultural inputs) for registration purpose or marketplace monitoring is a resource intense process for both the regulatory bodies and the product proponents. Regional harmonization that ensures mutual recognition and equivalence of data across countries and economic communities may reduce the burden, compared to duplicating similar efforts in each SSA country. COMPRO-II did initiate the discussion on harmonization, mutual recognition, and equivalence of data in the project countries, but it was concluded that the consultation needs to be taken at the level of regional economic communities with a focus on various inputs required in integrated soil fertility management

(ISFM) and integrated pest management (IPM). Finally, although COMPRO-II did achieve a lot in terms of capacity development, in selected countries (e.g. Tanzania, Nigeria, Uganda) there are still needs for improvement to create aseptic conditions for high quality analysis of microbial inoculants to prevent cross contamination of samples; this may imply some infrastructural adjustments and improved expertise given the high diversity of microbial inoculants. The incorporation of COMPRO-II recommendations in university curricula and short course training, which will be discussed under Objective 5 of the project (i.e. *Project management, monitoring and evaluation, and capacity building*), may address the issues of expertise need in the medium and long term.

Acknowledgement

The authors would like to acknowledge the invaluable contribution of the various stakeholders who participated in the consultation and sensitization meetings to facilitate the development and acceptance of the registration guidelines, quality standards, and SOPs for quality control in Ethiopia, Ghana, Kenya, Nigeria, Tanzania, and Uganda. A particular vote of thanks goes to the participating regulatory bodies and laboratories for quality control.

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Annex 1 Bio-fertilizers registration guidelines for Ethiopia

Guidelines for registration of bio-fertilizers in Ethiopia

Please don't use for citation

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Addis Ababa, Ethiopia

Acronyms

AEZ	Agro-Ecological Zones
ANOVA	Analysis of Variance
COMPRO II	Commercial Products II
GEP	Good Experimental Practices
GMO	Genetically Modified Organism
LQSP	Laboratory Quality System Procedure
MoA	Ministry of Agriculture
NGO	Non-Governmental Organization
SOP	Standard Operational Procedure

Definition of Terms

For the purpose of this document, the following definitions are used.

- Active agent: is the living microorganism in bio-fertilizer to which plant growth activity is attributed.
- Batch: specific quantity of materials (inoculant/ bio-fertilizer) manufactured in a single operation
- Batch number: a combination of numerals and/or letters used to identify material pertaining to a particular batch and serving to distinguish it from all other batches of like materials
- Bio-fertilizer/ inoculant: a substance which contains living microorganisms which colonize the rhizosphere or the interior of the plant and promote growth by increasing the supply or availability of plant nutrient and/or growth stimulus to the target crop, when applied to seed, plant surfaces, or soil.
- Carriers: materials used as support medium to maintain the viability of bio-fertilizers until application.
- Contaminant: is any living organism(s) other than the organism of interest which is present in the bio-fertilizer.
- Efficacy: it is the measurement of effectiveness of bio-fertilizer products in terms of dry mass /yield.
- Fertilizer: any man made or natural substance, organic or inorganic that is added to the soil or to the plant to supply those nutrients required for normal growth of plants.
- Genetically-modified organism (GMO): any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
- Inorganic fertilizer: is synthetic fertilizer that is applied to soils or plant tissues to supply one or more plant nutrients essential to the growth of plants.
- Lot: all packets/containers of a product material from the same batch of manufacture in a consignment or processed under the same condition

- Strain - is a well characterized population of organisms that descends from a single cell or a pure culture isolate.

Introduction

Inorganic fertilizers have played a vital role in raising agricultural productivity in Ethiopia for decades. Fertilizer use in Ethiopia has increased from 250,000 tons in 1995 to 400,000 tons of product in 2008 (MoA, various years). Despite the prevalence of significant improvement in fertilizer consumption in the past decade, crop plants recover only 25-35% of the nitrogen applied as fertilizers. The ever increasing cost of these chemical fertilizers and their associated risks on the environmental safety calls for the search of alternative means of plant nutrient management practices, such as bio-fertilizers.

Bio-fertilizers are microbial inoculants as well as organic product of microorganisms that help crop plants' uptake of nutrients by their interactions in the rhizosphere. It is clear that soil microorganisms play a pivotal role in increasing crop production by using different mechanisms. For instance, the largest amount of nitrogen sources, 175 million metric tonnes per annum comes from biological nitrogen fixation. Therefore, bio-fertilizers have brought hopes for many countries both economically and environmentally. They are likely to result in improvement in soil and environmental health and savings for farmers. The emphasis has largely been on promoting bio-fertilizers as safe and cheap products for resource poor farming communities and providing income generation prospects.

Despite the polyphasic studies revealed that Ethiopian soils harbour diverse groups of rhizobia that are very distinct (more than 80%) from the hitherto known taxa of the Family Rhizobiaceae according to Endalkachew (2007), the history of bio-fertilizer research and development in Ethiopia has recent start. The rhizobial study and collection from indigenous legumes of Ethiopia has begun in 1981 and 1986 at Nazreth and Holeta Agricultural Research Center, respectively. Mass production and use of rhizobial bio-fertilizers at field level has, however, been started around 2000.

Nowadays, bio-fertilizers are being introduced to the country by different organizations (NGOs and private agencies) in unauthorized or uncontrolled manner that could pose threat for the users unless protected by some sort of governmental rules and regulation. Such regulation and enforcing mechanism will insure availability of high quality of local inoculants and encourage importers of microbial inoculants to raise their standards. However, government programs for the registration and authorization of bio-fertilizers are missing. So, Setting up a formal registration and authorization mechanism is a crucial step

towards the wider and sustainable use of bio-fertilizers in the country. This would also have implication on building trust between producers and end users.

This guideline is developed for operators in the Ethiopian bio-fertilizer market who wants to register bio-fertilizer products. Following all the guidelines given and providing all the required information will speed up the registration process. Appropriate registration process of bio-fertilizers will enable a better marketplace monitoring to ensure that only products with the required seal of approval provided by Ministry of Agriculture are legally sold in Ethiopia. The guidelines enlist details of registration procedures including administrative, safety, quality, efficacy, and labelling requirements.

Objectives

General Objectives

The general objectives of bio-fertilizer registration guideline are as follows:

- To stipulate the procedures for regulating bio-fertilizers and also provide a general framework for the registration of bio-fertilizers in Ethiopia.
- To ensure that the Ethiopian environment and its population are protected against the potential risk associated with bio-fertilizer commercialization and use.
- To safeguard the interest of fertilizer enterprises in general, bio-fertilizer enterprises in particular and the end users.

Specific objectives

The specific objectives of bio-fertilizer registration guideline are as follows:

- To ensure that only registered bio-fertilizers are placed on the market and made available for use by farmers and other end users.
- To ensure that registered bio-fertilizers are used correctly and safely as well as to facilitate post-registration monitoring/surveillance of bio-fertilizers.
- To ensure that registration of a bio-fertilizer may be re-evaluated if new data becomes available following registration.
- To generate a register of approved bio-fertilizer products.

- To ensure that the labels of registered bio-fertilizers contain adequate information for proper, safe use and handling of the products
- To ensure that bio-fertilizers which were introduced in the Ethiopia marketplace prior to implementation of this guideline are re-evaluated for conformity to the requirements outlined herein.
- To facilitate national, inter-national and inter-regional trade in bio-fertilizers.

Importance of the Registration Guideline

This guideline for the registration of bio-fertilizers has been developed by the Ministry of Agriculture (MoA) to ensure bio-fertilizers placed in the Ethiopian market are in compliance with relevant standards and regulations. In this regard the registration will ensure that bio-fertilizers in the market are efficacious for the intended purpose and safe to plants, animals, humans, and the environment when used as directed. Registration of bio-fertilizers by MoA will facilitate control and monitoring of these products by ensuring that only registered products are legally approved for sell and use in Ethiopia. Therefore, this guideline has been developed to provide registration procedures to be implemented by MoA and followed by bio-fertilizer traders in Ethiopia for regulation and market facilitation purposes, respectively. Availability of documented guidelines will provide transparency on regulation procedures and alignment of business plan accordingly before and during application for the registration.

Scope of the Registration Guideline

This registration guideline shall only cover carrier based bio-fertilizers locally isolated or imported. For bio-fertilizers containing genetically modified organisms (GMOs), the MoA shall direct the product proponents/potential registrant to the appropriate regulatory authority in Ethiopia. Therefore, GMOs are out of the scope of this guideline.

Legal Issues

Ownership

The owner will be the manufacturer/supplier of the product. The applicant will be the registration holder in the case of imported products and local manufacturer for locally produces. The local agent and local manufacturer are responsible for the commercialization of the product when it is registered.

Confidential Data

Any information submitted to MoA for product registration is classified as confidential. However, the separate submission of data (by secure means: electronically or in sealed envelope) should be accompanied by a Disclosure Declaration.

Competence Assurance Certificate

In addition to the issuance of registration certificate for bio-fertilizer products, MoA issues competence assurance certificate for manufacturers, distributors and retailers of bio-fertilizer products.

Bio-fertilizer Registration Procedures

In order to import or sell bio-fertilizers, registration is required. An applicant must submit an application letter to the MoA, and completed application forms for registration to MoA for processing. After passed all the required evaluations and gets approval, the product will be registered.

Pre-submission of Dossier

Letter of Intention

A letter of intention should be submitted to the MoA with the format attached in Annex 1. It will include the composition and brief description of the intended use of the bio-fertilizer; the manufacturing company; the registrant's name and contact information; and the local agent's name and contact information when the registrant is not an Ethiopian resident. Equally important, the letter of intention should indicate whether the product has been registered for use in other countries in agricultural production. If it has not been registered elsewhere, the letter should substantiate the reason. If at a later date the product proponent decides to apply for registration of the bio-fertilizer, the letter of intention will be transferred into the application package. The pre-consultation meeting is scheduled not more than10 working days after the reception of the letter of intention, unless otherwise advised by the applicant.

Consultation

A consultation meeting is proposed to serve as communication tools and provide guidance and advice to registrants prior to submitting an application package for bio-fertilizers. To ensure that the consultation follow a standardized process, and the information provided by both the registry and the registrant is recorded and maintained, face to face meeting, usually requested for by a registrant is proposed. The details of information required during consultation meeting are indicated in Annex 2.

Feedback to Pre-submission of Registration Dossier

After the consultation meeting, MoA shall send a summary of the discussion and feedback on any issues that have not been adequately addressed during the discussion (e.g., information from an external source). MoA's feedback shall be sent in writing to the registrant not more than 20 working days to the physical address indicated in the letter of intention and using registered mail. Equally important, the feedback shall outline the way forward including, but not limited to, the following information:

1) Decision whether the product is suitable candidate for registration or not.
2) If the decision is positive, the applicant will proceed to further registration steps.
3) Notification of the procedure (Annex 3) to be followed for the submission of samples for efficacy trial purpose, the assigned appropriate research institution for undertaking the efficacy test, and the submission of efficacy data generated to MoA.
4) Confirmation that the applicant is a suitable registrant as being the owner of the bio-fertilizer or in a suitable relationship with the owner based on information provided during the consultation meeting.
5) Authorization to apply for the product registration by submitting all the required items in a single package.
6) A comprehensive list of the safety, efficacy, and marking and labelling requirements.
7) Confirmation of data waivers if applicable (e.g., in case of equivalence of data).
8) Information on the handling procedures of confidential business information.
9) Details on the required fees to be paid along with submission as well as the fee structure including annual fee and other costs (i.e. cost of reviews of the label and safety data in the application package).
10) Other administrative requirements as applicable.
11) Expected timeframe of application reviews.
12) When, based on information provided, the product requires review by MoA, an explanation of the applicable procedures.

13) The need of signing of MoU with assigned research organizations.

Application Procedures

Administrative Requirements

The administrative requirements are meant to provide applicants with enough information to prepare the registration package based on the regulatory requirements and procedures. Details of checklists to be used are indicated in Annex 4. The following outlines the minimum data required for the application package for bio-fertilizer registration.

Submission of application and registration dossier

Applicants shall be required to submit registration dossier that contains completed application form (Annex 5) and other required documents as per Annex 3. The registration dossier should be submitted in duplicate (one in authenticated hard copy and one electronic copy) to MoA.

Registration fees

The registration fee includes document/data review fees, payable to MoA. It doesn't include the cost for factory inspection, efficacy and safety data generation, and testing for compliance to standards; these payments should be paid directly to the institutions/organizations generating the data and they are not controlled by MoA. MoA only specifies the minimum data required; however, the efficacy and quality data should be generated by an institution approved by MoA. The fee structure applied by MoA for bio-fertilizers registration is available on request.

Authorized representatives

To ensure that confidential business information is not released to unauthorized individuals, the applicant should provide in writing a list of maximum three persons authorized to request information on the product file when necessary. Any other person who is not an MoA-authorized staff and who is not included in the list of the applicant shall not have access to information in the product file or details related to the registration process for the specific bio-fertilizer. The applicant can modify the list at any time in writing. However, MoA will not be responsible for any damage that may occur during the

transition period, i.e. from the initial list to the revised list of authorized individuals. It is the responsibility of the applicant to ensure that MoA receives the correct and valid information on time. Once the amended list is received MoA shall immediately implement the change.

Declaration of local agent

When an applicant is not a citizen of Ethiopia, he/she must have an Ethiopian citizen as local representative or agent (also known as country representative). An official letter signed by the product proponent and countersigned by the local agent should be submitted to MoA. The local agent must be included in the list of authorized representative(s).

Efficacy Evaluation

In addition to the administrative requirements, the application package should include efficacy data generated by an institution/organization approved by MoA. The efficacy data shall include the performance data generated based on the requirements in this registration guideline. A summary of the efficacy data should be submitted alongside any other relevant supporting data.

Upon reviewing the nature of guarantees or claims displayed on a product label, MoA shall determine the type of efficacy data to be submitted. Similarly, if the efficacy of a given use-pattern is not well established MoA may request efficacy data to substantiate the recommended use-pattern. Stated differently, each usage pattern or direction for use on the product label is treated as a claim, and must be supported by scientifically valid efficacy data. Anecdotal or testimonial evidence will not be accepted. Below are the minimum requirements for efficacy data; however, MoA reserves its rights to request additional information when deemed necessary.

Good Quality System Procedures

It is recommended that efficacy trials be conducted using Laboratory Quality System Procedures (LQSP; also known as Good Experimental Practices or GEP). The primary goal of LQSP (Annex 6) is to ensure that all efficacy trials conducted are of high quality and the results derived are reliable enough to support the registration of a bio-fertilizer. This is particularly important in the context of mutual recognition across countries. Hence, only institutions/organizations that can demonstrate adequate LQSP will be

approved by MoA to generate efficacy data for product registration. Importantly, the approval duration of the institutions/organizations and research scientists shall be subjected to renewal to ensure the sustainability of the LQSP.

Location of Efficacy Testing and Site Selection

The location of efficacy testing shall be recommended by MoA. Hence, MoA shall determine the minimum number of agro-ecological zones (AEZ) where a given bio-fertilizer should be tested. However, the site selection within the recommended AEZ is left at the discretion of the approved institutions/organizations. The AEZ choice shall also be based on the agricultural production regions for the intended crop(s). The minimum AEZ number shall also depend on where the applicant wants to sell or distribute the product of interest.

In all instances, the efficacy data shall be generated in an environment relevant for the intended use. For instance, greenhouse trials will not be enough to support the efficacy of a bio-fertilizer intended for field use.

Minimum Number of Trials

The minimum number of trials should be conducted during more than one growing/cropping season (temporal variability) and in different AEZ or trial sites (spatial variability), unless the product is meant for only a single AEZ. The minimum number of growing seasons shall be determined by MoA and communicated to the registrant in the feedback letter following the pre-submission meeting.

The minimum number of trials required to support product efficacy will vary, depending for instance on the intended usage pattern, intended crops, and label claims. For example, a product intended for soil application, to be used on a single crop with the claim of increased yield, would generally require a low number of trials. However, when the same product is intended for several crops, for several AEZs and the bio-fertilizer label includes several claims in addition to yield improvement; the minimum number of trials may significantly increase.

In general, the minimum number of trials is set to 6 when the various claims could be tested at the same time. When agreed upon during the pre-consultation meeting, MoA may grant a waiver for the temporal variability, but shall increase the spatial variability (i.e. accelerated trials). For instance, when the

minimum number of trials capturing the spatial and temporal variability is 6, then the minimum number of accelerated trials shall be 9 trial-sites in various AEZ.

Bio-fertilizer Recommended for Several Crops

When a bio-fertilizer is recommended for several crops, the following two options shall be discussed during the pre-consultation meeting to optimize the number of trial sites:

Representative crops

In the case where the similarities between crops is supported by scientific evidence in terms of physiology and production patterns, the crops may be grouped together based on similarities and the efficacy testing conducted using representative crops from each group. The grouping shall be approved by MoA before the beginning of the trials. Grouping will not be considered in the case of few crops (e.g., less than 3 crops).

Representative sites

When possible, the effect of the bio-fertilizer on the selected crops shall be evaluated at the same sites keeping the same minimum number of trials for each crop. In all instances, if the bio-fertilizer is tested on a reduced number of crops compared to the list on the product label, the label will have to specify the crop species that were used to generate the efficacy data.

Trial Design

A randomized complete block design (RCBD) in which the treatments are randomly distributed within each block is recommended. Other designs such as the completely randomized design (CRD) may be used for trials conducted in completely homogeneous environments, such as greenhouses or growth chambers. There is a general consensus that the trials should also be designed in a manner that allows at least 8 degrees of freedom to the error term during the analysis of variance (ANOVA).

Preventing Cross-contamination between Experimental Plots

Guard rows or border plots to prevent treatment overlap and/or drift of product or treatment from one plot to another are recommended. Guard rows are particularly important when the plot size is small. Plot size will vary depending on the crop of interest, the product, and the method of application of the product. The plot size will be discussed during the pre-consultation meeting.

Treatment Structure

Treatments with the bio-fertilizer intended for registration must be compared to one or more check treatments, including but not limited to (a) an untreated control, (b) appropriate comparative treatments (positive controls; for instance a registered bio-fertilizer intended for the same use and with the same mode of action), (c) Local practice and (d) Product to be tested.

Planting Window

When the product label does not recommend to sow the seeds treated with the bio-fertilizer immediately after treatment, the label should specify the timeframe that is allowed between the treatment and planting. Such a timeframe is known as the planting window. The planting window should be substantiated using scientific data to ensure that the required number of viable cells in the bio-fertilizer of interest can be recovered from the seeds at the end of the planting window. The planting window shall be demonstrated not only based on laboratory data (counting), but also field data obtained when the product is tested at the end of the planting window. A delay of one tenth of the recommended planting window will be tolerated; however, the tolerance will not exceed 7 days when the planting window is significantly long.

Expiry Date and Shelf Life for Bio-fertilizers

The active agents in bio-fertilizer products are subjected to degradation or loss of viability over time. A bio-fertilizer label shall display an expiry date, i.e. the date after which the required minimum number of viable cells can no longer be guaranteed. Alternatively, the product label shall display the manufacturing date and the shelf life; the shelf life represents the expected storage duration (from the manufacturing date) within which the required minimum number of viable cells can be guaranteed when the bio-fertilizer is stored under the recommended conditions.

Measurable Parameters

When evaluating the efficacy of a bio-fertilizer, data should be collected before planting, during the growing season, and at harvesting. MoA will discuss with the applicant, the minimum measurable parameters required, as this is a critical determinant in the registration process.

Before planting

To ensure that product efficacy is evaluated in appropriate conditions, the initial soil fertility level should be evaluated prior to the establishment of the trials. Soil analysis prior to treatment should include (but is not limited to): soil texture (hydrometer method), pH(1:2.5 dilution), cation-exchange capacity, organic matter content (Walkley and Black), availability of selected plant nutrients, functional microorganisms of interest (in this case of bio-fertilizers), etc. This information should be collected regardless of the label claims.

During the growing season

After the application of the treatment, minimum weather data including the ambient temperature, humidity, and rainfall should be collected. In addition to the initial soil testing, information on weather conditions could also be used to explain any spatial or temporal variability. Other measureable parameters shall be based on the label claims, but don't have to be limited to the label claims. Measurable parameters will include, but are not limited to, the following:

1) Visual symptoms of nutrient, abiotic, and biotic stress (when observed)
2) Shoot and root height and dry weight
3) Uptake of plant nutrients of interest at a specific growth stage
4) Number, weight, and colour of nodules in the case of rhizobium inoculants
5) Intensity of root colonization/infection, and root and hyphal length in the case of mycorrhizal inoculants
6) Root architecture in the case of plant growth promoting rhizobacteria

At harvesting

The following measurement parameters should be considered. Crop yield remains by far the most critical parameter:

1) Crop yields (particularly grain yield when applicable, haulms/biomass, husks, etc.)

2) Quality of the crop yields when applicable (based on label claim)
3) Number of Pods per plant and number of seeds per pod for legumes
4) Plant height and number of tiller

Data Analysis

The data should be statistically analyzed, including descriptive statistics and ANOVA using accepted software (e.g., SAS, R). The method of statistical analysis should be considered prior to conducting the trial. The level of significance and the mean separation techniques should be the ones that are commonly used in the field of interest (e.g., probability of 5% and the least significant difference i.e. LSD). Anecdotal or testimonial evidence should not be considered as a scientifically valid form of efficacy data, and therefore should not be accepted to support product approval for registration; however, such evidence could be used as background information. Hence, all label claims must be adequately supported by scientific data that has been statistically analyzed and demonstrates a statistically significant benefit. The statistical analysis should be consistent across AEZ for the same product and treatments.

Profitability Analysis

Economic evaluation of crop responses to bio-fertilizers is important to assess their profitability, particularly in the context of smallholder farmers. The benefit cost ratio (BCR) is one of the tools used to conduct such an evaluation, particularly when yield is considered. BCR is the ratio of the net value of extra crop produced to the cost of the bio-fertilizer (Eq. 1). In actual practices, a BCR of 2.5 and above is considered to be satisfactory for the adoption of the technology. However, some authors have indicated that a BCR > 1 is already attractive for farmers. Taking into consideration other costs, including credits and risk taken, the higher the BCR the better. For the purpose of bio-fertilizer registration, MoA shall accept BCR values ≥ 1. Such BCR values shall be shown in at least 75% of the trial sites for a bio-fertilizer to be registered by MoA.

$$\frac{Value\,of\,additional\,crop\,produced - cost\,of\,the\,biofertilizer}{Cost\,of\,the\,biofertilizer} \qquad \text{(Eq. 1)}$$

Safety Requirements

A package of safety data (Annex 7) should be prepared. In addition to the supporting document(s), a rationale not exceeding 5 pages to substantiate the safety of the bio-fertilizer should be provided. Basically, the applicant shall demonstrate that each ingredient in the product formulation is present at a level expected to be safe to humans, animals, plants, and the environment when used as directed. Also, the safety of the formulation when all the ingredients are mixed together should be demonstrated i.e. mixing the ingredients results in a product equally safe. Equally important, the level of non-guaranteed micro-organisms in the bio-fertilizer product should not be higher than the tolerance prescribed in the national bio-fertilizers standards. MoA will keep a database of approved SOPs to be used for quality control of bio-fertilizers sold in Ethiopia. No pathogenic micro-organism or ingredient will be tolerated in a bio-fertilizer intended for sale in Ethiopia. MoA reserves the right to ask for additional safety information on the bio-fertilizer not only during the registration process, but also during the post-registration period when deemed necessary. The level of contamination of bio-fertilizers will be evaluated by laboratories approved by MoA.

Labeling and Packaging Requirements

Product Label

The applicant should provide a proposed tentative product label to allow correct use of the bio-fertilizer during the efficacy testing and its safe handling. Based on the efficacy and safety data, the label will have to be amended accordingly into a commercial label. The commercial label will also have to include a registration number granted by MoA as a seal of approval. Equally important, the label of a bio-fertilizer sold in Ethiopia shall be at least in both English and Amharic languages.

Product labels shall not have any incorrect or misleading information, mark, brand, or name that would tend to deceive or mislead the end-user with respect to the composition or benefits of using the product. The approved product label shall be the only commercial label found in the marketplace for the registered bio-fertilizer.

Specific Requirements for Labelling and Packaging

The specific requirements for labelling and packaging are indicated in Annex 7.

Quality Requirements

Bio-fertilizer quality is one of the most important factors resulting in its success or failure. The standard operating procedures (SOPs) for the quality control of bio-fertilizers in Ethiopia (available on request) will provide detailed quality criteria of specific bio-fertilizers. The quality of bio-fertilizers sold in Ethiopia should meet the Ethiopian bio-fertilizer standard.

When MoA does not have a specific SOP to verify the quality of a new bio-ertilizer, the applicant will have to provide the procedure to MoA. MoA shall validate it in its approved laboratories before the bio-fertilizer can be registered. Sampling will be done as indicated in annex 8

Registration Decision and Feedback

When the evaluation of the registration dossier is completed, MoA will take one of the three (3) potential decisions below:

1) Full registration (FR) of the bio-fertilizer
2) Conditional registration (CR) of the bio-fertilizer (note: the conditions will be specified in the decision letter)
3) Denial of the registration of the bio-fertilizer (note: a rationale will be included in the decision letter)

MoA will make a decision related to the registration of the bio-fertilizer within a period of three months and will communicate the result in writing to the applicant including a rationale of the decision and information on the post-registration requirements.

All registered bio-fertilizer products will be subject to renewal of the registration (the application form will be available on request). In the case of conditional registration, the registrant will have to fulfil the requirements for full registration within six months. Failure to do so will lead to the registration being denied. There will be no room for renewal of conditional registration. In the case of full registration, upon continued compliance with the registration procedures and regulations, the registrant shall apply for the renewal of the registration every 3 years.

After initial registration is done, applicant is permitted to advertise and sell bio-fertilizers within the stipulated period of time. Renewal of registration may be granted for the various registration types. The MoA reserves the right to revoke, suspend or modify registration on its own initiative subject to emergence of post-registration data.

Appeal of a registration decision

When applicant/registrant is not satisfied by a decision made by MoA regarding the registration status of a bio-fertilizer, he/she has the right to appeal according to the Laws and Regulations of Ethiopia. MoA will provide the applicant with adequate guidance related to the appeal procedures and instances. The appeal should be presented in written form within 15 working days after decision is notified. MoA should respond to the appeal in written form within 15 working days after receiving the appeal.

Documentation of Registration Decisions

Once a decision is taken it will be recorded in the official Register. Hence, each bio-fertilizer registered will be assigned a specific registration number. The registration number will have to be included on the registration certificate as well as on the commercial product label. The registration number for conditional registration should include the letters "CR", whereas that of full registration will include "FR". The registration numbers will read as follows:

1) Registration number: MoA DDMMYYYYBFCRXX or
2) Registration number: MoA DDMMYYYYBFFRXX

Where DD stand for the day, MM for the month, YYYY for the year, BF for bio-fertilizer, CR for conditional registration, FR for full registration, and XX for a number from 01 to 99 in the precedence order of registration.

The history of a given product registration process should be kept in the Register. The Register of bio-fertilizers will be in electronic form; however, hard copy will be kept for a minimum of 3 years from the date of the registration decision. The renewal of the registration will not affect the registration number; a registered bio-fertilizer will keep the same registration number during its entire lifetime in the Ethiopian marketplace.

Certificate of Registration

When a bio-fertilizer is registered, the registrant shall get a registration certificate including, but not limited to, the following information:

1) Name of the registrant and local representative if it is not the same person
2) Company's name and physical address of the place of manufacturing of the bio-fertilizer
3) Name of the bio-fertilizer
4) Target crop
5) Registration number
6) Type of registration (full or conditional; also reflected in the registration number)
7) Period of validity
8) MoA's seal (i.e. seal of approval)
9) Full name and signature of MoA
10) Date of registration or registration renewal

Responsibilities of the Registrant after Registration

The responsibilities of the registrant are stipulated in the registration certificate or as separate conditions for registration. The activities that a registrant would be responsible for include among others to prevent product adulteration along the whole commercialization chain so as to ensure that the quality is maintained. Registrants shall be held responsible when their product in the marketplace is found to be non-compliant to the prescribed standards after registration.

Modification of Registration Status

The registration status of a bio-fertilizer product can be modified in the following instances:

Modification of Composition or Use of a Product

If after initial registration, there is cause to modify composition or modify use of a product, an application to modify the registration status must be made according to the data requirements in the application form. The need may arise from data emerging from post-registration monitoring of the use, effectiveness and adverse effects of the bio-fertilizer or from information coming from other countries where the same or similar products are in use. A modification to the registration may therefore be required by MoA based on

its dissatisfaction of emerging data or the need may arise from the registrant's own post-registration monitoring.

Revocation of Registration

A situation may arise where MoA as a result of emerging data, may conclude that a given bio-fertilizer presents too great a risk to continue its use or that the bio-fertilizer no longer meets the prescribed standards. In these situations registration may be revoked, but MoA would inform the registrant of the reasons for such action. In this case, the bio-fertilizer will effectively be classified as a prohibited bio-fertilizer, until the product owner ensures it complies again with the prescribed standards and qualifies for re-registration.

Renewal of Registration

When the validity of a registration is running out and the registrant wishes to continue marketing the product, an application for renewal should be submitted to the Minister not later than 3 months before the registration expires. Certificate of renewal must be granted before advertisement or sales can be resumed. If for some reason the registration is not renewed, the product will cease to be recognized as registered, and it would be illegal to engage in any regulated activities connected with it, including formulation, transport and distribution, sale and use. The product owner can decide to modify the product composition and use before it is renewed. The data requirements for renewal of registration are indicated in the application form.

Post-registration Surveillance

MoA shall conduct post-registration market surveillance to ensure that the quality standards are maintained throughout the marketing chain of bio-fertilizers based on the prescribed specification. If it is discovered that a bio-fertilizer quality had changed and product registration have to be modified based on emerging concerns, the registration certificate would be amended accordingly.

Concluding Remarks

This registration guideline for bio-fertilizers outlines the various requirements for the attention of MoA staff and product proponents. It allows for a transparent, fair, and timely review of applications for bio-

fertilizer registration in Ethiopia. All bio-fertilizers intended for sale in the Ethiopian market shall comply with these registration guidelines. Any bio-fertilizer product found in the Ethiopian market without the appropriate registration certificate and the related registration number shall be subject to enforcement including potential detention. For products that were found in the market prior to the implementation of this registration guideline, the product proponents are required to contact MoA to agree on the appropriate actions to make those products compliant to this bio-fertilizer regulatory framework.

Both MoA staff (including regulatory officers, inspectors, and laboratory staff involved in the quality control of bio-fertilizers) and product proponents are required to familiarize themselves with these guidelines. The quality control requirements (labelling, efficacy, quality, and safety data) are not limited to the registration process, but also apply to post-registration marketplace monitoring. Product proponents are required to ensure that the quality of the bio-fertilizers in the marketplace is up to the standards prescribed in the registration guidelines or applicable standard operating procedures for quality control, which are available on request. Stated differently, if a product in the marketplace no longer meets the quality standards (labelling, efficacy, and/or safety requirements), it will be subjected to enforcement actions including (but not limited to) detention or cancelation of the registration certificate.

To ensure timely access to innovative technologies by Ethiopian farmers, MoA will clarify the file review timeframe during the pre-submission meeting. Once all the required items are submitted, MoA will process the file in a timely manner. To prevent unnecessary delay, applicants are required to provide MoA with any clarification or item required at their earliest convenience. Hence, the registration process is interactive. Both parties (i.e. MoA and the applicant) will have to take advantage of it. However, the registrant shall follow up with MoA for the progress of the registration process only when the timeframe indicated in the feedback of the pre-submission meeting has elapsed.

After the registration of a bio-fertilizer by MoA, the registrant can commence legal sale of the product in the Ethiopian marketplace. He/she is also responsible for the quality of the product in the marketplace (commercial chain), unless there is significant evidence that the product has not been handled as prescribed on the product label by a third party (e.g., retailer). For instance, the product label shall clearly indicate that bio-fertilizer repackaging by unauthorized persons or adulteration is prohibited. Importantly, once a bio-fertilizer is registered, the registrant shall not make any modification to the product label or

product formulation (ingredients and their proportion in the product) without a written approval from MoA. Such changes represent a modification and will be reviewed by MoA to evaluate the impact on the product registration status.

When the validity of a registration is running out and the registrant wishes to continue marketing and selling the product, the registrant has to apply for the renewal of the registration certificate using the recommended application form (available on request). He/she will have to indicate in writing whether he/she has the intention of modifying the product label or formulation. If no change is expected, no additional information will be required except the application form. If changes are expected, the registrant has to provide details of the changes in writing. The information will be reviewed by MoA. MoA also reserves the right to require additional information including quality, efficacy, and/or safety data depending on the nature of the changes. Registrants are required to submit the renewal request of the registration certificate at least 3 months prior to the expiry date of the current certificate.

When a bio-fertilizer fails to comply with the regulatory framework after registration, it will be subject to enforcement actions that may include, but are not limited to, product detention or cancelation of the registration certificate. The situation could result either from a contravention by the registrant to a prescribed standard, or emergence of new data on the efficacy, quality, or safety of the bio-fertilizer. When a bio-fertilizer is detained or registration certificate cancelled, MoA will inform the product proponent or registrant in writing; the letter will include the reasons of the enforcement action and the requirements to address the issues. Detained bio-fertilizers will only be released when all the issues have been addressed. The same applies to the reactivation of the registration certificate; a newly signed registration certificate will have to be granted at his/her charge. If the product proponent or registrant cannot address the issues related to the detention of a product or cancelation of a registration certificate within the timeframe agreed upon with MoA, the products will be disposed at his/her charge.

As a result of the implementation of the registration guideline, MoA has started developing various SOPs intended to provide more details or clarification on the enforcement of the bio-fertilizer regulatory framework, including the fee structure, penalties on violation of regulations and procedures, and dispute settlement. Equally importantly, when a registrant requires clarification on a specific provision of these

guidelines, he/she is required to contact MoA for that effect. This also applies to the appeal process for any decision made by MoA under the Fertilizer Act/proclamation.

References

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3) CFIA (1997). T-4-114 – Sampling Procedures for Fertilizers. Canadian Food Inspection Agency
4) CFIA (2010). Guide to the Canadian Federal Regulatory Requirements for Fertilizers and Supplements. Crop Inputs Division; Plant Health and Biosecurity Directorate; Canadian Food Inspection Agency
5) The Fertilizer Association of India (2010). The Fertilizer (control) order 1985 (as amended up to June 2010). Ensuring food security. New Delhi, India.

Annexes

Annex 1: Format for Letter of Intention

Composition and brief description of the intended use of the bio-fertilizer	
Manufacturing company	
Registrant's name	
Contact information	
Local agent's name and contact information when the registrant is not an Ethiopian resident.	

Annex 2: Detail of Information Required During Consultation Meeting

A registrant should know the identity of the product. Identity of any bio-fertilizer is determined by its composition. The registrant shall provide the following identity information on the product to be registered:

Details on scientific name, taxonomic grouping and population of active agents.	
Target crops	
Type of bio-fertilizers	
Details on type and physiochemical characteristics of carrier.	
Details on contaminant(s)	
And any other details as determined by regulators usually on a case-by-case basis according to the nature of the bio-fertilizer proposed for	

registration.	
Tentative product marking and labelling information	
Proof of ownership of the bio-fertilizer to be registered	
Presentation of the research and development data related to the efficacy of the bio-fertilizer on yield and yield related components	
Profitability analysis	
Time, rate and method of application	
Brief description of product safety and quality	
Disclosure of any non- active ingredients	

Annex 3: procedure for submission of sample

1. Import permit application (form) cosigned by the applicant and research organization attached with Performa invoice

2. Issuance of import permit by the MoA

3. Issuance of import authorization by MoA at the port of entry up on appropriate inspection

4. Submission of sample to the research organization for efficacy test

Annex 4: Checklist Accompanying the Application Form for Bio-fertilizer Registration in Ethiopia

Checklist to verify the completeness of an application package submitted to MoA to seek for the registration of a bio-fertilizer		
Item	Included (Tick with √ when applicable)	
	Yes	No
Application form and study report 2		

Letter of intention 2		
Registration fees (a proof of payments from the bank as it is appropriate)		
List of authorized representatives 2		
Agreement between the local agent and the registration holder 1&2		
Signed MoU with assigned research organizations 2		
Batch certificate of test for the product and method employed for the test 1&2		
Manufacturing license of the specific product from the country of origin 1&2		
Local efficacy data as agreed upon with MoA 2		
Safety data sheet 2		
Certificate issued by appropriate institution confirming that the bio-fertilizer does not contain genetically-modified organisms 1&2		
Tentative product label 2		
Evidence for product registration in other countries or rationale showing why the product is not registered elsewhere 1&2		

Remark:

A. generated documents

1: need to be authenticated by the appropriate institution, signed and stamped by the registrant.

2: Signed and stamped by the registrant

B. Documents to be attached in the dossier by the MoA:

- import permit application

-Issued Import permit

-Issued import authorization

- Efficacy data

Annex 5: Application Form and data requirement for bio-fertilizer Registration in Ethiopia

Purpose of the application in maximum 20 words (attach letter of intention):	
a) Registrant's contact information	
Full name	
Physical address	
Postal address	
e-mail address	
Telephone	
Mobile phone	
Fax	
b) Contact information of the manufacturing plant (Note: if many plants are involved, list those which are relevant for this registration process):	
Full name	
Physical address	
Postal address	
e-mail address	
Telephone	
Mobile phone	
Fax	

c) Local agent's contact information (if not the same as the registrant)	
Full name	
Physical address	
Postal address	
e-mail address	
Telephone	
Mobile phone	
Fax	
d) Product name:	
e) Brand name (if any)	
f) Name of active ingredient(s) in the bio-fertilizer (for each ingredient provide number of cfu/g of finished product):	
g) Type and nature of carrier material	
h) Safety statement (declaration related to the bio-fertilizer safety; maximum 100 words):	
i) Product Quality	
physical characteristics [solid or liquid]	
guarantee analysis	
level of contamination	
pH	
moisture content	
particle size for bio-fertilizers in solid form	
efficiency	

j) Declaration: All the information in the application package (annex 3) including this application package is true to the best of our knowledge and has been prepared by our company or authorized individuals. Our company has full ownership of the bio-fertilizer for which we are seeking for registration. The bio-fertilizer does not contain genetically-modified organisms.	
k) Place, date, full name, and signature of one of the 3 authorized representatives other than the applicant/registrant and local agent:	
l) Place, date, full name, and signature of the applicant/registrant:	
m) Place, date, full name, and signature of the local agent (if different from the applicant/registrant):	

Annex 6: Good Quality System Procedures (GQSP)

The GQSP requirements include (but are not limited to):

Details of the experimental condition and surrounding areas

- test crop,
- plot area,
- weather condition,
- field layout
- soil condition
- rationale off choosing the trial sites
- trials conducted using the specific formulation and methods of application (i.e. use pattern) as indicated on the label.
- inclusion of one or more similar product (s) as reference
- complete address and geographical coordinates of trial locations
- appropriate number of trials by considering the diversity of the agroecology and intended use
- quality trial management practices are implemented
- proper trial planning, execution, assessment, record-keeping, and interpretation of data
- qualifications and training of staff conducting the trial and/or analysing the field data
- the use of proper equipment, facilities, protocols, methods of application and data recording
- internal procedures that provide verification of the proper use of GQSP

Annex 7: Details of Safety Requirements

The requirements to establish the safety of a bio-fertilizer include, but are not limited to, the following:

Summary of the technical dossier related to the safety of the product (i.e. bio-safety assurance statement on pathogenicity, gene flow, invasiveness, persistence, and effect on non-target organisms, among others)

1) Information on the safety of the carrier material (when applicable)
2) Information on the strain(s) including the source, identification, and taxonomy

Annex 8: Specific Requirements for Labelling and Packaging

Any of the items below that is not qualified as optional is by default mandatory.

1) Common name
2) Guarantee analysis: a statement that shows the content (concentration of the active ingredients) of the product, i.e. cfu of active agent(s) per gram of finished bio-fertilizer product. MoA will verify the guarantee analysis using the service of laboratories approved by MoA for quality control of bio-fertilizers
3) Directions for use: specifying application rates, frequency of application, target crops, application equipment, and method of application, among others (the directions for use should be based on the results of the efficacy trials)
4) Registration number
5) Batch number
6) Manufacturing date
7) Expiry date or shelf life
8) Company information: contact address including the physical address of the place of manufacture
9) Net weight using the International System (IS) of units of measure
10) Cautionary statement (safety statement)
11) Planting window or pre-planting treatment period
12) Storage conditions
13) Handling conditions
14) Disposal statement for both the bio-fertilizer and containers
15) Brand name
16) Net weight in local equivalence of the IS units of measure
17) Seller's guarantee: warranty statement in case of damage or product failure when product is used as per the direction for use
18) Label claims
19) List of ingredients
20) Website

Annex 9: Sampling Requirements for Quality Control

Product sample shall be significantly representative of the bio-fertilizer batches. Adequate precautions shall be taken to prevent contamination of the bio-fertilizer during the sampling process.

General requirements for sampling

1) Precautions and directions must be observed when drawing, preparing, and handling samples intended for quality control
2) To ensure that representative samples are taken, sampling must be carried out by a qualified, trained and experienced inspector
3) For packaged products, unopened packets should be sampled and sent to the laboratory using appropriate equipment to prevent possible contamination of samples during handling
4) Samples must be taken in the presence of the product proponent or his/her authorized representative
5) Collected samples should not show any visible sign of contamination
6) For quality control, samples shall be taken from representative lots in a random manner
7) Adequate and representative samples for testing should be taken. The product proponent shall retain one unit as a representative sample for re-testing in the case of dispute

Drawing samples

1) The number of sample-packets to be taken from a lot will depend on the size of the lot. The samples should be randomly selected using a well-established randomization procedure. The sample will be considered a legal sample as the result will be used as a proof of the product compliance to the regulatory requirements.
2) The inspector or any other authorized staff shall take 9 sample-packets from a given lot based on the batch number (3 of the samples will be sent to the laboratory approved by MoA for quality control; 3 will be handed to the product proponent in case he/she may want to send them to a reference laboratory to cross-validate the result from the approved laboratory; and the remaining 3 will be kept in adequate conditions for re-testing in case of conflicting results or dispute). The product proponent or his/her authorized representative shall sign onto the sampling form of the inspector. When analysing samples, each packet should be analysed separately.
3) The inspector or any other authorized staff should carry with him/her appropriate sampling forms on which to consign information about the sample and the sampling procedures. He/she should ensure to have appropriate sampling tools for taking and transporting samples to the laboratory. Each sample shall be sealed in cloth bags or any approved containers using the inspector seal after having put inside the sampling form filled out by him/herself and signed by the product proponent.

4) The total number of lots to be sampled will depend on how many there are. When the total number of lots is lower than or equal to 5, each of them will be sampled. When it is higher than 5, 5 randomly selected lots will be sampled. The minimum number of samples per lot shall be as shown in the table below:

Packets/bags per lot	Number of samples
≤5,000	03
>5,000 - ≤10,000	04
> 10,000	05

Note: number of randomly selected samples to be drawn from a lot

Annex 2 Bio-fertilizers registration guidelines for Ghana

GUIDELINES FOR REGISTRATION OF BIO-FERTILIZERS IN GHANA

ACRONYMS AND ABBREVIATIONS

ANOVA	**Analysis of Variance**
AEZ	**Agro-Ecological Zones**
COMPRO II	**Commercial Products II**
GEP	**Good Experimental Practices**
SOP	**Standard Operational Procedure**
REC	**Regional Economic Community**
SMEs	**Small and Micro Enterprises**
LMO	**Living Modified Organism**
MSDS	Material Safety Data Sheet
QA	Quality Assurance
QC	Quality Control
PFRD	Pesticide and Fertilizer Regulatory Division
PPRSD	Plant Protection and Regulatory Services Directorate

EXECUTIVE SUMMARY

The production and distribution of bio-fertilizers in the agro-input markets is on the ascendency in many countries including Ghana. The guidelines for the registration of bio-fertilizers have been developed by the Plant Protection and Regulatory Services Directorate (PPRSD) of the Ministry of Food and Agriculture (MoFA) to ensure that the circulation of such products for research or commercial purposes are authorised and that they are safe, efficacious, and as per label claims. This is part of the outcomes under Objective three of COMPRO II Project in Ghana and also contributes to the on-going work by other countries to ensure that the bio-fertilizer subsector is adequately regulated.

This document begins with an introduction of Bio-fertilizers, the scope and essence of the registration guidelines. The second section outlines details of the registration procedure and the third section provides guidance for the conduct of efficacy trials. The document has annexes of application forms, model certificates of registration and a sample label for bio-fertilizer products.

It is hoped that these guidelines for registration of bio-fertilizers in Ghana would increase the competitiveness of the agricultural sector in the country and facilitate farmers' access to innovative bio-fertilizer products that are safe, efficacious, and properly labelled for the end users.

DEFINITION OF TECHNICAL TERMS

Lot: All packets/containers of a product material from the same batch of manufacture in a single consignment.

Specific Lot: Packets/ containers of a product material from two or more batches of manufacture in a single consignment.

Batch: All inoculants that are prepared from a batch of fermentor or a group of flasks run at the same time and during the same time frame.

Batch number: Is a specific number used to distinguish each batch. The number could be combination of symbols including letters and figures. The number should at least include the date of manufacture (dd/mm/yyyy). The number should be printed on each product package.

Bio-fertilizer: A substance containing living microorganisms which colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of primary nutrient(s) and/or growth stimulus to the target crop, when applied to seed, plant surfaces, or soil (tentative or proposed definition).

Active ingredient: The microorganism and any associated metabolites in a bio-fertilizer to which plant growth activity is attributed.

Microbial fertilizer: A bio-fertilizer in which the sole or main active agent is a microorganism.

Microbial active agent: A microorganism (bacterium, alga, fungus, protozoan, virus, mycoplasma, rickettsia) and any associated metabolites, which aid soil health, plant growth, or improve soil fertility but excluding nematodes.

Indigenous microorganism: A microorganism originating naturally in the country or region in which the bio-fertilizer is being registered.

Non-indigenous microorganism: A microorganism originating from outside the country or region in which the bio-fertilizer is being registered.

Genetically-modified organism/living modified organism: Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Sample: A finite part of a statistical population whose properties are studied to gain information about the whole.

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1.0 INTRODUCTION

These guidelines are developed for operators in the Ghanaian bio-fertilizer market who wants to register bio-fertilizer products. Following all the guidelines given and providing all the required information will speed up the registration process.

Appropriate registration process of bio-fertilizers will enable a better marketplace monitoring to ensure that only products with adequate seal of approval provided by Plant Protection and Regulatory Services Directorate (PPRSD) are legally sold in Ghana. The guidelines enlist details of registration procedures including administrative, safety, quality, efficacy, and labelling requirements.

These guidelines form part of fertilizer regulatory framework which are guided by the Plants and Fertilizer Act, 2010 (Act 803) and the Plants Fertilizer Regulations 2012 (L.I 2193). If it is discovered that standards have to be modified based on emerging concerns, the registration guidelines would be amended accordingly.

1.1 Importance of Bio-fertilizer Registration

A bio-fertilizer is a substance containing living microorganisms which colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of primary nutrient(s) and/or growth stimulus to the target crop, when applied to seed, plant surfaces, or soil.

Bio-fertilizers, as microbial products, act as nutrient suppliers and/or soil conditioners that lower agricultural burden and conserve the environment. Good soil condition is imperative to increased crop production, as well as human and/or animal health welfare. However, materials such as bio-fertilizers which contain soil microbes, although used to sustain good soil condition, are treated as environmental issues. And as such, the circulation of such products for research or commercial purposes can be allowed after it has been proved to be safe, efficacious, and effective in consistent with label claims, and must be registered or certified for use in the country.

1.2 Purpose of This Registration Guideline

The purpose of this registration guideline is to stipulate the procedures for regulating bio-fertilizers and also provide a general framework for the registration of bio-fertilizers in Ghana. This will ensure that the Ghanaian environment and its population are protected against the potential dangers associated with bio-fertilizer commercialization and use. It will also safeguard the interest of fertilizer enterprises and the end users.

1.3 Objectives of Bio-fertilizer Registration

The objectives of bio-fertilizer registration are as follows:

- To ensure that only registered bio-fertilizers are placed on the market and made available for use by farmers.
- To ensure that only bio-fertilizers that are demonstrated to be safe and effective for intended use may be registered.
- To ensure that registered bio-fertilizers are used correctly and safely.
- To ensure that registration of a bio-fertilizer are re-evaluated if new data becomes available following registration.
- Generate a register of approved Bio-fertilizer products.
- To facilitate national, inter-regional and international trade in bio-fertilizers.
- To facilitate post-registration monitoring/surveillance of bio-fertilizers.

1.4 Scope of Bio-fertilizer Registration

These guidelines are limited to only bio-fertilizers which include:

- products containing micro-organisms to which plant growth activity is attributed and
- products containing microorganisms and any associated metabolite which aid plant growth, soil health or improves soil fertility.

1.4.1 Bio-fertilizers from Genetically Modified Organisms (GMOs)

The default position adopted in this guideline document is that there is a separate regulatory mechanism for approving the production, importation and use of GMOs in Ghana. The Biosafety Act, 2011 (Act 831) makes regulatory provisions for GMOs, therefore GMOs are

out of the scope of this guideline document.

1.5 Identity and Ownership of Bio-fertilizers being Registered

1.5. 1 Identity

A registrant should know the identity of the product. Identity of any bio-fertilizer is determined by its composition. The registrant shall provide the following identity information on the product to be registered:

- Details (Scientific name, taxonomic grouping) and population of active ingredients/active agents
- Details on type of carrier
- Details on contaminant(s)
- And any other details as determined by regulators usually on a case-by-case basis according to the nature of the bio-fertilizer proposed for registration.

1.5.2 Ownership

The owner will be the manufacturer/supplier of the product. The applicant will be the local representative who is registered to do business in Ghana. The applicant is responsible for the commercialization of the product when it is registered.

1.6 Confidential Data

Any information submitted to PPRSD for product registration is classified as confidential. However, the separate submission of data (by secure means electronically or in sealed envelope) should be accompanied by a *Disclosure Declaratio*n.

2.0 BIO-FERTILIZER REGISTRATION PROCEDURE

In order to import or sell bio-fertilizers, registration is required. An applicant must submit an application letter to the Honorable Minister of Food and Agriculture, and completed application forms (Annexes 1 and 2) for registration to PPRSD for processing, and if approved the product is registered.

2.1 Types of Registration

There are five types of registration that can be made; they include:

- Product Registration; entails the registration of bio-fertilizer products to be manufactured or imported.
- Company Registration
- Manufacturing Registration
- Distributor Registration
- Retail Registration

After initial registration is done, applicant is permitted to advertise and sell bio-fertilizers within the stipulated period of time (as indicated on the certificate of registration). Renewal of registration may be granted for the various registration types. The PPRSD reserves the right to revoke, suspend or modify registration on its own initiative subject to emergence of post-registration data.

2.2 Pre-submission consultation

In order to facilitate the registration of bio-fertilizers, intending registrants should request for a Pre-Submission Consultation with the PPRSD prior to making a full and formal application, to enhance familiarization with the registration procedures. The consultation will allow the registrants to understand the registration process as well as the safety, labelling, and efficacy requirements.

During this meeting, the following administrative requirements shall be discussed:

- Application letter to be sent to Honourable Minister of Food and Agriculture declaring intension to register your company (as a manufacturer or Importer) and the bio-fertilizer product(s).

- Application forms with checklist.
- Certificate of Incorporation and Certificate to Commence Business in Ghana for the local representative or importer.
- Product Dossier.
- Draft label of the product.
- Proof of ownership of the bio-fertilizer to be registered.
- Submission of sample for laboratory analysis and field trials.
- Approved fees to be charged.

2.3 Submission of Application Letter

An application letter for product and company registration shall be written and addressed to the Honourable Minister of Food and Agriculture indicating the intention of the application (Manufacturing or importing). If the product has already been registered elsewhere the registrant shall submit evidence of registration in other countries. In the case of a renewal of registration, the previous registration number given shall be provided.

2.4 Completion of Application Forms

The registrant will be required to complete application forms as detailed in Annexes 1 and 2. Information required shall include:

- Date of submission of application form
- Type of bio-fertilizer
- Product formulation including constituent materials
- Source of the material
- Well-documented physical-chemical-biological properties,
- Applicant and his/her contact information including the address and location
- Restrictions and cautions
- Signature of the registrant
- Name and Signature of PPRSD officer receiving application

- Name of manufacturer of active ingredient.

A checklist at the back of the application form will ensure that registrants provide all the necessary details for registration.

2.5 Product Dossier

The applicant is responsible for the content of the dossier. The dossier must contain the technical information on the bio-fertilizer, and this would include:

- Information on the strain(s) including the source, identification and taxonomy.
- Product composition
- Information on the carrier material and pre-treatment
- Product formulation
- Quality Assurance and Quality Control Procedures
- Product use (dosage, direction for use)
- Mode of action
- Packaging specification
- Manufacturing Process
- Efficacy trial report
- Material Safety Data Sheet (MSDS) of the product and ingredients
- Tentative Product Label

2.5.1 Safety requirements

A package of safety information should be prepared in addition to the supporting document, a rationale not exceeding 5 pages to substantiate the safety of the product should be provided. Basically, the product proponent should demonstrate that the micro-organism(s) in the product formulation is/are present at a level expected to be safe to human, animal, plants, and the environment. Also, the safety of the formulation when all the ingredients are mixed together should be demonstrated. The level of non-guaranteed micro-organisms should not be higher than the tolerance level prescribed in the applicable SOP for the specific bio-fertilizer. Pesticide and

Fertilizer Regulatory Division (PFRD) approved SOPs shall be used for quality control of bio-fertilizers sold in Ghana.

The requirements to establish the safety of bio-fertilizer include, but are not limited to, the following;

1. Summary (5 pages maximum) of the technical dossier related to the safety of the product (i.e. bio-safety assurance statement on pathogenicity, gene flow, invasiveness, persistence, effect on non-target organisms, among others)
2. Evidence (i.e. data and/or biographical references) supporting the safety of the bio-fertilizer.
3. Information on the carrier material (when applicable).
4. Manufacturing process.
5. Quality assurance (QA) and quality control (QC) procedures of the manufacturing plant (i.e. company self-evaluation on quality)
6. Information on the strain(s) including the source, identification and taxonomy.
7. Declaration that the bio-fertilizer does not contain GMO ingredients.
8. Material safety data sheet (MSDS) of the bio-fertilizer and ingredients (when available).
9. Any additional information and supporting documents or items deemed necessary by the applicant or PPRSD.

2.6 Product label

The registrant shall provide a tentative product label that meets the requirements in this guideline (Annex 5). The various sections of the product label shall be reviewed and approved before commercial use. The commercial label will have to include a registration number granted by the PPRSD as a seal of approval.

2.6.1 Requirements for Labeling and Packaging

Labels must not have any incorrect or misleading information or mark or brand or name that would tend to deceive or mislead a purchaser with respect to the composition or utility of the

product. The approved and registered product label must match the label being used in the marketplace.

The main panel (principal display panel) of the label must display at least the product name, active ingredient, product weight and the name and address of the registrant or the manufacturer. The label should also as specified by the regulations have a complete address of manufacturer or local agent. If an address stated on the label refers to the place of manufacture of the container, this must be clearly indicated (e.g., bags manufactured by). If the product is packaged outside Ghana, and contains the country's address on the label, and is imported for resale in Ghana, the words "imported by" or "imported for" must precede the country's address, unless the geographic origin of the pre-packaged product is also stated on the label.

All information on the label must be printed conspicuously, legibly and indelibly. All information must be printed in a font size that would be legible.

2.6.2 Specific requirements for labelling

The registrant shall provide the following label information on the product to be registered:

1. Product /brand name
2. Microbial active agent(s)
3. Direction for use (application rate, application frequency, rate frequency)
4. Registration number
5. Expiry date
6. Date of manufacture
7. Company information (manufacturer and local representative/agent, address and physical location)
8. Net weight (SI units)
9. Guarantee / label claim
10. Lot number
11. Cautionary statement
12. Planting window
13. Website (optional)

14. Storage conditions
15. Handling conditions
16. Disposal instructions (for product and containers)

2.7 Outcome of submission

The PPRSD shall inform the registrant of the outcome of the application after assessments and evaluation of data.

Normally, a response will come as follows:

(i) Registration granted with a certificate of registration and a PFRD Registration Number; the certificate will bear conditions of registration to be complied with, including any mandatory modifications to the intended use, label indications, etc. The certificate will also bear the use category (general use, restricted, severely restricted)

(ii) Registration refused, in which case the PPRSD shall provide reasons for refusal.

(iii)A request for re-run of laboratory analysis when the test result(s) is/are not satisfactory.

(iv)Request for field trial to analyse the effect of the product on crops and the environment.

If the registrant is not satisfied with either the conditions of registration or with a refusal to register the product, the registrant may make a complaint to PPRSD. If the outcome is not satisfactory to the registrant, he can appeal to Honourable Minister for Food and Agriculture, and perhaps ultimately to the courts, as has been provided for in the Plants and Fertilizer Act, 2010 (Act 803)

2.8 Registration fees

Registration fees are charged as per provisions in the Fees and Charges Legislative Instrument for the under listed items. These are reviewed annually;

a) Company Registration
b) Manufacturing Registration
c) Fertilizer Product Registration
d) Distributor Registration
e) Retail Registration

f) Application Forms

Fees for registration shall be paid to PPRSD. Fees for laboratory and field testing shall be paid through PPRSD to the approved institution.

2.9 Certificate of Registration

Certificates of registration for the product and company shall be awarded to the registrant after approval has been given by the PPRSD (Annex 3 and 4). Information on certificate shall include:

Company's name

Official address and location

Name of the bio-fertilizer

Registration number

Date of registration

Expiry date of registration

PFRD's seal (seal of approval)

Full name and signature of the director PPRSD and the Fertilizer Administrator.

2.10 Responsibilities of the Registrant after Registration

The responsibilities of the registrant are stipulated in the registration certificate or as separate conditions for registration. The activities that a registrant would be responsible for include product stewardship. Registrants shall be held responsible when their product in the marketplace is found to be non-compliant to the prescribed standards after registration.

Revocation of registration: A situation may arise where PPRSD as a result of emerging data, may conclude that a given bio-fertilizer presents too great a risk to continue its use or that the bio-fertilizer no longer meets the prescribed standards. In these situations registration may be revoked, but PPRSD would inform the registrant of the reasons for such action. In this case, the

bio-fertilizer will effectively be classified as a prohibited bio-fertilizer, until the product owner ensures it complies again with the prescribed standards and qualifies for re-registration.

Renewal of registration: When the validity of a registration is running out and the registrant wishes to continue marketing the product, an application for renewal should be submitted to the Minister not later than three months before the registration expires. Certificate of renewal must be granted before advertisement or sales can be resumed. If for some reason the registration is not renewed, the product will cease to be recognised as registered, and it would be illegal to engage in any regulated activities connected with it, including formulation, transport and distribution, sale and use. The product owner can decide to modify the product composition and use before it is renewed. The data requirements for renewal of registration are indicated in the application form.

2.12 Register of Bio-fertilizers

The Register of bio-fertilizers shall be kept on paper or electronic form at the Pesticide and Fertilizer Regulatory Division (PFRD) of the PPRSD. The renewal of the registration shall not affect the registration number; a registered bio-fertilizer shall keep the same registration number during the entire lifetime in the Ghanaian market.

2.13 **Post-registration Surveillance**

PPRSD shall conduct post-registration market surveillance to ensure that the quality standards are maintaind throughout the marketing chain of the bio-fertilizers based on the prescribed specification.

2.14 **Product Sampling requirements**

Standard operating procedures (SOPs) for sampling are meant to ensure consistency of product sampling including acquisition of representative samples. The following outlines the recommended SOPs for sampling that shall be implemented by the PPRSD to ensure adequate marketplace monitoring or surveillance of product registration to its lifetime in the marketplace.

2.14.1 **General requirements for product sampling**

1. Sampling must be carried out by an fertilizer inspector/authorized officer.
2. Precautions and directions must be observed when drawing, preparing, and handling samples intended for quality control.
3. To ensure that representative samples are taken, sampling must be carried out by an authorized fertilizer inspector.
4. For packaged products, unopened packets should be sampled and sent to the laboratory using appropriate equipment and procedure to prevent possible contamination of samples during handling.
5. Samples must be taken in the presence of the product proponent and/or his/her authorized representative.
6. Collected samples should not show any visible sign of potential contamination or exposure to a well-established contaminant.
7. For quality control (ascertaining the conformity), samples should be tested from each lot separately to determine whether a material meets the regulatory requirements with respect to prescribed standards or specifications.

2.14.2 **Drawing samples**

a) The number of sample-packets to be taken from a lot will depend on the size of the lot. The samples should be randomly selected using a well-established randomization tool or software when applicable. The sample will be considered a legal sample since the result will be used as a proof of the product compliance to the regulatory requirements.

b) The authorized inspector or any other authorized staff shall take three (3) sample-packets from the same lot. The sample should be taken in the presence of the product proponent or his/her authorized representative; the latter should sign on the sampling form of the inspector. When analysing samples, each packet should be taken separately.

c) The authorized inspector or any other authorized staff should carry with him/her appropriate sampling forms on which to document information about the sample and the sampling procedures (i.e. samples must be kept at recommended temperatures). Hence, each sample should be sealed in cloth bags or any approved containers. The

completed sampling form shall be placed in the container and the seal of the authorized inspector appended.

d) When the product proponent or her/his authorized representative wants to send samples to independent laboratory for potential cross-validation of the results; the authorized inspector or the authorized staff should randomly select three (3) additional sample-packets for each independent laboratory. The samples should be handled as described above.

e) When the total number of lots is lower than or equal to 5, each of them will be sampled; when it is higher than 5, 5 randomly selected lots will be sampled. The minimum number of samples per lot shall be as shown in table 1 below:

Table 1 Number of randomly selected samples to be drawn from a lot

Packets per lot	**Number of samples**
≤5,000	03
>5,000 - ≤10,000	04
> 10,000	05

2.15 **Requirements for Quality**

Quality of bio-fertilizers is one of the most important factors that can result in product success or failure. Quality of a product can lead to its acceptance or rejection by the end-users. Quality is about specifications for physical and chemical properties in quantitative terms for maintaining quality. This includes moisture content, particle size and the permissible limits of contaminants as well as specifications for quality checks of fertilizer samples. Description of quality may contain parameters like the microbial density at the time of manufacture, microbial density at the time of expiry, the expiry period, the permissible contamination, the pH, the moisture, the microbial strain, and the carrier. Quality has to be controlled at various stages of production (during mother culture stage, carrier selection, broth culture stage, mixing of broth and culture, packaging and storage). Quality requirement for the registration of bio-fertilizers in Ghana are as provided in the PFRD's SOPs.

3.0 Bio-fertilizer Efficacy Trials

The purpose of the trials is to determine the efficacy of the product prior to registration. The registrant will submit product dossier and safety information to PPRSD for this purpose.

An efficacy report on the product by an institution or organization in any other country may be attached to the dossier if available. The efficacy report should include quality data (i.e. guarantee analysis, level of biological contaminant(s) at a specified dilution level), and performance data.

3.1 **Product Efficacy Trials**

PPRSD shall engage the relevant research institution(s) to carry out the trial on its behalf, while doing the necessary monitoring. It is recommended that efficacy trials be conducted using Good Experimental Practices.

The Good Experimental Practices requirements include, but are not limited to:

- a thorough description of trial site where the experiment will be conducted
- a plan of the trial sites and surrounding areas
- description of trial conditions of the plot and crop
- conditions supporting the validity of chosen trial sites
- all trials should be conducted using the specific formulation and methods of application (i.e. use pattern) which are to appear on the product label
- alternative formulations/methods used at the trial site
- complete address and geographical coordinates of trial locations
- appropriate number of trials, using the application rates to appear on the product label in order to adequately demonstrate product efficacy
- quality trial management practices to be implemented
- proper trial planning, execution, assessment, record-keeping, and interpretation of data
- qualifications of staff conducting and/or analysing the trials
- the use of proper equipment, facilities, protocols, methods of application and data recording
- internal procedures that provide verification of the proper use of GEP

3.2 **Location of Efficacy Trials and Site Selection**

Efficacy trials shall be conducted in at least three (3) Agro Ecological Zones (AEZs). The choice of the agro-ecological zones should be based on the agricultural production regions for the intended crop(s). PPRSD will select a research institution that will determine the location for the trials.

3.3 **Minimum Number of Trials**

The minimum number of trials required to support product efficacy will vary depending for instance on the intended usage pattern, intended crops, and label claims. For example, a product intended for soil application, to be used on a single crop with the claim of increased yield would generally require a low number of trials. However, when the same product is also intended for foliar application (on the same product label), and for several crops, and claims yield increases and improved root biomass, the minimum number of trials may significantly increase.

When a product is recommended for crops grown in more than two AEZs, the minimum number of trials is set to 6. However when a product is intended for a crop grown in a single AEZ, the minimum number of trials could be reduced to half (i.e. 3trials). When more than one trial is recommended in the same AEZ, the site selection should show a spatial variability within the AEZ.

3.4 **Minimum Number of Trials for Spatial and Temporal Distribution**

The minimum number of growing seasons for efficacy trials shall be two. In general, the minimum number of trials should be conducted in more than one growing season (temporal variability) and in different locations within each agro ecological zone (spatial variability).

However when the proponent wants to expedite farmer access to a new technology that may have proven profitable elsewhere, PPRSD may grant a waiver for the temporal variability, but would require an improvement in the spatial variability. Under such a condition, the “accelerated

trials" method will be employed, where the minimum number of trials would be increased from six (6) to nine (9).

3.5 **Representative Crops**

When several crops are considered for the same bio-fertilizer the minimum number of trials may increase drastically to the extent that it is no longer affordable or scientifically relevant given the potential similarity across crops. In the case where the similarities between crops are supported by scientific evidence in terms of physiology and production patterns, the crops could be grouped together based on similarities and the efficacy testing conducted using a representative crop from each group.

3.6 **Mutual Recognition**

When data conducted elsewhere are found to be relevant in another country based on the similarity of the AEZ conditions, PPRSD may recommend a reduced number of trials to confirm the efficacy of the product in the local conditions. Generally, the required minimum number of trials would be reduced to a half and the temporal variability automatically waived. This mutual recognition would be granted based on the merit of the rationale and evidence provided to support the similarity of the agro-climatic conditions and also based on the existence of precedence.

3.7 **Measurable Parameters**

During assessment of product efficacy, considerations should be made prior to, after treatment and after harvest as follows.

3.7.1 **Prior to treatment**

To ensure that product efficacy is evaluated under appropriate conditions, the initial soil fertility level should be evaluated prior to the establishment of the trials. Soil analysis conducted prior to the treatment should include (but not limited to): soil texture, pH, cation-exchange capacity, organic carbon, availability of selected plant nutrient and functional microorganisms in the case of microbiological products.

3.7.2 **After treatment**

After the application of the bio-fertilizer, minimum weather data including the ambient temperature, humidity and rainfall should be collected. In addition to the initial soil testing, information on weather conditions could also be used to explain any spatial or temporal variability. Other measureable parameters would be based on the label claims.

3.7.3 **After harvest**

Considerations should be given to tissue analysis for nutrient uptake (i.e. major, secondary and micro- nutrients depending on the product of interest), crop yields (grain yield, haulms, husks, etc), quality of the crop yields when applicable (based on label claim) and functional microorganisms.

3.8 **Data Analysis**

The data should be statistically analyzed including descriptive statistics and analysis of variance (ANOVA) using accepted software (e.g., SAS). The method of statistical analysis should be considered prior to conducting the trial. The level of significance and the mean separation techniques should be the ones that are commonly used in the field of interest (e.g. 5% and the least significant difference i.e. LSD). Anecdotal or testimonial evidence should not be considered as a scientifically valid form of efficacy data, and therefore should not be accepted to support product approval or registration; however, such evidence could be used as background information. Hence, all label claims must be adequately supported by scientific data that has been statistically analyzed and demonstrates a statistically significant benefit. The statistical analysis should be consistent across AEZ for the same product and treatments.

3.8.1 **Profitability analysis**

Economic evaluation of crop responses to bio-fertilizer product is important to assess their profitability, particularly in the context of smallholder farmers. The benefit cost ratio (BCR) is one of the tools used to conduct such an evaluation particularly when yield is considered. BCR is the ratio of the net value of extra crop produced to the cost of the product. In actual practices, a

BCR of 2.5 and above is considered to be satisfactory for the adoption of the technology. Taking into consideration other costs, including credits and risk taken, the higher the BCR the better. Thus the average BCR must be ≥ 1.5 for product approval or registration. Such a BCR must be shown for at least 60 % of the trials.

$$BCR = \frac{\text{Value of additional crop produced} - \text{Cost of COMPRO}}{\text{Cost of COMPRO}}$$

3.8.2 **Requirements for Establishing Efficacy**

Efficacy establishment requirements for the registration of bio-fertilizers in Ghana are as follows:

- Good experimental practices
- Location of field trials based on production regions
- Experimental design (done by approved facilities)
- No. of Trials: at least for two seasons in at least three agro-ecological zones; five locations within each agro-ecological zone.
- Planting window (preferably field trials conducted at end of planting window), in accordance with the label claim (batch and date of manufacture) provided by the producer (verifiable).
- Laboratory data as required by PFRD of PPRSD.
-

REFERENCES

AATF [African Agricultural Technology Foundation].2013. A Guide to the Development of Regulatory Frameworks for Biopesticides in Sub-SaharanAfrica. Nairobi: African Agricultural Technology Foundation

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Bhattacharyya, P. and Tandon, H.L.S. (2012). Bio-fertilizer Handbook – research – production – application. Fertilizer Development and Consultation Organization 204-204A Bhanot Corner, Pamposh Enclave, New Dehli 110048 (India)

CFIA (1997). T-4-114 - Sampling Procedures for Fertilizers. Canadian Food Inspection Agency.

CFIA (2010). Guide to the Canadian Federal Regulatory Requirements for Fertilizers and Supplements. Crop Inputs Division; Plant Health and Biosecurity Directorate; Canadian Food Inspection Agency

Annex 1a: Application Form for Bio-fertilizer Registration

PESTICIDE AND FERTILIZER REGULATORY DIVISION	**FORM B**

APPLICATION FORM FOR FERTILIZER PRODUCT REGISTRATION

(A COMPLETED **FORM A** MUST ACCOMPANY THIS FORM)

PLEASE USE CHECKLIST ON BACK TO ENSURE A COMPLETE APPLICATION		
COMPANY NAME	PFRD ISSUED COMPANY NUMBER	DATE
PFRD FERTILIZER PRODUCT REGISTRATION NUMBER		
PRODUCTS TO BE REGISTERED		

FOR DEPARTMENTAL USE ONLY

PRODUCT REGISTRATION FEE

Number of products at GH ₵ 3,000.00 each: _____ products × GH₵ 3,000.00 = GH₵ _____.00

(Fee covers initial two year registration cycle)

Make cheque payable to: The Director, Plant Protection and Regulatory Services

Directorate.

TOTAL FEES: GH₵ _____.00

*Cheques returned by the bank will be charged the appropriate handling fee.

Processing of this Form will not be completed without field trial results proving the effectiveness or otherwise of the product.

Fertilizer Product Registration Checklist

FERTILIZER PRODUCT REGISTRATION INSTRUCTIONS FOR FORM B AND FORM B2

A completed **FORM A** is required for registration. An incomplete form may result in the rejection of your application. Complete Product Information and Declared Quality Parameters Form (Form B2) depending on number of products to be registered.

COMPANY INFORMATION

- Company Name: Enter the name of the company as it appears on the Form A.
- PFRD Company Number – the company number is assigned by PFRD. If you are applying for the first time, leave this box blank. If you already have products registered and are adding additional products, please place your assigned company number in the box. You can find your company number on your current registration certificate.
- Date: Enter the date you prepared the registration form.

- DEPARTMENT USE ONLY: Please do not write in this area.

- **PRODUCT REGISTRATION FEES:**

  The registration fees can be found in the Fees and Charges Legislative Instrument and is subject to annual review.

Fees for registration shall be paid to PPRSD. Fees for laboratory and field testing shall be paid through the PPRSD to the approved institution.

Current Registration fee is GH¢ 3,000.00 per product for initial two years, thereafter renewable every two years.
Attach a cheque payable to the Director, Plant Protection and Regulatory Services Directorate.

- PRODUCT INFORMATION: (FORM B2)
  - Product Name: Enter the complete name found on the product label.
  - Mode of Application and Maximum Rate of Application: Complete this section using the highest rate and maximum number of applications allowed during a growing season.
  - Product label: Attach copy of the product label as prescribed in the Guidelines for Registration of Bio-fertilizers in Ghana.
- DECLARED QUALITY PARAMETERS: (FORM B2)
  - Enter a value for each quality parameter on the product label. The value must match the value on the label. Do not list values for quality parameters not guaranteed on the label.

Annex 1b: Attachment to annex 1a

PESTICIDE AND FERTILIZER REGULATORY DIVISION	FORM B2

BIO-FERTILIZERS

PRODUCT INFORMATION				
PRODUCT NAME				
MODE OF APPLICATION: **MAXIMUM APPLICATION RATE:**				
MICROBIAL ACTIVE AGENT(S):				
DECLARED QUALITY PARAMETERS				
Carrier Base			**Infectivity potential / Efficiency character**	
Viable Cell Count			**Contamination level**	
Ph			**Moisture Percent by Weight**	
Particle Size			**Total viable propagules / gm of product**	
DEPARTMENTAL USE ONLY				
LABORATORY ANALYSIS				
Carrier Base			**Infectivity potential / Efficiency character**	

Viable Cell Count			**Contamination level**	
Ph			**Moisture Percent by Weight**	
Particle Size			**Total viable propagules / gm of product**	

Annex 2: Company Registration Form

PESTICIDE AND FERTILIZER REGULATORY DIVISION FORM A

APPLICATION FORM FOR COMPANY REGISTRATION

PLEASE USE CHECKLIST ON BACK TO ENSURE A COMPLETE APPLICATION

INDICATE THE ACTIVITY FOR WHICH YOU ARE APPLYING TO BE REGISTERED (PLEASE TICK)

☐ Manufacturing/Blending ☐ Importing

BACKGROUND INFORMATION

FULL LEGAL NAME OF APPLICANT, COMPANY OR BUSINESS
APPLICATION DATE
POSTAL ADDRESS

PHYSICAL LOCATION OF BUSINESS	
EVIDENCE OF REGISTRATION OF BUSINESS(YES/NO) ATTACH REGISTRATION CERTIFICATE IF ANY	
TELEPHONE NUMBER	
FAX	
E-MAIL	WEB SITE ADDRESS

COMPANY REGISTRATION FEE

MANUFACTURING/BLENDING - **GH₵ 2,500.00**

IMPORTING - **GH₵ 1,000.00**

FOR DEPARTMENTAL USE ONLY

DATE OF RECEIPT OF APPLICATION: PFRD ISSUED

COMPANY NUMBER:

Cheque Amount (GH₵)	Cheque Number	Date Issued	Date Received	Receipt Number (GCR#)

REMARKS:

……..

…… ……

NAME OF OFFICER RECEIVING THE APPLICATION DESIGNATION

SIGNATURE

Fertilizer Company Registration Checklist

Submit originals to PFRD and keep copies for your file.

Your company will receive a PFRD Fertilizer Registration Certificate as confirmation of your company registration.

- Form A, "Application form for Company Registration" includes company name and address.

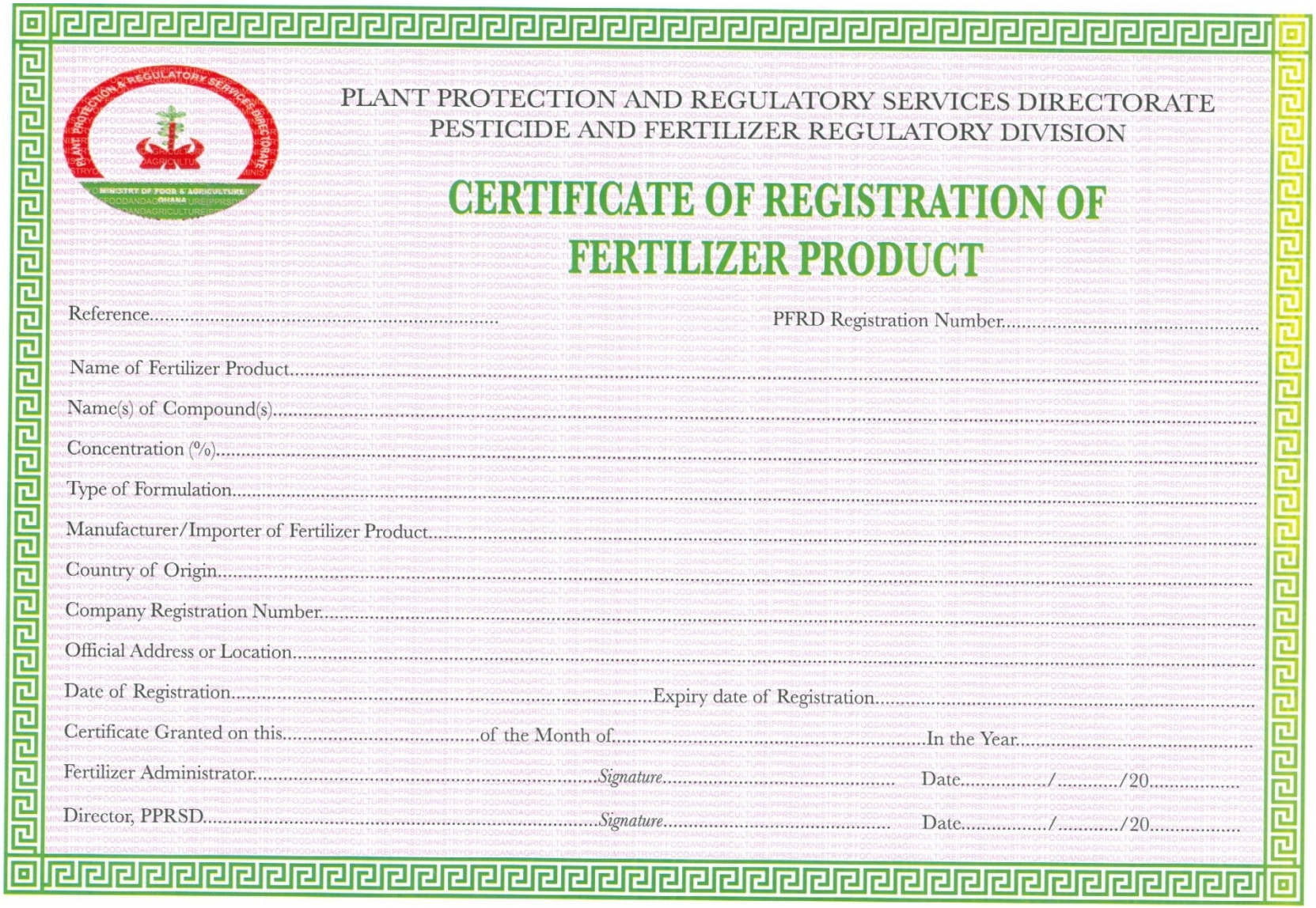
- Attach Business Registration Certificate.

- Company Registration Fee:

The registration fees can be found in the Fees and Charges Legislative Instrument and is subject to annual review.

- Current Registration fee of GH¢ 2,500.00 in case of manufacturers for initial five years renewable after every two years.
- Current Registration fee of GH¢1,000.00 in case of importers for initial two years, renewable every two years.
- Attach a cheque payable to the Director, Plant Protection and Regulatory Services Directorate.
-

Annex 3: Certificate of Registration of Bio-fertilizer Product



PLANT PROTECTION AND REGULATORY SERVICES DIRECTORATE
PESTICIDE AND FERTILIZER REGULATORY DIVISION

CERTIFICATE OF REGISTRATION OF FERTILIZER PRODUCT

Reference..... PFRD Registration Number.....

Name of Fertilizer Product.....

Name(s) of Compound(s).....

Concentration (%).....

Type of Formulation.....

Manufacturer/Importer of Fertilizer Product.....

Country of Origin.....

Company Registration Number.....

Official Address or Location.....

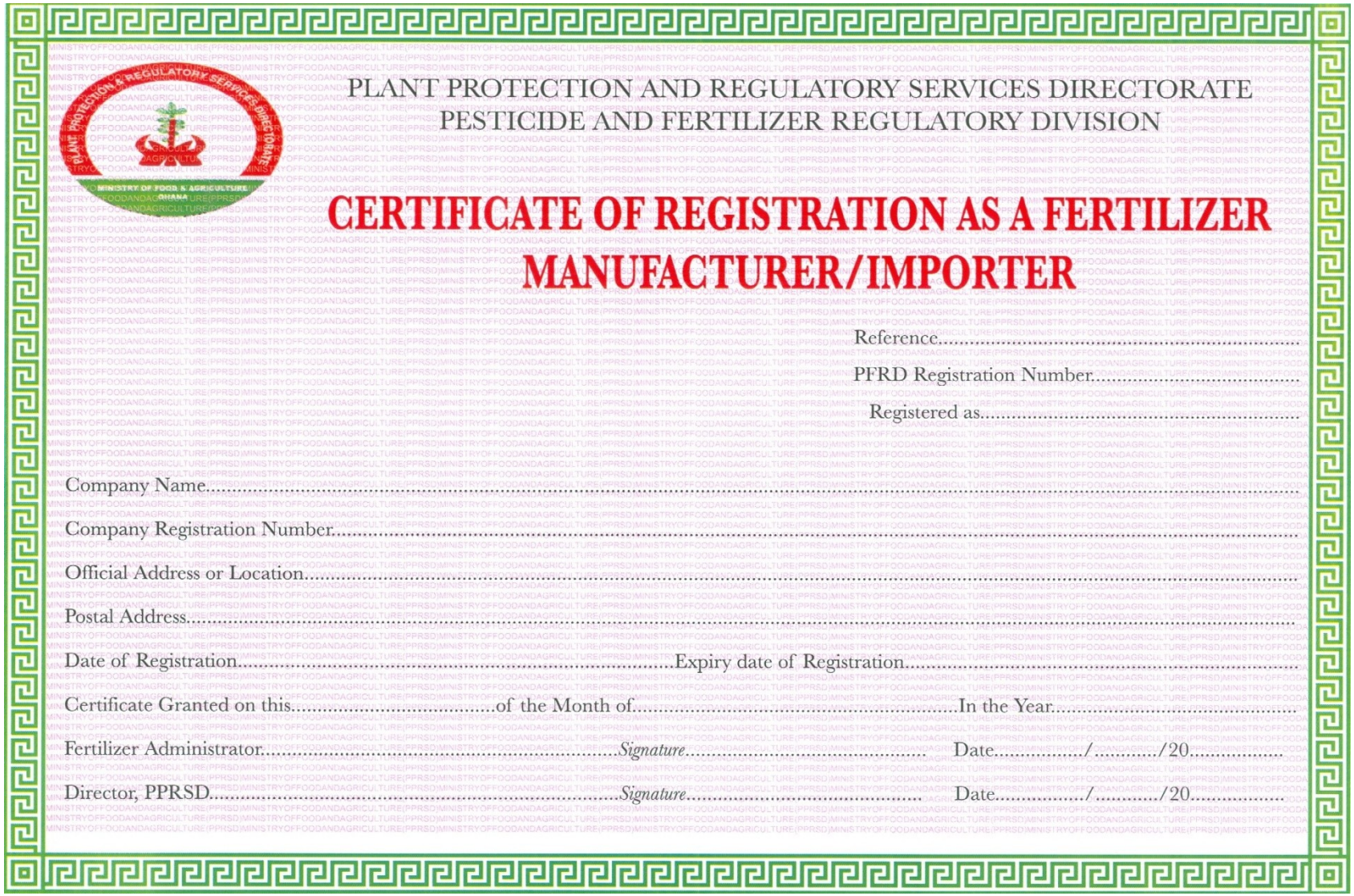
Date of Registration.....Expiry date of Registration.....

Certificate Granted on this.....of the Month of.....In the Year.....

Fertilizer Administrator.....*Signature*..... Date...../...../20.....

Director, PPRSD.....*Signature*..... Date...../...../20.....

Annex 4: Certificate for Registration of Company



PLANT PROTECTION AND REGULATORY SERVICES DIRECTORATE
PESTICIDE AND FERTILIZER REGULATORY DIVISION

CERTIFICATE OF REGISTRATION AS A FERTILIZER MANUFACTURER/IMPORTER

Reference.....

PFRD Registration Number.....

Registered as.....

Company Name.....

Company Registration Number.....

Official Address or Location.....

Postal Address.....

Date of Registration.....Expiry date of Registration.....

Certificate Granted on this.....of the Month of.....In the Year.....

Fertilizer Administrator.....*Signature*..... Date...../...../20.....

Director, PPRSD.....*Signature*..... Date...../...../20.....

Annex 5: Model Label for a Bio-fertilizer

PRODUCT AND COMPANY DETAILS

- **Product name**
- **Brand name**
- **Microbial active agent(s) (active ingredient(s))**
- **Registration number**
- **Date of manufacture**
- **Expiry date**
- **Company information (manufacturer and local representative/agent, address, physical location, Website)**
- **Net weight**
- **Guarantee / label claim**
- **Lot number**

DIRECTION FOR USE

- **Planting window / Mode of Application**
- **Application rate**
- **Application frequency,**
- **Time of Application**
- **Units of measure (Use SI units)**

PRECAUTION AND FIRST AID

- **Cautionary statement and Symbols**
- **First Aid**
- **Storage**
- **Disposal**

Annex 3 Bio-fertilizers registration guidelines for Kenya

This annex includes the interim measures for registration of bio-fertilizers in Kenya, pending the ratification and gazetting of the soil fertility bill in Kenya, a process that has been facilitated by the Alliance for a Green Revolution in Africa

GUIDELINES FOR INTRODUCTION AND USE OF BIO-PRODUCTS, BIOLOGICAL CONTROL AGENTS AND RELATED PRODUCTS

KENYA STANDING TECHNICAL COMMITTEE ON IMPORTS AND EXPORTS

Version 2

Sections	
1.	Introduction
2.	Acronyms and Abbreviations
3.	Interpretation
4.	Scope
5.	Communication
6.	Establishment of the Kenya Standing Technical Committee on Imports and Exports (KSTCIE)
7.	Role of Secretariat
8.	Role of Expert Reviewers
9.	Role of the Applicant
10.	Handling of Applications
11.	Registration of approved products and articles
12.	Non-Compliant Products and Articles
13.	Parallel Registration
14.	Label Extension
15.	Import of products and articles-
16.	Export and re-export of products and articles
17.	Commercialization
18.	Release of Biological Control Agents (BCAs)
19.	Prohibited BCAs

Introduction

In the recent past, there has been an increase in the use of biological products and articles including biological control agents, bio-fertilizers and organic fertilizers which are currently being offered for sale without adequate regulatory framework. Their applications and approval have been handled by the Kenya Standing Technical Committee on Imports and Exports (KSTCIE) without a legal backing, making it very difficult to enforce compliance.

They are intended to fill this gap by providing a mechanism for regulating biological control agents and beneficial organisms, bio-fertilizers and organic fertilizers, soil amelioration and amendment products, biostimulants and plant growth regulators thereby facilitating safe introduction of biological materials into the country. They also cover manures, compost, wood ash, refuse and organic fertilizers but do not cover raw; manures, compost, wood ash, municipal refuse and organic fertilizers obtained locally for own use.

This guideline will endeavor to ensure that circulation of such products for research, commercial or any other purposes has been authorized and that they are safe and effective as per label claims.

It is anticipated that these guidelines will be useful tool in national procedures for the regulation of biological products in Kenya and will provide better approaches to assessing the risks associated with biological products. Its review will be done when need arises and in cases of any new legislations.

Acronyms and Abbreviations

CBI	Confidential Business Information
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
KSTCIE	Kenya Standing Technical Committee on Imports and Exports
GMO	Genetically Modified Organisms
KEPHIS	Kenya Plant Health Inspectorate Service
MSDS	Material Safety Data Sheet
SOP	Standard Operating Procedure
QA	Quality Assurance
QC	Quality Control
LMO	Living Modified Organisms
WHO	World Health Organization
PRA	Pest Risk Analysis
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
NPPO	National Plant Protection Organization

1. Short title These regulations may be cited as the Plant Protection Act, (Regulations for introduction and use of biological control agents, beneficial organisms, bio-products, related products and regulated articles) Regulations, 2014.

2. Interpretations In these Regulations, unless the context otherwise requires-

"Beneficial organism" means any organism directly or indirectly advantageous to plants, or plant products, including biological control agents;

"**Bio product"** means a biological agricultural chemical product where the constituents comprises or is derived from biological sources, renewable sources, living organism (plant and plant residues, animal or microorganism) with or without modification. These include many products commonly referred to as botanicals, organics or herbals. They include Biological chemicals (plant hormones, plant growth regulators, bio stimulants, enzymes and vitamins), Extracts (plant and animal extracts), Wastes (plant, animal and human wastes), Microbial agents (bacteria, fungi, mycorrhiza, viruses, nematodes, protozoans) and other living organisms (arthropods, plants and animals).

"Bio fertilizer" means a preparation or substance containing living organisms which colonize or are intended to colonize the rhizosphere or the interior of the plant that helps or enhances plants to take up nutrients or solubilize or mobilize soil nutrients;

"Biological control agent" means a natural enemy, antagonist or competitor or other organism used for pest control;

"**Bio-pesticide"** means a generic term generally applied to a biological control agent, or formulation and applied in a manner similar to a chemical pesticide and normally used for the reduction of a pest population and usually derived from such natural material as animals, plants, fungi, bacteria, other microorganisms and certain minerals. They are classified as microbial and macrobial pesticides, plant incorporated protectants (pesticidal substances that are produced by plants from genetic materials added to the plants) and biochemical pesticides (naturally occurring

	substances that control pests).
"Committee"	means the Kenya Standing Technical Committee on Imports and Exports unless otherwise specified;
"**Consignment"**	means a quantity of plant, plant products and or other articles being moved from one country to another and covered when required by a single phytosanitary certificate;
"**Containment"**	means application of phytosanitary measures in and around an infested area to prevent spread of a pest;
"Export/Import"	means intentional transboundary movement from one country to another country;
"Extracts"	means a natural product derived from plant, animal or other organisms by use of a solvent or other means
"Genetically or living modified organism"	means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
"**Inspector**"	means a person authorized by a National Plant Protection Organization to discharge its functions;
"Local agent"	means a person who is registered and legally operating in Kenya;
"**Monitoring**"	means an official ongoing process to verify phytosanitary situations;
"**Microbial and Macrobial biopesticide**"	means a pest control product of naturally occurring microorganism (microbiological agents: viruses and rickettsia, bacteria, protozoa, fungi) and macro organisms (macro biological agents such as predators, parasitoids and entomopathogenic nematodes) respectively intended for the control of invertebrate pests, weeds, pathogens of crops and pests of livestock and public health concern, and to which effects of the pest control products or active agent are attributed but does not include a component that by itself is not primarily responsible for the control effect of the pest control product or genetically modified living microorganisms and macro organisms;
"National Plant Protection	means official service established by a government to discharge the functions specified by the International Plant Protection

Organization"	Convention;
"Natural enemy"	means an organism which lives at the expense of another organism in its area of origin and which may help to limit the population of that organism. This includes parasitoids, parasites, predators, phytophagous organisms and pathogens;
"Organism"	means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids
"Parallel registration"	means registration of a trade name based on the strength of an existing fully registered product from the same manufacturer and source and with authorization from the person holding the registration;
"Parasitoid"	means an insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult;
"**Pest**"	means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products
"Phytosanitary measure"	means any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non- quarantine pests;
"Quarantine"	means official confinement of regulated articles for observation and research or for further inspection, testing or treatment;
"Quarantine pest"	means a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled;
"**Regulated article**"	means any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved
"Release (into the environment)"	means intentional liberation of an organism into the environment;
"Risk assessment"	means the qualitative identification, evaluation and estimation of the levels of risk involved in a situation, their comparison against benchmarks or standards, and determination of an acceptable level of risk

"Screening for completeness" means ensuring that all mandatory fields in the application form have been filled. Where information is not available the non-mandatory fields shall be indicated as such.

3. Scope

(1) These regulations cover bio-fertilizers, biological control agents, beneficial organisms, manures, compost, wood ash, refuse, soil amelioration and amendment products, plant growth regulators, biostimulants, and organic fertilizers.

(2) These regulations does not cover raw; manures, compost, wood ash, municipal refuse and organic fertilizers obtained locally for own use

(4) These regulations do not cover inorganic fertilizers and chemical pesticides, bone ash and bone meal that are covered under an existing law.

(5) These regulations cover the development of import conditions for plants, plant products and regulated articles.

(6) These regulations may impose restrictions where significant risks to human, animal, health and environment is identified if the material is moved within the country.

4. Communication

The Committee shall sensitize the public on the requirements of this regulation.

5. Establishment of the Kenya Standing Technical Committee on Imports and Exports (KSTCIE)

There is established a specialized committee for the purpose of better carrying out the function of regulating the products and items in this regulation.

The membership of the committee shall consist of:

(a) A Chairperson appointed by the Cabinet Secretary;

(b) Representative, State Department of Agriculture;

(c) Representative of Director, Kenya Plant Health Inspectorate Service;

(d) Representative of Director, Kenya Agricultural and Livestock Research Organisation;

(e) Representative of Director, Pest Control Products Board;

(f) Representative of Director, Department of Veterinary Services;
(g) Representative of Director, National Environment Management Authority;
(h) Representative of Director, National Museums of Kenya;
(i) Representative from relevant institution of higher learning;
(j) Two representatives of relevant private sector players.

(II) Member(s) under sections (b) to (i) shall be appointed by name by their respective institutions or departments taking into consideration the technical nature of the committee; an alternate member may also be appointed by name to ensure continuity.

(III) The chairperson appointed under section (a) above shall have relevant competence to these regulations; shall serve for a period of three years, renewable once.

(IV) Members under section (j) shall be nominated by the relevant private sector associations or umbrella body or institution and shall serve for a period of three years.

The Committee may co-opt any person with expert knowledge to act in an advisory capacity in any case where it appears to the committee that such knowledge is required for proper determination of an application before it.

The Committee may create as necessary subcommittees for better execution of specialized tasks.

The Committee shall perform the following functions-

i. Consider and determine applications relating to introduction of items covered by the scope of this regulation for the purpose of essential scientific research, experiment, education or commercial production;
ii. To develop and recommend systems and approaches designed to guard against the introduction of organisms that may be harmful to plant, animal, human health and environment;
iii. Determine suitability of facilities, firms or institutions and processes producing biological organisms, bio-products and matters regulated herein and generation of data for purpose of export of the plants, products or organisms.;

iv. Determine suitability and register firms or institutions having capacity to carry out performance trials. In making this determination, the Committee will;

(i) Consider availability of qualified scientists, facilities of the institution, capacity for testing, reports or protocols developed before, proposed charges for the experiments, consistent adherence to provided trial guidelines;

(ii) May refer or may delegate the cases which require clearance under other laws to the relevant arms of government for determination to inform further decision by the Committee including living modified organisms and items posing radiation risks;

v. The Committee shall establish appropriate procedures to better carry out the activities provided in these regulations. These procedures will include rules relating to operations of the Committee including participation of applicants, reviewers in the Committee and handling of confidential information. Establish a criteria for nominating expert reviewer;

vi. The Committee shall develop import conditions for plants, plant products and regulated articles;

vii. The Committee members shall sign a confidentiality agreement in the format (provided in Annex 10).

(5) The Committee shall hold a minimum of four meetings in a year, being once every three months convened by the secretariat in consultation with the chairman

(6) During the Committee meeting the date of the next meeting shall be set and made public.

(7) The Secretariat of the Committee shall be at the Kenya Plant Health Inspectorate Service, KEPHIS or its successor thereof.

6. Role of the Secretariat

The secretariat shall perform the following functions:-

(1) Receive applications on behalf of the Committee;

(2) Screen applications for completeness to ensure all information including that required for risk assessment is provided;

(3) Confirm whether cases having same strains of organism(s) or ingredients have been handled before and their recommendations;

(4) Where there is precedent confirmed in (3) above, the information will be

provided to the Committee;

(5) Distribute applications for review to at least two experts or relevant arms of government for risk assessment or for clearance;

(6) Conduct internal risk assessment of the applications;

(7) Receive comments and recommendations from review experts;

(8) Prepare summaries of the applications for discussion in the Committee meetings;

(9) Provide feedback to applicants regarding any issues pertaining to their application and communicate the decisions of the Committee;

(10) Implement the decisions of the Committee;

(11) Ensure confidentiality of the application process Including handling of applications, safe archiving, retrieval and document access control

(12) Sign a confidentiality agreement in the format (provided in Annex 10);

(13) Pay the expert reviewers upon submission of report based on rates determined by the secretariat.

(14) The Secretariat shall pay Committee members allowances commensurate with existing government rates for such committees

7. Role of Expert Reviewers

(1) Review applications submitted to them by the Secretariat using the criteria (provided in annex 9);

(2) Maintain high level of confidentiality when handling client's applications;

(3) Commit to confidentiality by signing a confidentiality agreement in the format (provided in Annex 10);

(4) Submit a written expert opinion on the subject application within ten (10) working days;

(5) Participate in Committee meetings when called upon.

8. Role of the Applicant

(1) Submit complete application(s) to the Secretariat;

(2) Duly inform Secretariat of any changes in regard to an application;

(3) Declare any information considered to be confidential business information (CBI) provided in the application;

(4) Make required payments.

(5) Participate in committee meetings when called upon. An applicant may request to be absent.

9. Handling of Applications

(1) A person shall not import, export, manufacture, formulate, distribute, stock, re-package, or store for sale any of the products or articles under these regulations without approval of the Committee;

(2) Upon submission of an application in the format shown in annex 1, the Secretariat shall acknowledge receipt;

(3) An application shall be screened for completeness within three (3) working days and the Secretariat shall communicate to the applicant to confirm whether the application is complete;

(4) Where the information in the mandatory fields in the application form has not been provided, the application shall be considered not received;

(5) A register of received applications shall be maintained at the Secretariat;

(6) Within ten (10) working days of receipt of the application, the Secretariat shall distribute applications to at least two independent expert reviewers;

(7) Within ten (10) working days the independent expert reviewer shall submit the review report in print and electronic copies to the Secretariat;

(8) After the report has been received, a decision shall be made by the Committee within four (4) months;

(9) Where the application pertains to a bio pesticide, the Committee shall provide a referral letter to the relevant government agency;

(10) Where the application pertains to all other products under these regulations, which are produced or obtained locally the applicant shall provide;

(i) Proof that the material has been obtained locally, in particular;

a) a declaration made to the Committee or any other declaration as required by any other act indicating the place and date obtained or,

b) Proof of obtaining the material from a repository such as a gene bank, credible laboratory showing the reference number, or

c) Intellectual property rights including trademarks, patents, or access permits

(ii) Confirmation of identity of the material from a credible laboratory or institution

(iii) A performance trial report where relevant or available

(iv) Details of facility where production will be carried out for purposes of inspection;

(a) For purposes of inspection the facility shall meet the requirements provided in annex 2;

(b) A facility inspection fee of Kenya shillings 5,000 shall apply, reimbursement of mileage and subsistence costs shall apply;

(c) Upon inspection a report shall be availed by the Secretariat to the Committee for purposes of facility registration;

(d) The inspection report shall be included in the summary of the risk assessment for discussion by the Committee.

(11) Upon submission of risk assessment reports, whether local or imported, and the Committee considers the material safe for introduction;

(i) The Committee shall provide the list of approved firms or institutions to undertake performance trials;

(ii) Trials shall follow the guidelines provided in annex 3;

(iii) The trials shall be conducted in two sites, and where there is consistency of the results between the sites, only a third trial in the second season would be required. Where there is no consistency in results between the two sites, then results from two sites will be required in the second season. This will take into account variations in soils and agro ecological zones;

(iv) Where a product or article is intended for use only in greenhouses, trials shall be conducted in a representative greenhouse for two crop cycles

(v) The Committee shall determine circumstances where greenhouse trials shall be sufficient or where different number of sites or seasons shall be sufficient

(vi) At least two monitoring visits to the trials sites shall be conducted;

(vii) The firms or institutions conducting the v trials will avail progress reports;

(viii) Upon successful completion of the trials, the firm or institution conducting the trial shall submit a final report to the Committee;

(ix) The Committee may revoke, suspend or modify an approval subject

to emergence of new information that affects the current approval status.

10. Registration of Approved Products and Articles

(1) Upon successful trials, products shall be approved by the Committee and assigned a unique approval number which shall appear in a registration certificate as shown in the annex 4;

(2) The registration certificate shall be issued upon payment of a fee of Kenya shillings thirty thousand only (Kshs 30,000);

(3) The unique approval number will appear on the label and the product will adhere to the existing labeling standard;

(4) Registration shall be renewable every three years based on post registration monitoring, and payment of a fee of shillings twenty thousand only (Kshs 20,000).

(5) The applicant shall submit an application form and the label for renewal

(6) A register of approved products shall be maintained by the Secretariat.

10. Non-Compliant Products and Articles

Products and articles found within the country that are not approved by the Committee shall be intercepted, destroyed or sent back to country of import or origin by an inspector at the cost of the person importing, exporting, manufacturing, formulating, distributing, stocking, re-packaging, retailing or storing.

11. Parallel Registration

Where the Committee receives an application for a product or regulated article where the source, isolate, strain or species is the same as one already registered or approved in the country;

(1) The applicant shall:

(i) Fill the application form;

(ii) Provide letter of access from the manufacturer;

(iii) Provide letter of no objection from the local agent or first applicant;

(iv) Borrow the approved label information of the original approved product and only change the trade name.

(2) The application is presented to the Committee for evaluation and

decision;

(3) If approved, the product shall be registered upon payment of Kenya shillings 30,000;

(4) Each parallel registration shall have its own registration number; however, this shall be linked to the original registered product by indicating the original registration product number on the parallel registration certificate;

(5) Voluntary cancellation of a product applies to the registered product and the parallel products;

(6) A person may cease trade in a registered product or article without necessarily canceling the registration of the parallel product by transferring access of the original application to the parallel product;

(7) If the letter of access is withdrawn by the person holding the original registration then the parallel registration is automatically revoked. The parallel registrations cannot be used to register other parallel products;

(8) Parallel registrations are exempt from local performance trials if intended use(s) is identical to that of the original registered product;

(9) If new uses are intended, then performance trials shall be undertaken as in label extensions. In case of parallel registration where label extension is required, the extension shall apply to all other parallel products and the original registered product;

(10) The Committee shall exercise discretion in determining the number of parallel products on a case-by-case basis.

12. Label Extension

(1) Where the applicant requires the product to be approved for additional use, the Committee may use risk assessment information from the first application or conduct additional risk assessment where necessary;

(2) The Committee may delegate the requirement in (1) above to any of its Committees.

(3) Once the label extension is granted the use applies to all parallel

registrations as well as the original registration;

(4) Instructions for label extensions shall originate from the local agent.

13. Import of Products and Articles

(1) Import of samples for trials or research:

(i) The Committee shall provide authority to the Secretariat for issuance of import permit as provided in annex 5;

(ii) The quantities imported for trials shall be limited to those adequate to conduct the trials as guided by the trial protocol;

(iii) Where applicable the Committee may require applicants to establish quarantine facilities for holding imported consignments in particular where beneficial organisms are to be imported for research targeting pests of economic importance;

(iv) Requirements for quarantine facilities are provided in annex 6.

(2) Import of material upon approval for commercialization or use other than for trials and research

(i) An application for import permit shall be made and issued for each consignment for a registered product;

(ii) A product guarantee such as certificate of analysis, batch analysis, certificate of conformity or any other document that confirms the quality of the expected consignment shall accompany the application or the consignment;

(iii) A sample import permit is provided in annex 5;

(iv) An export certificate issued by the competent authority in the exporting country shall accompany the consignment. The certificate shall include among other things;

a) The registration number where applicable

b) The details of the product which is not limited to name, identity, accession number, strain, and purity

c) Statement of compliance with import conditions

d) Country of origin or export

14. Export and Re-Export of Products and Articles

(1) Export or re-export of products and articles under these regulations shall comply with international import requirements for such material, requirements of importing country and any other laws including material transfer requirements;

(2) Where specific request for certification is made to the Committee for export or re-export, an export certificate shall be issued as long as the material originates from a source that is approved by the Committee. A sample of an export certificate is provided in annex 7.

15. Commercialization

(1)

mported consignments intended for distribution shall be stored in facilities that have been approved and licensed by the Committee;

(2) An application for registration as a biological products merchant shall be made using Annex 11.

(3) These facilities shall provide adequate protection and minimize exposure to unintended users;

(4) Owners of facilities shall ensure that persons involved in handling the products and articles in those facilities are trained adequately;

(5) The premises shall be inspected annually for compliance as guided by the checklist in Annex 12;

(6) There shall be different categories of premises. These categories shall pay an annual fee as follows;

(i) Manufacturer, formulator, merchants, distributor, re-packaging, warehousing and storage or a combination thereof: Kshs 5,000

(ii) Retailer Kshs 1,000

16. Release of Biological Control Agents

(1) Where after risk assessment, the Committee considers the introduction of biological control agents (BCAs) to be safe for release to the environment;

(i) The Committee will issue a written approval indicating the type of release, the target and conditions of release;

(ii) The Committee will ensure culturing for at least one

generation, where applicable, to ascertain purity of the culture and freedom from other hyper-parasites and pathogens or associated pests, notwithstanding regulation 8 (9).

(2) There shall be different type of releases as follows;

(i) Controlled release. This shall be limited to specific areas or targets and the Committee shall identify measures to delineate such areas and targets.

(ii) Uncontrolled release. This shall be release where the BCA is not specific to the target or where no specific measures are made to limit the area(s) of release, in this case;

(a) the Committee may allow BCAs to be passed directly for release provided that there is adequate experience or information of safe release elsewhere

(b) the Committee shall limit the uncontrolled releases of BCAs that have a wide host range

(3) Release of BCAs into the environment shall be notified to the public

(4) Every release shall be accompanied by an Environmental Management Plan in the format provided in annex 8, which the applicant shall comply with.

17. Prohibited BCAs The Committee will from time to time publish a list of prohibited BCAs.

18. Transition Clauses (1) All approvals and decisions previously made by the Kenya Standing Technical Committee on Import and Exports (KSTCIE) established by any other statute or order shall be deemed to be approvals under the Committee established by these regulations;

(2) Any application which had been made prior to establishment of these regulations-

a. Shall continue under the original application procedure if they had reached the Committee stage;

b. Shall continue under these regulations if they had not reached the Committee stage;

(3) All Products or articles that were approved by the previous Committee shall be deemed to have been approved by the Committee established by these regulations and shall be assigned unique reference numbers;

(4) Facilities that were approved by the previous Committee shall be deemed approved by the Committee established by these regulations.

19. Offences and Penalties

Any person who contravenes the provisions of these regulations commits an offence and shall be liable to a fine Kshs. 2,000 or imprisonment for six (6) months or both.

ANNEXES

Annex 1a: Application form for Biofertilisers

Information for applicants

1. The applicant is responsible for the content of the information submitted;
2. The application should be submitted in 4 hard copies, separately bound;
3. All parts should be filled by summarising the required information in the spaces provided and references to clearly labelled annexes;
4. A cover letter should accompany this application form;
5. In case of more than one product, the applicant must fill a separate form for each product;
6. An applicant who is not a resident in Kenya must appoint an authorised local agent permanently resident in Kenya. A confirmation letter of the same should accompany this application;
7. The application will be processed subject to payment of the fees as prescribed in these regulations;
8. Additional information relating to the application may be required.

PART A: GENERAL INFORMATION	
1. Name of applicant/ Company	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
5. Name of Manufacturer	
6. Address of the manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided	
7. Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other)	

8. Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc)	
9. Quantity/ Amount proposed for importation	

PART B:DETAILS OF THE ORGANISM	
1. The scientific name(s) of the organism (Genus, species, strain/variety) *All must be provided*	
2. Common Name	
3. The type of organism/ micro-organism (Bacteria, virus, fungus, nematode, insect, mite etc)	
4. Are the organisms live or dead? If killed describe the process used (*Attach evidence)*	
5. Biology of the organism(*attach annexes and acceptable and peer reviewed publications*)	
6. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (*Detailed descriptions*).	
7. Mode of dispersal/ spread of the organism	
8. Mode of action of the organism	
9. Origin of organism and world distribution	
10. Natural occurrence (Ecosystem where it is found naturally)	
11. Natural enemies of the organism	
12. Is the organism genetically modified? *If genetically modified, describe.*	
13. Specificity to target	
14. Description of benefit	
15. Description of negative effects caused	
16. Stability of the organism in the environment.	
17. Environmental requirements	
18. Effect on availability of soil nutrients and water.	
19. Impact in its area of distribution	
20. List of countries where the organism/product is introduced. *(attach evidence*)	

21. Details of trials done elsewhere and results.(*Attach annexes)*	

PART C: IDENTITY AND INFORMATION OF PRODUCT FOR STATED ORGANISM		
1. Trade/commercial name		
2. Purpose of introduction (i.e. Research, commercial, personal use, other)		
3. Origin of Product (*country and state/district)*		
4. Product Type/ function (e.g. Soil amendment, soil inoculant etc.)		
5. Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc		
6. Formulation Details		
6.1 Type of formulation: (Peat, liquid, etc.)		
6.2 Declare full composition of Active organism(s) (a.o) (Information on a.o may be attached in sealed envelope)		
Active organism(s): (Common name/s)	Minimum count of a.o	Maximum count of contaminants (CFU)
6.3 Details of Formulator (Names, Postal address, Physical address)		
6.4 Details of trademark owner (Names, Postal address, Physical address)		
6.5 Is the product registered in country of manufacture?		Yes ☐ No ☐ If no give reasons
6.6 Is the product registered in other countries		Yes ☐ No ☐ State the countries
6.7 Certificate of analysis from the Country of origin.		Available ☐ Not available ☐
6.8 Specify other Physical characteristics of the product		

such as grade, matrix etc.	
7. Production	
7.1 Describe production method	
7.2 Purification /quality control procedures applied in production and check for contaminants (Attach separately)	
7.3 Shelf life	
7.4 Market label for the country of manufacture (Attach as annex)	
7.4.1 Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in annex*	
8. **Information on product use**	
8.1. Mode of application	
8.2. Area of application e.g. leaves, roots, seeds	
8.3. Dosage rates and frequency of application	
9. Mode of action. *(Attach all supporting scientific publications)*	
10. Description of benefits *(Attach all supporting scientific publications)*	
11. Effect on availability of soil nutrients and water.	
12. Environmental requirements. *(Attach all supporting scientific publications)*	
13. Information on Combined use/Compatibility with other crop protection measures	
14. Details of trials done elsewhere and results. *(Attach all supporting scientific publications)*	
15. Packaging	
15.1 Type of Packaging material / container:	
15.2 Pack size(s):	
15.3 Disposal of empty container(s):	
20.The proposed point of entry into the country	
21.The proposed final disposition of the organism such as destruction, treatment or destined for general	

Release	

PART D. SAFETY INFORMATION			
1. TOXICOLOGY (Formulated product)			
1.1 Rat:	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
1.2 Rabbit	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
1.3 Skin Sensitization in guinea pig:(tick)	None ☐ Mild ☐ Moderate ☐ Severe ☐		

1.4 WHO classification:	Ia	Ib	II	III

1.5 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets	
Material Safety data (summarise material safety data sheet information here) (Attach MSDS)	
1.6 Summary of environmental effects	
1.6.1 Toxicity to bees	
1.6.2 Toxicity to fish and other aquatic organisms	
1.6.3 Toxicity to birds	
1.6.4 Toxicity to earthworms and soil micro-organisms	
1.6.5 Toxicity to other non-target organisms	
1.6.6. Toxicity to other non-target plants	
1.6.6 Persistence in environment	
1.6.7 Other effects: Specify	

PART E: PROJECT PLAN	

1. Nature and objectives of the activities proposed	
2. Project participants; roles and responsibilities	
3. Documents procedures and record keeping	
4. Duration,; contingency plans; manner of transport; containment; storage; destruction and decontamination (*attach additional sheet if necessary)*	
5. The address, physical description and geographical coordinates of the specific site or sites where the activities will be conducted. The site may include for example, an entire facility, a laboratory, a growth chamber or a field	

Any necessary additional information that will be useful to support the evaluation process will be accepted.	
PART F: DECLARATION	
For and on behalf of..... I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
…… Name in full (Printed)	……. Signature
……..…… Official Title	…….. Date
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……..... Signed : Date:

Annex 1b: Application form for Soil amendments, Soil ameliorators, Organic fertilizer, Manure, Wood ash, Refuse and Compost

Information for applicants

1. The applicant is responsible for the content of the information submitted;
2. The application should be submitted in 4 hard copies, separately bound, as a technical information as required;
3. All parts should be filled by summarising the required information in the spaces provided and references to clearly labelled annexes.
4. A cover letter should accompany this application form.
5. In case of more than one product, the applicant must fill a separate form for each product.
6. An applicant who is not a resident in Kenya must appoint an authorised local agent permanently resident in Kenya. A confirmation letter of the same should accompany this application.
7. The application will be processed subject to payment of the fees as prescribed in these regulations.
8. Additional information relating to the application may be required.

PART A: GENERAL INFORMATION	
i. Name of applicant/ Company	
ii. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
iii. Name of Local agent (if different from applicant)	
iv. Address of the local agent (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
v. Name of Manufacturer	
vi. Address of the manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided	
vii. Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other)	
viii. Amount proposed for importation	

PART B: ORGANIC ACTIVE INGREDIENTS	
Details of the Organic Source	
i. The scientific name(s) of the plant/animal/other (please state) where the product was derived (Genus, species, strain/variety) *All must be provided*	
ii. Common Name of the plant/animal/ other (please state)	
iii. Are the organisms live or dead? If killed describe the process used (*Attach evidence)*	
iv. Biology of the plant/animal/ other (please state) (*attach annexes and acceptable and peer reviewed publications*)	
v. Hyper-parasites, contaminants, pests or likely pests to be associated with the animal/plant (*Detailed descriptions*).	
vi. Description of benefit	
vii. Mode of action of the organism/plant/ other (please state)	
viii. Origin of plant/animal/ other (please state) and world distribution	
ix. Natural occurrence (Ecosystem where it is found naturally)	
x. Natural enemies of the plant/animal/ other (please state)	
xi. Is the plant/animal/ other (please state) genetically modified? *If genetically modified, describe.*	
xii. Specificity to target	
xiii. Details of invasiveness of the plant/animal/ other (please state)	
xiv. Description of negative effects caused	
xv. Environmental requirements for the plant/animal/ other (please state)	
xvi. Effect ofplant/animal/ other (please state) on availability of soil nutrients and water	
xvii. Impact of plant/animal/ other (please state) in its area of distribution	

PART C: IDENTITY AND INFORMATION OF PRODUCT	
1. Trade/commercial name	
2. Purpose of introduction (i.e. Research, commercial, personal use, other)	
3. Origin of Product (*country and state/district)*	

4. Product Type/ function		
5. Intended use:		
6. Formulation Details		
7. Type of formulation: (e.g. EC, WP, etc.)		
8. Declare full composition of Active ingredient(s) (Technical grade/Formulation) (Information on a.i may be attached in sealed envelope)		
Active ingredient(s): (Common name/s)	Minimum a.i.% purity	a.i. Range %
9. Details of Formulator (Names, Postal address, Physical address)		
10. Details of trademark owner (Names, Postal address, Physical address)		
11. Is the product registered in country of manufacture?		Yes ☐ No ☐ If no give reasons
12. Is the product registered in other countries		Yes ☐ No ☐ State the countries
13. Certificate of analysis from the Country of origin.		Available ☐ Not available ☐
14. Specify other Physical characteristics of the product such as grade, matrix etc.		
15. Production		
15.1 Describe production method		
15.2 Purification/quality control procedures applied in production		
15.3 Shelf life		
15.4 Market label for the country of manufacture (Attach as annex)		
15.5 Proposed market label (Attach as annex) A Tentative product label that meets the requirements of labeling as indicated in annex		
16 Usage information		

16.1 Mode of application	
16.2 Area of application e.g. leaves, roots	
16.3 Dosage rates and frequency of application	
17 Mode of action. *(Attach all supporting scientific publications)*	
17.1 Description of benefits *(Attach all supporting scientific publications)*	
17.2 Effect on availability of soil nutrients and water.	
17.3 Environmental requirements. *(Attach all supporting scientific publications)*	
17.4 Information on Combined use/Compatibility with other crop protection measures	
17.5 Details of trials done elsewhere and results. *(Attach all supporting scientific publications)*	
18 Packaging	
18.1 Type of Packaging material / container:	
18.2 Pack size(s):	
18.3 Disposal of empty container(s):	
18.4 The proposed point of entry into the country	
18.5 The proposed final disposition of the organism such as destruction, treatment or destined for general Release	

PART D. SAFETY INFORMATION

1. TOXICOLOGY (Formulated product)

1.1. Rat:	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
1.2. Rabbit	Skin irritation	Eye irritation	
None			
Mild			
Moderate			

Severe				
1.3. Skin Sensitization in guinea pig:(tick)	None ☐	Mild ☐	oderate ☐	Severe ☐
1.4. WHO classification:	Ia	Ib	II	III

1.5. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets	
Material Safety data (summarise material safety data sheet information here) (Attach MSDS)	
1.6. Summary of environmental effects	
1.6.1. Toxicity to bees	
1.6.2. Toxicity to fish and other aquatic organisms	
1.6.3. Toxicity to birds	
1.6.4. Toxicity to earthworms and soil micro-organisms	
1.6.5. Toxicity to other non-target organisms	
1.6.6. Toxicity to other non-target plants	
1.6.7. Persistence in environment	
1.6.8. Other effects: Specify	

Project plan	
Nature and objectives of the activities proposed	
Project participants; roles and responsibilities	
Documents procedures and record keeping	
Duration,; contingency plans; manner of transport; containment; storage; destruction and decontamination (*attach additional sheet if necessary)*	
The address, physical description and geographical coordinates of the specific site or sites where the activities will be conducted. The site may include for example, an entire facility, a laboratory, a growth chamber or a field	

Any necessary additional information that will be useful to support the evaluation

process will be accepted.	
PART E: DECLARATION	
For and on behalf of..... I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
…… … Name in full (Printed)	…… Signature
……..…… Official Title	…….. Date
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……..... .. Signed : Date:

Annex 1c: Application form for introduction of Biopesticides and Beneficial organisms

Information for applicants

1. The applicant is responsible for the content of the information submitted;
2. The application should be submitted in 4 hard copies, separately bound;
3. All parts should be filled by summarising the required information in the spaces provided and references to clearly labelled annexes;
4. A cover letter should accompany this application form;
5. In case of more than one product, the applicant must fill a separate form for each product;
6. Incase of beneficial organisms which are not formulated into products, the applicant must provide all other required information minus information on the product;
7. An applicant who is not a resident in Kenya must appoint an authorised local agent permanently resident in Kenya. A confirmation letter of the same should accompany this application;
8. The application will be processed subject to payment of the fees as prescribed in these regulations;
9. Additional information relating to the application may be required.

PART A: GENERAL INFORMATION	
1. Name of applicant/ Company	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
5. Name of Manufacturer	
6. Address of the manufacturer (*Physical	

location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided	
7. Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other)	
8. Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc	
9. Quantity/ Amount proposed for importation	

PART B:DETAILS OF THE ORGANISM	
1. The scientific name(s) of the organism (Genus, species, strain/variety) *All must be provided*	
2. Common Name	
3. The type of organism/ micro-organism (Bacteria, virus, fungus, nematode, insect, mite etc)	
4. Category (Macrobial, Microbial etc)	
5. Methods of identification	
6. Are the organisms live or dead? If killed describe the process used *(Attach evidence)*	
7. Biology of the organism (*attach annexes and acceptable and peer reviewed publications)*	
8. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism *(Detailed descriptions).*	
9. Relationship to known plant and animal parasites	
10. Mode of dispersal/ spread of the organism, Invasiveness, and colonisation ability	
11. Mode of action of the organism	
12. Natural occurrence (Ecosystem where it is found naturally)	
13. Origin of organism and world distribution and uses	
14. Is the organism genetically modified? *If*	

genetically modified, *15. a)Approval from the Kenya biosafety Authority* 16. *b) Describe.*	
17. Host range	
18. Specificity to target	
19. Description of benefit	
20. Effect to non-target organisms	
21. Stability of the organism in the environment.	
22. Environmental requirements	
23. Effect on availability of soil nutrients and water.	
24. Impact in its area of distribution	
25. List of countries where the organism/product is introduced. (*attach evidence)*	

PART C: IDENTITY AND INFORMATION OF PRODUCT		
1. Trade/commercial name		
2. Origin of Product (*country and state/district)*		
3. Product Type/ function (e.g. insecticide, fungicide, etc.)		
4. Target pest and host		
5. **Formulation Details**		
5.1. Type of formulation: (e.g. EC, WP, etc.)		
5.2. Declare full composition of the product (Active agent (s) and inert ingreadients) (Detailed information on formulation may be provided separately in a sealed envelope)		
Active agent(s): (Common name/s)	Minimum a.i.% purity	a.i. Range %
5.3. Details of Formulator (Names, Postal address, Physical address)		
5.4. Details of trademark owner (Names, Postal address, Physical address)		

5.5. Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)	Yes ☐ No ☐ If no give reasons
5.6. Is the product registered in other countries	Yes ☐ No ☐ State the countries
5.7. Certificate of analysis from the Country of origin.	Available ☐ Not available ☐ Give reasons
5.8. Specify other Physical characteristics of the product such as grade, matrix etc.	
6. Production	
7.1 Describe production method	
7.2 Quality control -method	
7.3 Shelf life	
7.4 Market label for the country of manufacture (Attach as annex)	
7.5 Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in annex*	
7. **Information for product use**	
7.1. Mode of application	
7.2. Area of application (Greenhouse/ open field)	
7.3. Stage of the crop	
7.4. Dosage rates and frequency of application	
8. Mode of action. *(Attach all supporting scientific publications)*	
9. Description of benefits *(Attach all supporting scientific publications)*	
10. Effect on availability of soil nutrients and water.	
11. Environmental requirements. *(Attach all*	

supporting scientific publications)	
12. Information on Combined use/Compatibility with other crop protection measures	
13. Efficacy of the product in trials done elsewhere and results. *(Attach all supporting scientific publications)*	
14. Packaging	
14.1. Type of Packaging material / container:	
14.2. Pack size(s):	
14.3. Disposal of empty container(s):	
15. The proposed point of entry into the country	
16. The proposed final disposition of the organism such as destruction, treatment or destined for general release	

PART D. SAFETY INFORMATION

1. TOXICOLOGY (Formulated product) For microbial products only

1.1. Rat:	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
1.2. Rabbit	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
1.3. Skin Sensitization in guinea pig:(tick)	None ☐ Mild ☐ Moderate ☐ Severe ☐		

1.4. WHO classification:	Ia	Ib	II	III

1.5. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry,

pets	
Material Safety data (summarise material safety data sheet information here) (Attach MSDS)	
1.6. Summary of environmental effects	
1.6.1. Toxicity to bees	
1.6.2. Toxicity to fish and other aquatic organisms	
1.6.3. Toxicity to birds	
1.6.4. Toxicity to earthworms and soil micro-organisms	
1.6.5. Toxicity to other non-target organisms	
1.6.6. Toxicity to other non-target plants	
1.6.7. Persistence in environment	
1.6.8. Metabolites	
1.6.9. Other effects: Specify	

PART E: PROJECT PLAN	
1. Nature and objectives of the activities proposed	
2. Project participants; roles and responsibilities	
3. Documents procedures and record keeping	
4. Duration,; contingency plans; manner of transport; containment; storage; destruction and decontamination (*attach additional sheet if necessary)*	
5. The name, address and physical location of the specific site or sites where the activities will be conducted. The site may include for example, an entire facility, a laboratory, a growth chamber or a field	

Any necessary additional information that will be useful to support the evaluation process will be accepted.

PART E: DECLARATION	
For and on behalf of..... I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
…… Name in full (Printed)	……. Signature
……..…… Official Title	…….. Date
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……..... Signed : Date:

Annex 1d: Application form for introduction of Biostimulants and Plant growth regulators

Information for applicants

1. The applicant is responsible for the content of the information submitted;
2. The application should be submitted in 4 hard copies, separately bound, as a technical information as required;
3. All parts should be filled by summarising the required information in the spaces provided and references to clearly labelled annexes.
4. A cover letter should accompany this application form.
5. In case of more than one product, the applicant must fill a separate form for each product.
6. An applicant who is not a resident in Kenya must appoint an authorised local agent permanently resident in Kenya. A confirmation letter of the same should accompany this application.
7. The application will be processed subject to payment of the fees as prescribed in these regulations.
8. Additional information relating to the application may be required.

PART A: GENERAL INFORMATION	
i. Name of applicant/ Company	
ii. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
iii. Name of Local agent (if different from applicant)	
iv. Address of the local agent (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided*	
v. Name of Manufacturer	
vi. Address of the manufacturer (*Physical location, *Postal address, *Telephone, *Cell	

	phone, *Email, website, fax) *All must be provided	
vii.	Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other)	
viii.	Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc	
ix.	Quantity/ Amount proposed for importation	

PART B: ORGANIC ACTIVE INGREDIENTS		
Details of the Organic Source		
i.	The scientific name(s) of the plant/animal where the product was derived (Genus, species, strain/variety) *All must be provided*	
ii.	Common Name of the plant/animal	
iii.	Are the organisms live or dead? If killed describe the process used (*Attach evidence)*	
iv.	Biology of the plant/animal (*attach annexes and acceptable and peer reviewed publications*)	
v.	Hyper-parasites, contaminants, pests or likely pests to be associated with the animal/plant (*Detailed descriptions*).	
vi.	Relationship to known plant and animal parasites	
vii.	Description of benefit	
viii.	Mode of action of the organism	
ix.	Origin of plant/animal and world distribution	
x.	Natural occurrence (Ecosystem where it is found naturally)	
xi.		
xii.	Is the plant/animal genetically modified? *If genetically modified, describe.*	
xiii.	Host range	
xiv.	Specificity to target	

xv.	Details of invasiveness of the plant/animal	
xvi.	Effects to non-target organisms	
xvii.	Environmental requirements for theplant/animal	
xviii.	Effect of plant/animal on availability of soil nutrients and water	
xix.	Impact of plant/animal in its area of distribution	

Part C: Identity and Information of Product		
16. Trade/commercial name		
17. Origin of Product (*country and state/district)*		
18. Product Type/ function (e.g. Soil amendment, soil inoculant, biostimulant etc.)		
19. Target pest and host		
20. **Formulation Details**		
20.1 Type of formulation: (e.g. EC, WP, etc.)		
20.2 Declare full composition of the product (Active agent (s) and inert ingredients) (Detailed information on formulation may be provided separately in a sealed envelope)		
Active agent(s): (Common name/s)	Minimum a.i.% purity	a.i. Range %
20.3 Details of Formulator (Names, Postal address, Physical address)		
20.4 Details of trademark owner (Names, Postal address, Physical address)		
20.5 Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)		Yes ☐ No ☐ If no give reasons
20.6 Is the product registered in other countries		Yes ☐ No ☐ State the countries
20.7 Certificate of analysis from the Country of origin.		Available ☐ Not available ☐ Give reasons

20.8 Specify other Physical characteristics of the product such as grade, matrix etc.	
21. Production	
7.1 Describe production method	
7.2 Quality control -method	
7.3 Shelf life	
7.4 Market label for the country of manufacture (Attach as annex)	
7.5 Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in annex*	
22. **Usage information**	
8.1. Mode of application	
8.2. Area of application (Greenhouse/ open field)	
8.3 Stage of the crop	
8.4. Dosage rates and frequency of application	
23. Mode of action. *(Attach all supporting scientific publications)*	
24. Description of benefits *(Attach all supporting scientific publications)*	
25. Effect on availability of soil nutrients and water.	
26. Environmental requirements. *(Attach all supporting scientific publications)*	
27. Information on Combined use/Compatibility with other crop protection measures	
28. Efficacy of the product in trials done elsewhere and results. *(Attach all supporting scientific publications)*	
29. Packaging	
15.1 Type of Packaging material / container:	
15.2 Pack size(s):	
15.3 Disposal of empty container(s):	

20.The proposed point of entry into the country	
21.The proposed final disposition of the organism such as destruction, treatment or destined for general Release	

Part D. Safety Information

2. TOXICOLOGY (Formulated product)			
1.1 Rat:	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
1.2 Rabbit	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
1.3 Skin Sensitization in guinea pig:(tick)	None ☐ Mild ☐ Moderate ☐ Severe ☐		

1.4 WHO classification:	Ia	Ib	II	III

1.5 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets
Material Safety data (summarise material safety data sheet information here) (Attach MSDS)
2.6 Summary of environmental effects

1.6.1 Toxicity to bees	
1.6.2 Toxicity to fish and other aquatic organisms	
1.6.3 Toxicity to birds	
1.6.4 Toxicity to earthworms and soil micro-organisms	

1.6.5 Toxicity to other non-target organisms	
1.6.7. Toxicity to other non-target plants	
1.6.8 Persistence in environment	
1.6.8 Metabolites	
2.6.7 Other effects: Specify	

Project plan	
Nature and objectives of the activities proposed	
Project participants; roles and responsibilities	
Documents procedures and record keeping	
Duration,; contingency plans; manner of transport; containment; storage; destruction and decontamination (*attach additional sheet if necessary)*	
The name, address and physical location of the specific site or sites where the activities will be conducted. The site may include for example, an entire facility, a laboratory, a growth chamber or a field	

Any necessary additional information that will be useful to support the evaluation process will be accepted.	
PART E: DECLARATION	
For and on behalf of..... I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
…… Name in full (Printed)	……. Signature
……..…… Official Title	…….. Date

Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks ……..... Signed : Date:

Annex 2: Requirements for a Local Bio-control Production facility

Site information

Name of the facility……
Location…….……
Contact Person ……
Physical address……
Telephone No ……
Email address……

Site Requirements

1. Should be isolated
2. Should be well drained
3. Double door system should be in place
4. Have one entrance only
5. Restricted entry to facility with restriction orders strategically placed
6. A disinfection trough at entrance
7. Personnel should be well trained and conversant with required procedures
8. There should be restricted movement of material from the facility
9. Documented quality control procedures in place as described by International Organization for Biological Control (IOBC) and/or ISPM No.3 (details of how quality control is achieved to ensure only high quality products are availed/sold to the users should be provided
10. Identification manuals and equipments should be available to ensure true to type during production (brief summary should be provided)
11. Packing procedures should be in place
12. The packing area should be well designed to eliminate any contamination
13. Information on the original source of the natural enemy in mass production should be availed
14. Details on how (or where) was/ (is being) the identification done should be available
15. Intended use (crops and range in application rates) should be provided
16. There should be measures in place to contain occasional infection/contamination

General Observations…….

Recommendations…….

Approved ☐ **Not approved** ☐

Owner's/Manager's Name/Signature…….Date…….

Inspector' Name/Signature…….Date……

Annex 3: Performance Trials guidelines

1. Introduction

(a) Name of the principal researcher and research institution

(b) Location of the trial

(c) Common Name of the active ingredient/agent/constituent and tested formulation, Name, type.

(d) Provide name, type and concentration of the formulation

(e) Source of the formulation tested

(f) Provide Manufacturer/Registrant/Agent/Distributor etc.

(g) Information on Reference product.

Use a locally registered reference product with comparable mode of activity/similar usage where there is no reference product with comparable mode of activity/similar usage, the product shall be compared with the control.

(h) Attributes against which tested: Specify……

2. Objectives

(a) Objective (s) State clearly the objective of the performance trials

3. Materials and methods to include:-

(a) Crops, species , Cultivars and varieties

(b) Plant growth stage at application time.

(c) Period of testing. …….

(d) Soil type …….

(e) Soil conditions. …….

(f) Describe in detail experimental design, size and number of plots treated/replicates…. …….

(g) Describe Control and untreated areas…….

(h) Provide information on application rates ……..….

(i) Describe in detail the number, timing, methods of application and equipment to be used...

(j) Provide climate/weather conditions during trial period (where applicable) ……..

(k) Evidence of performance of a local reference standard product included in the trials alongside the product under test. Use locally registered reference standard……

(l) Report the application and assessment dates……..……

(m) Indicate size and frequency of sampling …….…….

(n) Assessment of parameters. Use of referenced methodology where applicable……

4. Results

i. Statistical analysis of the data. Use appropriate internationally acceptable statistical package e.g. Mstat C, SAS etc…The quantifiable benefits from using the products obtained from the trial will be used to determine performance ……

ii. Provide the effects on quality and yield of the treated crops……

iii. Note and specify any detrimental effects on beneficial organisms and other non-target organisms, the undesirable or unintended side effects,

iv. State main findings……..……

v. Clearly state the final recommendations…….

5. NOTE

i. You are advised to inform KEPHIS of the commencement of the experimental/efficacy trials through a letter of invitation for officers to visit the trial site.

ii. The trial should be carried out according to the approved protocol for experimental/efficacy trial by the research institute.

iii. At the conclusion of the experimental /efficacy trials, a detailed report shall be submitted to KEPHIS for consideration.

iv. The company shall bear the expenses for the entire trials.

Annex 4: Registration certificate

<table>
<tr><td colspan="3">KSTCIE CERTIFICATE(logo)
Certificate No.
Registration No.
FIELD OF ATTENTION:
ISSUED TO:
STANDARD AND OR REGULATION:
VALID UNTIL:
The committee declares to have inspected the unit(s) and or products of the above mentioned applicant and found them compliant with regulations.
This certificate covers the unit(s) and or product(s) as mentioned herein.
This certificate is in force, provided that the above mentioned applicant continues meeting the conditions laid down in the client contact with the KTCBP.

Date of certification
Place and date of issue On behalf of the Cabinet Secretary
MoALF
Certifier:

Units covered:</td></tr>
<tr><td>Certificate of Registration of Bio products and or organism Mode of Registration:
Temporary
Full
Provisional
Experimental use
(Delete as appropriate)
Registration No……..</td><td>Previous registration No. if applicable. (See next column.)
----------</td><td>Is this a modified or renewed registration?
☐Yes ☐No
The product/organism was previously registered for experimental use only:
☐Yes ☐No.</td></tr>
<tr><td>Name of responsible person/certificate holder</td><td>Position</td><td>Bio Product Business License No.</td></tr>
<tr><td colspan="3">Company</td></tr>
</table>

Address Tel No. Fax. No. Email address		
Emergency contact details	Tel. No. (landline) Mobile No.	Fax No. Email address
Microbial active agent(s) where applicable		
Other active ingredients if any		
Type of product registered in this certificate	**Active agent/technical grade/formulated product** (Delete any not applicable)	
Registration details of registration of other active agents/ component products still in force		
Type of formulation (code)	**Trade Name**	**% active agent(s)** (List all with %)
Use category	**General use/restricted/severely restricted** (Delete as appropriate}	
Conditions of registration and use	(Attach extra sheet as necessary)	
Date registered:	**Expiry date:**	**Renewal application required by:**
Signed by or on behalf of Registrar of --------	**Stamp of Registration Authority**	**Additional observations** (e.g. in case registration revoked)

Annex 5a: Import Permit for organic fertilizers, soil conditioners, soil amelioration products and related products

STATE DEPARTMENT OF AGRICULTURE

KENYA PLANT HEALTH INSPECTORATE SERVICE

PERMIT FOR IMPORTATION OF SOIL, ORGANIC MANURES, ROOTING OR POTTING MIXTURES AND RELATED PRODUCTS

(Plant Protection Act Cap 324)

Serial Number: …….. ***Date……..***

Permit No: **HQS (Issuing station)/continuing number /Year**

The importer must furnish the supplier with a copy of this permit before the shipment is dispatched.

Permission is hereby granted to……

Of……

To import from……

The following … (Description and quantity)……

Subject to the following conditions:

1) All (Parts imported)…… to be obtained/manufactured in (country of manufacturer or import) ……

2) Soil and Articles to be used only for approved purpose or at the facility of the permittee or authorized user located at ……

3) The consignment must be declared on arrival to an inspector. The inspector reserves the right to treat, destroy or refuse the importation.

4) Each consignment shall be accompanied by an original of this permit and a Phytosanitary certificate (International model or equivalent) from the country of origin or export.

5) The importer must undertake to kill all seeds, pathogens and insects in organic manures, composts, rooting and/or potting mixtures before dispatch.

6) All unconsumed soil, containers and effluent must be destroyed by autoclaving, incinerating, heat treatment (At 180°F/83°C for ten minutes) or chemical treatment after the end of the analysis work if imported for such purpose.

7) The soil/rooting media to be shipped in sturdy, leak proof containers.

Additional declarations*

*The permit is valid for six months from the Date of Issue, and may be cancelled at any time

Import of genetically modified material must comply with the Biosafety Act, 2009.

Official stamp…… Signed …….

2.4.1.1.1.1 For: Director of the National Plant Protection Organization.

Annex 5b: Import Permit for biological control agents, beneficial organisms, and bio fertilizers

STATE DEPARTMENTOF AGRICULTURE

KENYA PLANT HEALTH INSPECTORATE SERVICE

BIOLOGICAL IMPORTATION PERMIT

(Plant Protection Act Cap 324)

Serial No: .....

Date.....

Permit No: **HQS (Issuing station)/continuing number /Year**

One copy of this permit must be furnished by the importer to the supplier before the biological shipment is dispatched:

Permission is hereby granted to (Applicant).....

To import from: .....

Quantity permitted.....

The organism/product described below:

1. **The organism/product**
   a. Genus, Species, Author.....
   b. Type of Parasite: .....
   c. Predator of weed.……
   d. Predator of insect/ arthropod.....
   e. Stage(s) shipped:
   f. Dates originally field collected .....
   g. State or Country.....

2. **Original host or parent host plant or organism** (Genus, Species, Author).....
   a. Stage/part ….....……
   b. Intended host/target if different from original……
   c. Other hosts .or sources of material.....
   d. Laboratory host (If different from original host) …….
   e. To be tested in the lab against.....
   f. To be used for (purpose .....
   g. Host plant of target pest…

Approval date and reference. .....

Intended use **Intended Host** **Type of study**

A. Immediate field Release

B. Lab. Culture with eventual field release

C. Study of performance only

A statement of where the biological agent or product has already been used and the degree of success attained ……..

3. Any treatment done or to be done before shipment on the organism or product

4. Any document already granted by the exporting country other than the export certificate.

5. Importation of the organism is subject to the following conditions:

i) The supplier must provide documents endorsing that an authorised officer of the plant protection service examined the shipment and were found to be to the best of his knowledge free from any undesirable species (hyperparasites pest insects of predators, weed seeds, etc.)

ii) The consignment to be inspected on arrival and the importing authority reserves the right to treat, destroy, or refuse the importation)

All packing material must be entirely free from soil, live plant material, leaf mould and must be autoclaved before discarding

*The permit is valid for six months from the Date of Issue, and may be cancelled at any time by the Director of Agriculture or by the officer issuing the permit on his Behalf

Import of genetically modified material requires compliance with the Biosafety Act 2009.

Official Stamp *Signed……*

For Director of the National Plant Protection Organization

Annex 6: Requirements for quarantine facility for biological control agents, beneficial organisms and bio fertilizers

NB: Based on these requirements, a checklist will be prepared.

Site information:
1. The site should be isolated and well drained
2. A double door system should be in place
3. Have only one entrance to the facility
4. Have restricted entry to the facility
5. Construct a disinfection trough at the entrance
6. Personnel should be trained in handling the predatory mites
7. Movement of material from the facility should be restricted to avoid spread of the mites to other areas
Other information:
8. Quality control procedures as described by International Organisation for Biological Control (IOBC) and/or *ISPM No. 3. - Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms.* Details of how quality control will be achieved should be clearly stated. This will ensure only high quality products are availed/sold to the users.
9. Identification manuals and identification equipments to ensure true to type during production and to aid in spot-checking before packing.
10. Original source of natural enemy in mass production
11. How (or where) the identification was/(is being) done
12. Intended use (crops and range in application rates)
13. Measures to contain occasional infection/contamination entomopathogenic fungi, thrips and other contaminants of the predatory mite especially before or during harvesting of the predatory mites.
14. Proposed Packaging area
15. Control of local pests (e.g. rodents, whiteflies, ants) and exclusion from the facility by sealing all the points of penetration, including electrical and plumbing conduits (except for open ground facilities)
16. Protective clothing (e.g. a dedicated laboratory coat and footwear or shoe covers, disposable gloves) to be worn by all staff and visitors and removed on exit from the facility
17. Decontamination of personnel upon exit of areas containing risk material

Annex 7: Export certificate for biological control agents and beneficial organisms, bio fertilizers, organic fertilizers and related products

STATE DEPRTMENT OF AGRICULTURE
KENYA PLANT HEALTH INSPECTORATE SERVICE-
EXPORT CERTIFICATE FOR BIOLOGICAL CONTROL AGENTS AND BENEFICIAL

1. Name and Address of Exporter	PHYTOSANITARY CERTIFICATE No.
3. Dealer's name and address of Consignee	4. To Plant Protection Organization of
5. Place of origin	6. Declared means of Conveyance
7. Declared point of Entry	8. Distinguishing marks
9. Number and description of packages	10. Name of regulated Article(s)

ORGANISMS, BIO FERTILIZERS, ORGANIC FERTILIZERS AND RELATED PRODUCTS

11. Scientific identity of Regulated Article(s)	12. Quantity declared
13. This is to certify that the Article(s) described above has/have been inspected according to appropriate procedures and are considered to be free from quarantine pests and practically free from other injurious pests in conformity with the current phytosanitary regulations of the importing country.	
14. Additional declaration:	
15. Disinfestation and/or disinfection treatment…… 16. Chemical (Active ingredient)…….. 17. Duration and temperature…… 18. Concentration……. Date…….	Place of issue Date:……. Name of Inspector 19. Signature of Authorizing officer….. Official Stamp
20. Any additional information	

Annex 8: Format for Environmental Management Plan

Environmental Management Plan

This EMP is designed for biological control agents, beneficial organisms and bio fertilizers.

This EMP should become part of the safety documents after direct changes have been made to reflect the activities.

To ensure the purpose of this EMP will be achieved, the environmental management plans will be established as follows:

Authorized person or firm	
Date of authorization	
Item authorized	

Outline

I. Objectives to be achieved
II. Management strategies
III. Tasks
IV. Responsibilities
V. Frequency
VI. Monitoring and reporting
VII. Corrective actions

Detailed Plan

1. Description of measure to manage risks identified during risk assessment.
2. Mechanisms to establish effects on non targets and the environment not noticed during application process.
3. Waste management where material will be produced or manufactured stored or disposed in the environment including disposal of expired material.
4. Commitment or measures to comply with existing environment laws and occupational safety relating to the production, manufacture, use and handling of the approved material.
5. Exposure monitoring plan.
6. Mechanism for public feedback or public information regarding emerging risks or effects related to the approved material.

7. Adequate label and signage on safe use of material.
8. Means of recall or corrective action including replacement with superior versions of the organisms or product.
9. Impact response plan in case of any incidents related to the organism article or product including where human and plant health in threatened.
10. Reporting hazards to the committee.
11. Mechanisms for review of the environment management Plans.
12. Current contact of person in the firm responsible for environmental stewardship of the organism or product.

Annex 9: Criteria for review of applications

"Risk assessment" means the identification, evaluation and estimation of the levels of risk involved in a situation including evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing country according to the sanitary or phytosanitary measures which might be applied and of the associated biological economic consequences; or the evaluation of potential adverse effects on plant, human or animal health and environment from the presence of additives, contaminants, toxins or disease causing organisms in food beverages or feedstuff. In this regard, the following criteria has been set for review of applications:

No.	Item	Yes	No
A.	**DETAILS OF THE APPLICATION**		
	Name of applicant:_____ **Biological Material:** _____ **Source of material (country) etc**) _____ _____		
B.	**RISK ASSESSMENT**		
	1) Potential to be a pest, vector or invasive species Does the biological material have the ability to be injurious to plants or plant products?		
	Brief information (if available) on an immediate or long-term harmful effect on the environment or its biological diversity_____		
	Does the biological material have Potential to transmit disease?		
	Brief information (if available) on mode of transmission of the named agents, disease caused and symptoms_____		
	Does the biological material have the ability to establish itself, persist, out-compete indigenous species, take over new environments and threaten biological diversity?		
	Provide a brief description on invasiveness _____		
	2) Potential to be infective Does the biological material have the ability to cause disease or pose a		

	risk of harm to humans and/or other organisms?		
	Brief description on infectiveness_____		
	3) Potential to be allergenic Does the biological material have the ability to cause hypersensitivity or adverse effect(s) on humans and/or other organisms (e.g. due to production of toxin, secondary metabolites, and/or structural components)?		
	Brief description on specific hypersensitivity_____		
	4) Toxicological effects on mammals Does the biological material produce toxin or biologically active substance which might be present and may pose a hazard to mammals?		
	List the harmful chemical toxins present and Indicate routes of exposure_____		
	5) Eco-toxicological effects on non-targets Does the biological material produce toxin or biologically active substance which might be present and may pose a hazard to non-targets (e.g. bees, earthworms, fish etc)?		
	Provide a brief description_____		
	6) Behavior in the environment i.e. persistence, mobility, in soil, water or air How does the biological material behave in the environment?		
	Brief description_____		
	7) Presence of contaminants in acceptable limits Does the biological material contain any contaminants?		
	Check and provide acceptable limits_____ _____		
	8) Genetic and environmental stability Is the product genetically and environmentally stable?		
	Provide a brief description_____ _____		
	9) Uncertainties What are the uncertainties? _____		
C.	**Any other comment/information**		

	_____			
D.	**DETAILS OF REVIEWER**			
	Name of reviewer			
	Institution			
	Contacts (Postal & physical address, Email, Mobile)			
	Signature		Date	

Annex 10: Confidentiality Agreement Form

NON-DISCLOSURE AND CONFIDENTIALITY AGREEMENT

This Agreement ("Confidential Agreement") is entered into by and between the undersigned contracted expert (hereinafter referred to as the "Receiving Party") and Kenya Standing Technical Committee on Imports and Exports (KSTCIE) through its Secretariat at Kenya Plant Health Inspectorate Service (hereinafter referred to as "KSTCIE Secretariat").

WHEREAS

(A) The KSTCIE has the mandate to undertake risk analysis to facilitate safe production, export, import and release of biological control agents and other beneficial organisms as well as live microorganisms and products containing live organisms, and

(B) The KSTCIE is desirous that the contracted expert undertakes risk assessment, evaluates the information provided by applicants and makes informed recommendations to KSTCIE Committee.

(C) Dossier owner/applicant has invested considerable time and money in developing information regarding to the product dossier (the "Confidential Business Information (CBI)"), which has commercial value and is not generally or publicly known.

(D) Dossier owner/Applicant will disclose the CBI to KSTCIE Secretariat who in turn will disclose the CBI to the Receiving Party for purposes of evaluation.

(E) The Receiving party has the capacity and has accepted the request to review the Dossier within the stipulated timeline.

NOW, THEREFORE, in consideration of KSTCIE Secretariat disclosing Dossier owner`s/Applicant `s CBI to Receiving Party, Receiving Party IT IS AGREED as follows:

1. The CBI is a valuable trade secret of Dossier owner/Applicant and that any disclosure or unauthorized use thereof will cause irreparable harm and loss to Dossier owner/Applicant.
2. All CBI shall be and remains the sole and exclusive property of Dossier owner/Applicant and shall be held in the strictest confidence by Receiving Party. However, CBI submitted by Dossier owner shall be retained by the Receiving party herewith referred as KSTCIE Secretariat.
3. Receiving Party shall not copy CBI or any portion thereof without Dossier owner/Applicant prior written consent.
4. Receiving Party shall return to KSTCIE Secretariat the Dossier submitted for review immediately upon completion of the review.

5. Receiving Party shall not, without the prior written consent of Dossier owner/Applicant, through KTCBP Secretariat, disclose to any person any portion of the CBI.
6. Receiving party shall submit review comments to KSTCIE Secretariat who shall hold it in utmost confidentiality.
7. The agreement shall be deemed to commence on.....and shall continue until.....
8. The agreement may be terminated by either party upon seven (7) days written notification to the other party. Upon receiving a termination notice from the KSTCIE Secretariat, the Receiving Party shall cease the evaluation and immediately return the Dossier to the Secretariat.

The obligations set out in the Sections above ``regarding confidential information`` of this Agreement shall not apply to any CBI with respect to which the Receiving Party can demonstrate:

1. Is or becomes available to the public through no breach of this Agreement;
2. Was previously known by Receiving Party without any obligation to hold it in confidence;
3. Is received by Receiving Party from a third party free to disclose such information without restriction;
4. Is independently developed by Receiving Party without the use of the CBI;
5. Is approved for release by written authorization of Owner, but only to the extent of and subject to such conditions as may be imposed in such written authorization;
6. Is required by law or regulation to be disclosed, but only to the extent and for the purposes of such required disclosure; or
7. Is disclosed in response to a valid order of a court or other governmental agency

This agreement is the complete agreement of the contracted expert and the KSTCIE and supersedes all prior understandings regarding the evaluation to which this Agreement directly relates.

IN WITNESS WHEREOF, the respective parties have executed this agreement on the dates indicated below.

For KTCBP	**RECEIVING PARTY**
Signed…… …….	Signed…….....……
Name……	Name: …….....…
Institution……..…	Institution……...……
Postal address……..…	Postal address…….
Physical address……	Physical address…….....
Mobile No ……..…	Mobile No…….....…

Email: ……..……..... Email……....

Date…….....…… Date…….....

Official Stamp…….....

Annex 11: APPLICATION FOR REGISTRATION AS A BIOLOGICAL PRODUCTS` MERCHANT

Name…….....

Postal address …….....

Telephone Number…….....

Location of premise…….....

Premise type(Tick where applicable)

Manufacturer	☐	Re packaging	☐
Formulator	☐	Warehousing	☐
Merchant	☐	Distributor	☐
Storage	☐	Retailer	☐

The biological products will be kept in a premise where adequate provisions are available to separate the products and where the articles will be kept which could have an adverse effect on the quality of products. At anytime during official working hours, even without previous appointment, I/we will allow the inspector(s) entry into the premise and thereby provide them with the facilities necessary to carry out the inspection work.

Declaration: In signing this application, I/we also declare that I/we are conversant with and shall observe the various regulations governing the products.

Date..... Signature.....

Stamp.....

Annex 12a: CHECK LIST FOR INSPECTION OF A BIOLOGICAL PRODUCTS RETAIL PREMISE

Name…….....

Postal address …….....

Telephone Number…….....

Location of premise…….....

ITEM	YES	NO	COMMENTS
Adequate and knowledgeable personnel who are conversant with biological material matters			
Adequate storage space			
Well ventilated storage space			
Do you have distributive channels, agents, sub agents and stockiest (where applicable)			
Do you understand that biological products should not be mixed with dangerous chemicals, kept in moist floors, too high humidity and excessive temperatures			
Carefully maintained premises affording maximum protection against entry of insects, vermin or other animals			
Overall comment			
Recommendation			

Approved ☐ Not approved ☐

Date of next inspection…….....
Owner's/Manager's Name/Signature……Date……
Inspectors Name/Signature……. Date…….

Annex 12b: CHECK LIST FOR INSPECTION OF A BIOLOGICAL PRODUCTS WAREHOUSE PREMISE

Company Name…….....

Postal address …….....

Telephone Number…….....

Location of premise…….....

ITEM	YES	NO	COMMENTS
Is the premise properly designed and suitable for use as a warehouse			
Is the premise bird and vermin proof			
Is the facility wind and water tight			
Is the floor in sound condition, clean and free from debris and other obstructions having adequate traffic and pedestrian routes			
Is adequate lighting provided for			
Are there adequate and properly positioned personnel doors			
Does the premise have clear signage			
Is the office adequately staffed and equipped to provide stock control and other documentation (Document control)			
Is there a waste disposal arrangement in place			
Overall comment			
Recommendation			

Approved ☐ Not approved ☐

Date of next inspection…….....
Inspectors Name…….....
Signed ……. **Date**……

Annex 4 Bio-fertilizers registration guidelines for Nigeria

NATIONAL AGENCY FOR FOOD AND DRUG AND ADMINISTRATION AND CONTROL (NAFDAC)

REGISTRATION AND REGULATORY AFFAIRS DIRECTORATE

GUIDELINE FOR REGISTRATION OF IMPORTED BIO-PESTICIDES AND BIO-FERTILIZERS

1. APPLICATION FOR REGISTRATION:

(a) Pre-submission consultation between the Applicant and the Agency:

(i) An applicant shall apply for a Pre-submission consultation to;

The Director, Veterinary Medicines and Allied Products Directorate
Plot 1, 3rd Floor Isolo Industrial Estate, Oshodi-Apapa Express Way,
Isolo, Lagos.

An application for the registration of a Bio-pesticide or Bio-fertilizer product shall be made by the manufacturer represented by a duly registered company in Nigeria.

2. DOCUMENTATION

The following documents (all originals and two (2) sets of photocopies) are to be submitted to the LOD's office, R & R Directorate.

(a) Company shall write an application for registration of the bio-pesticide and bio-fertilizer and submit a Bank draft of Five Hundred Naira only (N500.00) for registration form per product. This shall be drawn in favour of the National Agency for Food and Drug Administration and Control (NAFDAC).

(b) **Power of Attorney or Contract Manufacturing Agreement:**

Power of Attorney shall be:

i) Notarized by a Notary public in the country of manufacture.

ii) Issued by the manufacturer of the product.

iii) Signed by the MD, GM, Chairman or President of the Company, stating the names of the products to be registered.

iv) Valid for at least five (5) years.

OR

(c) **Contract Manufacturing Agreement:**

i) Certificate of Manufacture and Free Sale from the statutory body responsible for the safety of the product in the country of origin.

ii) Shall be signed by both parties stating names and designations of the signatories with the names of all the products to be registered and other relevant clauses clearly explained in an unambiguous language.

iii) This should be authenticated by the Nigerian Embassy in the country of origin. Where no Nigerian Embassy exists in the country of manufacture authentication can be carried out by the High Commission or Embassy of any West African country or Commonwealth Countries. CMFS should indicate the name of manufacturer and active ingredient(s) of products to be registered.

(c) Certificate of Incorporation of the Importing Company (Local Representative) with the Corporate Affairs Commission, Nigeria.

(e) Certificate of analysis of the product to be registered indicating the name and designation of the analyst.

(f) Field trial report from an approved field trial center in respect of the biological efficacy of the particular bio-pesticide/bio-fertilizer in Nigeria shall be submitted.

(g) **GMP Invitation letter:** A letter of invitation to inspect the factory abroad shall be written by the manufacturer and shall state the following;

MANUFACTURER INFORMATION: Name of company, full location address of the factory, e-mail address and current phone no. & fax no. (not administrative office address), name of contact person overseas, telephone no. e-mail address. Name of airport closest to the location and guid map illustrating the shortest land /air route to the factory overseas.

LOCAL AGENT INFORMATION: Name of company, full location address and functional telephone no., fax no. & e-mail address. Name(s) of product(s) for registration, name & mobile phone no. of contact person in Nigeria.

NOTE: This letter is to be submitted by the local agent here in Nigeria.

(h) Company shall submit two (2) copies of Dossiers produced according to NAFDAC Dossier Format to Animal Health and Finished Chemical Division (AHFC) together with one (1) sample and two (2) labels per product for vetting.

(i) Evidence of trade mark registration in the appropriate class. Bio-pesticides and bio-fertilizers are in class 1

(j) A notarized declaration as prescribed by the Agency.

LABELING

Labeling shall be informative and accurate.

i. Minimum requirement on the package label shall include:

(a) Name of product, brand name and common or Genus and specie name(s) of Active ingredient(s) in their percentage concentration or cfu per gram of product.

(b) Net weight or measure of content in metric units.

(c) Batch number, manufacturing date, Expiry date.

(d) Name & full location address of manufacturing plant.

(e) Precautions for storage and handling in transit.

(f) Full description for application and safe use. Description for use must be adequate, appropriate and clear.

(g) Risk and safety phrases.

(h) Pictograms.

ii. Any bio-pesticide and bio-fertilizer product whose name, package or label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.

iii. Any bio-pesticide and bio-fertilizer product which is labeled in foreign language, shall not be considered for registration unless an English translation with the inclusion of the three Nigerian major languages is included on the label.

TARIFFS

Applicant shall submit Bank Draft of Two Hundred and Seventy Six Thousand Seventy Five Hundred Naira (₦ 276,075.00) per imported Bio-pesticide or Bio-fertilizer product.

Break down:

=N=13,500	Import Permit
=N=127,575	Processing fees (VAT inclusive)
=N=135,000	Product Licensing

NOTE

(a) Failure to comply with these requirements may result in disqualification of the application or lead to considerable delay in processing of registration

(b) Registration of a product does not automatically confer advertising permit. A separate approval shall be required if the product is to be advertised.

(c) NAFDAC may withdraw the Certificate of Registration in the event that the product is advertised without express approval from the Agency.

(d) NAFDAC reserves the right to revoke, suspend or vary the certificate during the validity period.

(e)Filling an application form or paying for an application form does not confer registration Status.

(g) All correspondence in respect of Bio-pesticide and Bio-fertilizer Registration should be Addressed to:-

The Director-General
National Agency for Food and Drug
Administration and Control (NAFDAC)
Plot 2032, Olusegun Obasanjo Way,
Zone 7, Wuse, Abuja
Tel: 09-5240996
Fax: 09-5240994

Attention: Director,
Registration and Regulatory Affairs Directorate.
Plot 1, Isolo Industrial Estate, Oshodi-Apapa Express Way,
Isolo, Lagos.

Tel: 01- 4772452, 4748627

E-mail: nafdacrr@linkserve.com

Website: www.nafdac.org

NB: PLEASE ENSURE THAT YOU HAVE A FUNCTIONTIONAL E-MAIL AND PHONE NUMBER

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL (NAFDAC)

Bio-fertilizer Registration Regulations 2014

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL (NAFDAC)

BIO-FERTILIZERS REGISTRATION REGULATIONS 2014

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of National Agency for Food and Drug Administration and Control Cap N1 Laws of Federation of Nigeria 2004 and powers enabling it in that behalf, the GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honorable Minister of Health hereby makes the following Regulations:-

Scope

1. These Regulations prescribe the minimum requirements for importation, exportation, manufacture, advertisement, distribution sale and use of bio-fertilizers in Nigeria.

Prohibition

2. (1) Except as provided in these Regulations no bio-fertilizer shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations.

(2) Notwithstanding the provisions of subsection (1) of this regulations, the manufacture, formulation or importation of a bio-fertilizers as sample for the purpose of registration, field trial or research shall be undertaken with the approval of the Agency.

(3) No person shall be involved in the sale or distribution of bio-fertilizers in units other than packages, in which it has been originally contained, wrapped or packaged.

Classification of Bio-fertilizers

3. Bio-fertilizers shall be classified as appropriate into:

1. Nitrogen fixing bio-fertilizers
2. Phosphate bio-fertilizers;
    a. Phosphorus solubilizing bio-fertilizers
    b. Phosphorus mobilizing bio-fertilizers
3. Micronutrients bio-fertilizers.
4. Plant growth promoting rhizobacteria.
5. Compost bio-fertilizers

Application for Registration

4. (1) No person shall manufacture or formulate any bio-fertilizers unless it has been registered in accordance with the provisions of these Regulations.

(2) The application for bio-fertilizer registration shall be made on a prescribed application form obtainable from the Agency.

(3) Each application for registration shall be accompanied with a non-refundable fee as the Agency may, from time to time prescribe.

Submission of Application

Application for the registration of bio-fertilizers shall be submitted with the following:

5. (1) (a) Power of Attorney or a contract manufacturing agreement between the manufacturer and the applicant duly notarized in the country of origin to register the bio-fertilizer in Nigeria

(b) Certificate of manufacture and free sale of the bio-fertilizer from the statutory body responsible for the safety of the bio-fertilizers in the country of origin.

(c) Company's certificate of incorporation in Nigeria.

(d) Evidence of trade mark registration

(e) Original certificate of analysis of the bio-fertilizer.

(f) Field trial report of trials conducted in Nigeria by an approved research institute in more than 2 agro ecological zones for 2 cropping seasons to determine the biological efficacy and effectiveness of the bio-fertilizer

(g) Guaranteed analysis of the bio-fertilizer stating;

i. The genus and species name of the microorganism in the bio-fertilizer.

ii. The minimum number of active viable cells per gram of the genus and species of microorganism in the bio-fertilizer.

(h) Evidence of substantiation of special labeling claims on the character, quality and safety of the bio-fertilizer.

(i) Invitation letter for Good Manufacturing Practice (GMP) inspection from oversea manufacturers; or

(j) Application letter for inspection of local production facility for bio-fertilizers manufactured in Nigeria.

(k) A notarized declaration as prescribed by the Agency.

(l) Specimen labels of the bio-fertilizer.

(m) Adequate samples of the bio-fertilizer as determined by the Agency.

(n) Dossier in the format prescribed by the Agency.

(o) Safety Data Sheet (SDS) that contains the following information:

i. Identification of the Materials and Supplier.
ii. Hazard identification.
iii. Composition/information on ingredients.
iv. First aid measures.
v. Fire fighting measures.
vi. Health Hazard Data.
vii. Stability and reactivity.
viii. Spills or Leak procedures.
ix. Physical, chemical and biological properties.
x. Toxicological information
xi. Ecological information
xii. Transport information
xiii. Handling and storage condition
xiv. Commercial Applications.
xv. Exposure control
xvi. Personal Protection Equipment.

(2) No person shall submit false notarized declaration to the Agency for the purpose of registration of a bio-fertilizer.

Establishment inspection

6. The Agency shall undertake the inspection of an establishment for the purpose of registration of bio-fertilizer.

Labeling

7. The labeling of bio-fertilizers shall be legible, unambiguous, in English Language and shall include the 3 major Nigerian languages and in accordance with the Bio-fertilizer Labeling Regulations 2014

Issuance of certificate of registration

8. (1) The Agency may approve an application for the registration of bio-fertilizers if:

a. The application contains the information required under these regulations.

b. The bio-fertilizer contains ingredients that have been previously assessed or evaluated in accordance with these Regulations and meets the requirement of registration under these Regulations.
c. Premises where the bio-fertilizer is to be stored, manufactured, warehoused or sold has been found suitable by the Agency.

(2) Where the Agency is satisfied with the application for registration and receives a satisfactory field trial reports in respect of the bio-fertilizer, the bio-fertilizer shall be issued with a certificate of registration.

(3) Where the application for registration or field trial reports or both are unsatisfactory, the applicant shall be informed in writing with reasons.

Validity of approval

9. The certificate of registration shall be valid for a period of 5 years from the date of issue.

Invalidation of Certificate of Registration

10. (1) The Agency may suspend, withdraw or cancel the certificate of registration of a bio-fertilizer if:

(a) The standard of quality, safety and efficacy as prescribed in the documentation for registration are not being complied with; or
(b) The grounds on which the bio-fertilizer was registered were later found to be false or incomplete; or
(c) New information has become available to the Agency which renders the bio-fertilizer unsafe or dangerous or ineffective; or
(d) The premises in which the bio-fertilizer is imported, manufactured, packaged or stored by or on behalf of the holder of the certificate of registration are unsuitable for the import, manufacturing, packaging, storage and use of the bio-fertilizer; or
(e) The holder of a certificate of registration notifies the Agency in writing of his intentions to stop the manufacture, importation, distribution, sale or use of the bio-fertilizer; or
(f) There is adverse effect on non-target animal or plant.

(2) A person whose certificate of registration has been suspended shall desist from dealing in bio-fertilizers in any manner until:

(a) The reason for the suspension is determined and resolved.
(b) Approval is given by the agency to resume operations.

Demand for the evidence of registration

11. A manufacturer or importer of bio-fertilizer shall be required to produce, within forty eight hours, the evidence of registration in respect of any bio-fertilizer manufactured or imported by him or by any person duly authorized by the Agency.

Advertisement

12. No advertisement shall be published, screened or broadcast without prior approval of the Agency, in accordance with the Bio-fertilizer Advertisement Regulations 2014.

Packaging

13. (1) Every package for a bio-fertilizer shall be approved by the Agency.

(2) The package of a bio-fertilizer shall be designed to;

(i) Maintain the integrity of the product under normal storage conditions, display and distribution.

(ii) Permit the withdrawal of some or all of the contents in a manner that is safe to the user.

(iii) Permit the closing of the package in a manner that prevents the spillage of the Bio-fertilizer under normal handling conditions.

(iv) Minimize the degradation or change of its contents under normal storage conditions.

Storage/Distribution

14. (1) Bio-fertilizers shall be stored and displayed in accordance with the conditions stated on the label.

(2) Bio-fertilizers shall not be stored or displayed with human food or animal feed.

Mandatory reports

15. (1) A manufacturer or importer of bio-fertilizers shall keep record of distribution and submit a mandatory report to the Agency annually indicating the names and addresses of companies supplied as well as the quantities supplied.

(2) Any establishment engaged in the manufacture, importation, distribution, sale or storage of bio-fertilizers shall submit preliminary and final reports to the Agency of any adverse effect on non-target animal or plant and loss of efficiency associated with the bio-fertilizers occurring in Nigeria or elsewhere.

Disposal

16. Disposal of any expired, degraded or obsolete bio-fertilizers shall be carried out by the competent authority in the presence of staff of the Agency.

Penalty

17. (1) Any person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction:

(a) In case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding ₦50,000 or both fine and imprisonment : and

(b) In case of a body corporate, to a fine not exceeding ₦100, 000.

(2) Where an offence under these regulations is committed by a body corporate or firm or other association of individuals:

(a) Every director, manager, or other similar officer of the corporate; or

(b) Every partner or officer of the firm; or

(c) Every trustee of the body concerned; or

(d) Every person concerned in the management of the affairs of the association; or

(e) Every person who was purporting to act in a capacity referred to in this paragraph, are severally guilty of what offence and liable to be proceeded against and punished for that offence in the same manner as if they had themselves committed the offence, unless they

prove that the act or omission constituting the offence took place without their knowledge, consent or connivance.

Forfeiture

18. In addition to the penalty specified in Regulation 17 above of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the Bio-fertilizer and whatsoever is used in connection with the commission of the offence.

Interpretation

19. In these Regulations, unless the context otherwise requires,

"Accredited Research Institute" means an approved standard establishment endowed for doing research.

"Agency" means the National Agency for Food and Drug Administration and Control (NAFDAC).

"Bio-fertilizer" means substances which contain living microorganisms which when applied to the seed, plant surface, or soil, colonizes the rhizosphere or the interior of the plant and promote growth by increasing the supply or availability of primary nutrients to the host plants.

"Certificate of analysis" means a certificate issued by a certified analyst certified for the relevant analysis**,** indicating the full chemical and physical composition for the particular bio-fertilizer and its maximum levels of potentially harmful elements permitted in bio-fertilizer.

"Competent authority" means Government agency or statutory authority.

"Compost bio-fertilizers" means bio-fertilizers that contain microorganism that breaks down organic matter to enrich soil with nutrients.

"Container" means the packaging in which a measured amount of a bio-fertilizer is offered for sale;

"Field trial" means a scientific evaluation conducted by an approved research institution on a bio-fertilizer in accordance with direction specified for the use of that bio-fertilizer, to ascertain and establish the claims made on the label.

"Field trial centre" means a location approved for the field trial of a bio-fertilizer.

"Guaranteed analysis" means the stated minimum and/or maximum nutrient value of a bio-fertilizer;

"Label" means any writing, printed or graphic matter relating to, and accompanying the bio-fertilizer.

"Micro-nutrients bio-fertilizer" means bio-fertilizers that contain microorganism (bacterial species) that can solubilize or degrade silicate, zinc and aluminum silicate in soils e.g. Bacillus spp.

"Nitrogen fixing bio-fertilizers" means a bio-fertilizer using living organisms (bacteria, fungus, protozoa) to continuously supply nutrients especially nitrogen, phosphorus and potassium into soil for agricultural purposes.

“Phosphate bio-fertilizers” means bio-fertilizers that solubilizes the insoluble phosphate from organic and inorganic phosphate sources.

“Plant growth promoting rhizobacteria” means bio-fertilizer that promotes plant growth by improved nutrient availability and phytohomones production.

"Plant nutrient" means an essential macro or micro-element present in bio-fertilizer.

Citation

21. These Regulations may be cited as Bio-fertilizers Registration Regulations 2014.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL (NAFDAC)

Bio-fertilizer Labeling Regulations 2014

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL (NAFDAC)

BIO-FERTILIZER LABELING REGULATIONS 2014

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of National Agency for Food and Drug Administration and Control Cap N1 Laws of Federation of Nigeria 2004 and powers enabling it in that behalf, the GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL WITH THE APPROVAL OF THE HONORABLE MINISTER OF HEALTH hereby makes the following Regulations:-

Scope

1. These Regulations shall apply to the labeling of bio-fertilizers.

Prohibition

2. Except as provided in these Regulations, no person shall manufacture, import, export, distribute, advertise, sell or use a bio-fertilizer in Nigeria unless it is labeled in accordance with the provisions of these Regulations.

Labeling information

3. (1) All information on a label shall be prominent, legible and distinct.
   (2) All information shall be in English language and shall include the 3 major Nigerian Languages.
   (3) Labeling shall be informative and accurate and neither promotional in tone nor false or misleading.
   (4) The labeling claims shall be based on data derived from field trial reports.

Name and address on label

4. (1) The label of a bio-fertilizer shall specify conspicuously the name and location address of the manufacturer, and where applicable name and address of packer or distributor.
(2) Where a bio-fertilizer is not manufactured by a person whose name appears on the label, the name and location address of the manufacturer shall be indicated by a phrase that reveals the connection between the parties e.g. "Manufactured by…….for…….”
‘Manufactured for……by…….", or any other wording that expresses the facts.

Declaration of ingredients

5. The label of a bio-fertilizer shall indicate;
(1) Genus and species of the microorganism.
(2) The minimum number of active viable cells per gram of bio-fertilizer of the active genus or species of the microorganism.
(3) Class of the bio-fertilizer.

Net content

6. Bio-fertilizer label shall contain the content of the active ingredients expressed;

i. In the case of a liquid bio-fertilizer, as a percentage by mass, or mass per unit volume, or both, as may be required by the Agency.
ii. In the case of dust, wettable powder or other dry formulations, as a percentage by mass; or
iii. Where subparagraphs (i) and (ii) do not apply, in terms acceptable to the Agency and the active ingredient shall include the viscosity, specific gravity, particle size or such other properties or specifications determined by the Agency.

Date marking instructions

7. (1) The day, month and year of manufacture and expiry shall be clearly stated in an un-coded chronological order on both the inner and outer label.

(2) The batch number shall be indicated on the label of all bio-fertilizers.

(3) The batch number and date markings shall not be pre-printed on the label.

Storage condition

8. The required storage conditions shall be specified on both the inner and outer label.

Trade Mark

9. The trade mark shall be displayed on the label in a manner such that it shall not give a wrong impression of the nature and quality of the bio-fertilizer.

Registration number

10. Every bio-fertilizer shall bear the Agency Registration Number issued on registration in a manner as prescribed by the Agency.

Precautionary statement

11. Bio-fertilizer shall be clearly labeled with conspicuous precautionary statements written legibly and indelibly in English and the 3 major Nigerian Languages indicating;

(a) Feeding the bio-fertilizer to animals is illegal.

(b) The bio-fertilizer is not to be used on pasture land or other grazing area for animals

(c) A person should wash his or her hands after the use of the bio-fertilizer.

(d) The bio-fertilizer should be kept out of reach of children.

Toxicological Information

12. The following toxicological information shall be included on the label of any bio-fertilizer:

(a) Information identifying any significant hazards with respect to the handling, storage, display, distribution and disposal of the bio-fertilizer.

(b) Instruction on procedures to alleviate the hazards.

(c) Instruction on decontamination procedures and disposal of the bio-fertilizer and the empty package.

(d) Information essential for the treatment of a person poisoned or otherwise injured by the bio-fertilizer and shall;

i. Describe the symptoms of poisoning.

ii. State remedial measures.

iii. State the ingredients that may affect the treatment.

Additional Labeling requirement for bio-fertilizer

13. The following information shall also be indicated on the bio-fertilizer label:

(a) A statement directing the user to read the label, this statement shall be in the following form "READ THE LABEL BEFORE USE";

(b) The class of such bio-fertilizer;

(c) Type of formulation;

(d) The Guaranteed analysis of the bio-fertilizer stating ;

i. The genus and species name of the microorganism in the bio-fertilizer.

ii. The minimum number of active viable cells per gram of bio-fertilizer of the active genus or species of microorganism in the biofertilizer.

(e) The use of bio-fertilizers shall be declared and shall include:

i. Methods of application

ii. Field of application

iii. Intervals of application.

(f) Warning or cautions and hazard statements.

(g) Methods of disposal of containers.

Penalty

14. (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction:

(a) In case of an individual to imprisonment for a term not exceeding two years or to a fine not exceeding N50, 000 or to both such imprisonment and fine.

(b) In the case of a corporate body to a fine not exceeding N100, 000

(2) Where an offence under these regulations is committed by a corporate body or other association of individual-

(a) Every director, manager, secretary or other similar officer of the corporate body or

(b) Every partner or officer of the firm; or

(c) Every trustee of the body concerned; or

(d) Every person concerned in the management of the affairs of the association; or

(e) every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture

15. In addition to the penalty specified in Regulation 14 above of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the Bio-fertilizer and whatsoever is used in connection with the commission of the offence.

Interpretation

16. In these Regulations, unless the context otherwise requires –

"Agency" means the National Agency for Food and Drug Administration and Control (NAFDAC);

“Bio-fertilizer” means substances which contain living microorganisms which when applied to the seed, plant surface, or soil, colonizes the rhizophere or the interior of the plant and promote the growth by increasing the supply or availability of primary nutrients to the host plants.

"Expiry date" means any date after which a bio-fertilizer is not recommended for use;

“Field trial” means a scientific evaluation conducted by an accredited research institution on a bio-fertilizer in accordance with direction specified for the use of that bio-fertilizer, to ascertain and establish the claims made on the label of that bio-fertilizer.

"Label" means any writing, printed or graphic matter relating to, and accompanying the bio-fertilizer.

"Package" means any suitable container in which any bio-fertilizer is wholly or partly placed or packed;

Citation

17. These regulations may be cited as Bio-fertilizer Labeling Regulations 2014.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL (NAFDAC)

Bio-Pesticide Registration Regulations 2014

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

BIOPESTICIDES REGISTRATION REGULATIONS 2014

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 29 of NAFDAC Cap NI Laws of Federation of Nigeria 2004 and powers enabling it in that behalf, the GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health makes the following Regulations:

Scope

1. These Regulations prescribe the minimum requirements for the importation, exportation, manufacture, distribution, advertisement, sale and use of bio-pesticides in Nigeria.

Prohibition

2. (1) Except as provided in these Regulations no bio-pesticide shall be imported, exported, manufactured, distributed, advertised, sold or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations.

(2) Notwithstanding the provisions of subsection (1) of this regulations, the manufacture, formulation or importation of a bio-pesticide as sample for the purpose of registration, field trial or research shall be undertaken with the approval of the Agency.

(3) No person shall package, label or advertise a bio-pesticide in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quality, composition, merit or safety.

Classification of bio-pesticides

3. Bio-pesticides shall be classified into:
   (1) Microbial pesticide
   (2) Biochemical pesticides
   (3) Plant incorporated protectant pesticides.

Application for registration:

4. (1) No person shall manufacture or formulate a bio-pesticide unless it has been registered in accordance with the provisions of these regulations.

(2) The application for a bio-pesticide registration shall be made on a prescribed application form obtainable from the Agency.

(3) Each application for registration shall be accompanied with a non-refundable fee as the Agency may, from time to time prescribe.

Submission of application

(5) (1) Application for the registration of bio-pesticides shall be submitted with the following:

(a) Power of Attorney or a contract manufacturing agreement between the manufacturer and the applicant duly notarized in the country of origin to register the bio-pesticide in Nigeria.

(b) Certificate of manufacture and free sale of the bio-pesticide from the statutory body responsible for the safety of the bio-pesticide in the country of origin.

(c) Company certificate of incorporation in Nigeria.

(d) Evidence of trademark registration.

(e) Original certificate of analysis of the bio-pesticide.

(f) Field trial report of trials conducted in Nigeria by an approved research institute in more than 2 agro ecological zones for 2 cropping seasons to determine the biological efficacy and effectiveness of the bio-pesticide

(g) Guaranteed analysis of the bio-pesticide stating;

iii. The genus and species name of the microorganism in the bio-pesticide.

iv. The minimum number of active viable cells per gram of the active genus and species of microorganism in the bio-pesticide.

(h) Evidence of substantiation of special labelling claims on the character, quality and safety of the bio-pesticide.
(i) Invitation letter for Good Manufacturing Practice (GMP) inspection from oversea manufacturers; or
(j) Application letter for inspection of local production facility for bio-pesticides manufactured in Nigeria.
(k) A notarized declaration as prescribed by the Agency.
(l) Specimen labels of the bio-pesticide.
(m) Adequate samples of the bio-pesticide as determined by the Agency.
(n) Dossier in the format prescribed by the Agency
(o) Safety Data Sheet (SDS) that contains the following information:

xvii. Identification of the Materials and Supplier.
xviii. Hazard identification.
xix. Composition and information on ingredients.
xx. First aid measures.
xxi. Fire fighting measures.
xxii. Health Hazard Data.
xxiii. Stability and reactivity.
xxiv. Spills or Leak procedures.
xxv. Physical, chemical and biological properties.
xxvi. Toxicological information
xxvii. Ecological information
xxviii. Transport information
xxix. Handling and storage condition
xxx. Commercial Applications.
xxxi. Exposure control
xxxii. Personal Protection Equipment.

(2) No person shall submit false notarized declaration to the Agency for the purposes of registration of a bio-pesticide.

Labelling

6. The labelling of bio-pesticide shall be legible, unambiguous, in English Language and shall include the 3 major Nigerian languages and in accordance with the Bio-pesticide Labelling Regulations 2014.

Establishment inspection

7. The Agency shall undertake the inspection of an establishment for the purpose of registration of bio-pesticide.

Issuance of certificate of registration

8. (1) The Agency may approve an application for the registration of bio-pesticide if:
   d. The application contains the information required under these regulations.
   e. The bio-pesticide contains ingredients that have been previously assessed or evaluated in accordance with these regulations and meets the requirement of registration under these Regulations

f. Premises where the bio-pesticide is to be stored, manufactured, warehoused or sold has been found suitable by the Agency.

(2) Where the Agency is satisfied with the application for registration and receives a satisfactory field trial reports in respect of the bio-pesticide, it shall be issued with a certificate of registration.

(3) Where the application for registration or field trial reports or both are unsatisfactory, the applicant shall be informed in writing with reasons.

Validity of approval

9. The certificate of registration shall be valid for a period of 5 years from date of issue.

Invalidation of Certificate of Registration

10. (1) The Agency may suspend, withdraw or cancel the registration of a bio-pesticide if;

(g) Standard of quality, safety and efficacy as prescribed in the documentation for registration are not being complied with; or

(h) The grounds on which the bio-pesticide was registered were later found to be false or incomplete; or

(i) New information has become available to the Agency which renders the bio-pesticide unsafe or dangerous or ineffective; or

(j) The premises in which the bio-pesticide is imported, manufactured, packaged or stored by or on behalf of the holder of the certificate of registration are unsuitable for the import, manufacturing, packaging or storage and use of the bio-pesticide; or

(k) The holder of a certificate of registration notifies the Agency in writing of his intentions to stop the manufacture, importation, distribution, or sale of the bio-pesticide; or

(l) There is adverse effect on non-target animal or plant.

(2) A person whose certificate of registration has been suspended shall desist from dealing in that bio-pesticide in any manner until:

(c) The reason for the suspension is determined and resolved.

(d) Approval is given by the agency to resume operations.

Demand for evidence of registration

11. A manufacturer or importer of bio-pesticides shall be required to produce within forty eight hours the evidence of registration in respect of any bio-pesticide manufactured or imported by him or by any person duly authorized by the Agency.

Advertisement

12. No advertisement shall be published, screened or broadcast without prior approval of the Agency in accordance with the Bio-pesticide Advertisement Regulations 2014.

Packaging

13. (1) Every package for a bio-pesticide shall be approved by the Agency.

(2) The package of a bio-pesticide shall be designed to

(i) Maintain the integrity of the bio-pesticide under normal storage condition, display and distribution.

(ii) Permit the withdrawal of some or all of the contents in a manner that is safe to the user.

(v) Permit the closing of the package in a manner that prevents the spillage of the bio-pesticide under normal handling conditions.

(vi) Minimize the degradation or change of its contents under normal storage conditions.

Storage/distribution:

14. (1) Bio-pesticide shall be stored and displayed in accordance with any conditions stated out on the label.

(2) Bio-pesticide shall not be stored or displayed with human food or animal feed.

Mandatory Reports

15. (1) A manufacturer or importer of bio-pesticide shall keep record of distribution and submit a mandatory report to the Agency annually indicating the names and addresses of companies supplied as well as the quantities supplied.

(2) Any establishment engaged in the manufacture, importation, distribution, sale or storage of bio-pesticide shall submit preliminary and final reports to the Agency of any adverse effect on non-target animal or plant and loss of effectiveness associated with bio-pesticide occurring in Nigeria or elsewhere.

Disposal

16. Disposal of any expired, degraded or obsolete bio-pesticide shall be carried out by the competent authority in the presence of staff of the Agency.

Penalty

17. (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of:

(a) an individual, to imprisonment for a term not exceeding two year or to a fine not exceeding ₦50, 000 or both imprisonment and fine; and

(b) a body corporate, to a fine not exceeding ₦100, 000.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals:-

(a) every director, manager, secretary or other similar officer of the body corporate; or

(b) every partner or officer of the firm or

(c) every trustee of the body concerned; or

(d) every person concerned in the management of the affairs of the association; or

(e) every person who was purporting to act in a capacity referred to in paragraph (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture

18. In addition to the penalty specified in Regulation 16 above of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the bio-pesticide and whatsoever is used in connection with the commission of the offence.

Interpretation

19. In these regulations, unless the context otherwise requires,

"Agency" means the National Agency for Food and Drug Administration and Control (NAFDAC).

"Bio-pesticides" are pesticides derived from such natural materials as animals, plants, bacteria, and some minerals and include microorganisms, naturally occurring substances that control pest.

"Certificate of Analysis" means a certificate issued by an analyst certified for the relevant analysis**,** indicating the full chemical and physical composition for the particular bio-pesticide and its maximum levels of potentially harmful elements permitted in bio-pesticide.

"Competent Authority" means Government agency or statutory authority.

"Container" means the packaging in which a measured amount of a bio-pesticide is offered for sale;

"Field trial" means a scientific evaluation conducted by an accredited research institution on a bio-pesticide in accordance with direction specified for the use of that bio-pesticide, to ascertain and established the claims made on the label of that bio-pesticide.

"Field trial centre" means a location approved for the field trial of a bio-pesticide.

"Label" means any writing, printed or graphic matter relating to, and accompanying the bio-pesticide

"Microbial pesticide" means a biopesticides consisting of micro-organisms as the active ingredient.

"Plant incorporated protectant pesticide" means pesticidal substances produced by plant containing added genetic materials.

Citation

20. These regulations may be cited as Bio-pesticides Registration Regulations 2014.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL (NAFDAC)

Bio-pesticide Labeling Regulations 2014

NATIONAL AGENCY FOR FOOD AND DRUG ADMINSTRATION AND CONTROL (NAFDAC)

BIO-PESTICIDE LABELING REGULATIONS 2014

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of National Agency for Food and Drug Administration and Control Cap N1 Laws of Federation of Nigeria 2004 and powers enabling it in that behalf, the GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honorable Minister of Health hereby makes the following Regulations:-

Scope

8. These Regulations shall apply to the labeling of bio-pesticide. .

Prohibition

9. Except as provided in these Regulations, no person shall manufacture, import, export, distribute, advertise, sell or use any bio-pesticide unless it is labeled in accordance with the provisions of these Regulations.

Labeling information

10. (1) A label shall be prominent legible and distinct.

(2) All information shall be in English language and shall include 3 major Nigerian languages.

(3) The labeling shall be informative and accurate and neither promotional in tone nor false or misleading.

(4) The claims made on labeling shall be based on data derived from field trial reports.

Name and address on label

4. (1) The label of bio-pesticide shall specify conspicuously the name and location address of the manufacturer and where applicable, name and address of packer or distributor.

(2) Where a bio-pesticide is not manufactured by a person whose name appears on the label, the name and location address of the manufacturer shall be indicated by a phrase that reveals the connection between the parties e.g. "Manufactured by…….for…….". 'Manufactured

for……by…….", or any other wording that expresses the facts.

Declaration of ingredients

5. The label of the bio-pesticide shall indicate;

(1) Genus and species of the microorganism.

(2) The minimum number of active viable cells per gram of bio-pesticide of the active genus or species of the microorganism.

(3) Class of the bio-pesticide.

Net content

6. A bio-pesticide label shall contain the content of the active ingredients expressed;

iv. In the case of a liquid bio-pesticide, as a percentage by mass, or mass per unit volume, or both, as may be required by the Agency.

v. In the case of dust, wettable powder or other dry formulations, as a percentage by mass; or

vi. Where subparagraphs (i) and (ii) do not apply, in terms acceptable to the Agency and the active ingredient shall include the viscosity, specific gravity, particle size or such other properties or specifications determined by the Agency.

Date marking instructions

7. (1) The day, month and year of manufacture and expiry shall be clearly stated in an un-coded chronological order on both the inner and outer label.

(2) The batch number shall be indicated on the label of all bio-pesticides.

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(3) The batch number and date markings shall not be pre-printed on the label.

Storage condition

8. The storage conditions shall be specified on both the inner and outer label.

Trade Mark

9. The trade mark shall be displayed on the label in a manner such that it shall not give a wrong impression of the nature and quality of the bio-pesticide

Registration number

10. Every bio-pesticide shall bear the Agency Registration Number issued on Registration certificate in a manner as prescribed by the Agency.

Precautionary statement

11. Bio-pesticides shall be clearly labeled with conspicuous precautionary statements written legibly and indelibly in English and shall include the 3 major Nigerian languages indicating;

(e) The bio-pesticide is not to be ingested.

(f) A person should wash his or her hands after the use of the bio-pesticide.

(g) The bio-pesticide should be kept out of reach of children.

Toxicological Information

12. The following toxicological information shall be included on the label of any bio-pesticide;

(a) Information identifying any significant hazards with respect to the handling, storage, display, distribution and disposal of the bio-pesticide.
(b) Instruction on procedures to alleviate the hazards.
(c) Instruction on decontamination procedures and disposal of the bio-pesticide and the empty package.
(d) Information essential to the treatment of a person poisoned or otherwise injured by the bio-pesticide and shall
(i) Describe the symptoms of poisoning.
(ii) Remedial measures.
(iii) State the ingredients that may affect the treatment.

Additional labeling requirement for bio-pesticide

13. The following information shall also be indicated on the bio-pesticide label:
(h) A statement directing the user to read the label, this statement shall be in the following form "READ THE LABEL BEFORE USE";
(i) The class of such bio-pesticide;
(j) Type of formulation;
(k) The Guaranteed analysis of the bio- pesticide stating ;
iii. The genus and species name of the microorganism in the bio-pesticide.
iv. The minimum number of active viable cells per gram of bio-pesticide of the active genus or species of microorganism in the bio- pesticide.
(l) The use of bio- pesticide shall be declared and shall include;
iv. Methods of application
v. Field of application
vi. Intervals of application.
(m) Warning or cautions and hazard statements;
(n) Methods of disposal of containers.

Penalty

14. (1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction:-
(a) In case of an individual to imprisonment for a term not exceeding two years or to a fine not exceeding ₦50, 000 or to both imprisonment and fine.
(b) In the case of a corporate body to a fine not exceeding ₦100, 000.
(2) Where an offence under these regulations is committed by a corporate body, firm, or other association of individual-
(a) Every director, manager, secretary or other similar officer of the corporate body; or
(b) Every partner or officer of the firm; or
(c) Every trustee of the body concerned; or
(d) Every person concerned in the management of the affairs of the association; or
(e) every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture

15. In addition to the penalty specified in Regulation 14 above of these Regulations, a person

convicted of an offence under these Regulations shall forfeit to the Agency the bio-pesticide and whatsoever is used in connection with the commission of the offence.

Interpretation

16. In these regulations, unless the context otherwise requires:

"Agency" means the National Agency for Food and Drug Administration and Control.

“Bio-pesticides” are pesticides derived from such natural materials as animals, plants, bacteria, and some minerals and include microorganisms, naturally occurring substances that control pest.

"Expiry date" means any date after which bio pesticide or related bio-pesticide is not recommended for use;

“Field trial” means a scientific evaluation conducted by an approved research institution on a bio-pesticide in accordance with direction specified for the use of that bio-pesticide, to ascertain and established the claims made on the label of that bio-pesticides.

"Label" means any writing, printed or graphic matter relating to, and accompanying the bio-pesticide;

"Package" means suitable container in which any bio-pesticide is wholly or partly placed or packed;

Citation

17. These regulations may be cited as the Bio-pesticide Bio-pesticides Labeling Regulations 2014.

Annex 5 Bio-fertilizers registration guidelines for Tanzania

Tanzania Fertilizer Regulatory Authority

Guidelines for Registration of Bio-fertilizers in Tanzania

July, 2014

1. **INTRODUCTION**

In Tanzania, bio-fertilizers are currently captured in the Fertilizers Act under the definition of supplement. These guidelines for registration of bio-fertilizers in Tanzania are therefore developed to provide more guidance not only to applicants/registrants, but also to the staff of the Tanzania Fertilizer Regulatory Authority (TFRA) to ensure consistency in the registration process of bio-fertilizers. The implementation of the registration guidelines as well as applicable standard operating procedures (SOPs) for quality control will also enable the enforcement of compliance. Thus, bio-fertilizers intended for commercialization in Tanzania will have to comply with these guidelines to ensure product safety, quality, efficacy, and proper labelling.

Therefore, the key objectives of these registration guidelines are as follows:

1) To ensure that only registered bio-fertilizers are placed in the marketplace and made available for use by farmers
2) To ensure that only bio-fertilizers that are demonstrated to be of high quality, safe, and efficacious for intended use are registered
3) To ensure that the labels of registered bio-fertilizers contain adequate information for proper, safe use and handling of the products
4) To ensure that marketplace monitoring/surveillance after bio-fertilizer registration is institutionalized
5) To ensure that bio-fertilizers which were introduced in the Tanzanian marketplace prior to implementation of these guidelines are re-evaluated for conformity to the requirements outlined herein

The scope of these registration guidelines shall only cover bio-fertilizers containing naturally occurring microorganisms; in other words, microorganisms that have not been genetically engineered. For bio-fertilizers containing genetically modified organisms (GMOs), the TFRA shall direct the product proponents/potential registrant to the appropriate regulatory authority in Tanzania. Such an issue could be discussed during the pre-consultation meeting. Therefore, GMOs are out of the scope of these guidelines.

2. USE OF THE GUIDELINES

The guidelines for the registration of bio-fertilizers have been developed by TFRA to ensure bio-fertilizers placed in the Tanzanian market are in compliance with relevant standards and regulations. In that regard the registration will ensure that bio-fertilizers in the market are efficacious for the intended purpose and safe to plants, animals, humans, and the environment when used as directed. Registration of bio-fertilizers by TFRA will facilitate control and monitoring of these products by ensuring that only registered products are legally approved for sale and use in Tanzania. Therefore, these guidelines have been developed to provide registration procedures to be followed by TFRA and bio-fertilizer traders in Tanzania for regulation and market facilitation purposes. Availability of documented guidelines will provide transparency on regulation procedures and alignment of business plan accordingly before and during application for the registration.

SCOPE

Registration guidelines shall only cover bio-fertilizers containing naturally occurring microorganisms that have not been genetically modified in any way, and in any other case shall be declared by the registrant or manufacturer.

3. REGISTRATION PROCEDURES

3.1 Pre-submission

3.1.1 Letter of intention

When requesting a pre-submission meeting, a letter of intention should be addressed to the Chief Executive Officer (CEO) of TFRA. It will include at least a brief description (maximum 2 pages) of the intended use of the bio-fertilizer; the manufacturing company; the registrant's name and contact information; and the local agent's name and contact information when the registrant is not a Tanzanian resident. Equally important, the letter of intention should indicate whether the product has been approved for use in other countries in agricultural production. If it has not been used elsewhere, the letter should substantiate the reason. If at a later date the product proponent decides to apply for registration of the bio-fertilizer, the letter of intention

will be transferred into the application package. The pre-consultation meeting is scheduled within 10 working days after the reception of the letter of intention, unless otherwise advised by the applicant.

3.1.2 **Consultation**

A pre-submission consultation meeting is proposed to provide guidance and advice to registrants prior to submission of an application package for registration. The pre-consultation meeting shall be face-to-face. Prior to or during the meeting, the following information shall be supplied in addition to the letter of intention:

- Details of the identity of the bio-fertilizer
- List of active agent(s)
- Tentative product marking and labelling information
- Proof of ownership of the bio-fertilizer to be registered
- Presentation of the research and development (R&D) data related to the efficacy of the bio-fertilizer (if available)
- Brief rationale of product safety and quality (maximum 2 pages)

The discussion is intended to ensure that the registrant submits a comprehensive application package for the bio-fertilizer registration. TFRA will answer questions of the registrant and clarify any issues related to the registration guidelines, quality control criteria, or regulatory requirements.

3.1.3 **Feedback to applicants on the pre-submission meeting**

After the consultation meeting, TFRA shall send a summary of the discussion and feedback on any issues that have not been adequately addressed during the discussion (e.g., information from an external source). The summary shall include a comprehensive list of items required for the registration process. TFRA's feedback shall be sent in writing to the registrant within 20 working days to the physical address indicated in the letter of intention and using registered mail. Equally important, the feedback shall outline the way forward including, but not limited to, the following information:

i. Confirmation that the applicant is a suitable registrant as being the owner of the bio-fertilizer or in a suitable relationship with the owner based on information provided during the pre-consultation meeting.
ii. Authorization to apply for the product registration by submitting all the required items in a single package.
iii. A comprehensive list of the safety, efficacy, and marking and labelling requirements.
iv. Confirmation of data waivers if applicable (e.g., in case of equivalence of data).
v. Information on the handling procedures of confidential business information (CBI).
vi. Details on the required fees to be paid along with submission as well as the fee structure including annual fee and other costs (i.e. cost of reviews of the label, efficacy, quality, and safety data in the application package; cost of the quality control; and cost of efficacy trials).
vii. Other administrative requirements as applicable.
viii. When, based on information provided, the product requires review by multiple registration authorities (e.g., TFRA and the Tropical Pesticides Regulatory Institute [TPRI]), an explanation of the applicable procedures.
ix. Expected timeframe of application reviews.

3.2 **Application procedures for registration of a bio-fertilizer**

3.2.1 **Administrative requirements**

The administrative requirements are meant to provide applicants with enough information to prepare the registration package based on the regulatory requirements and procedures. ***Annex 1*** includes details of the checklist to be used. The following outlines the minimum items required for the application package for bio-fertilizer registration.

3.2.1.1 *Application form*

Applicants shall be required to complete an application form (***Annex 2***) by providing a summary of the information about the product as described in the application form.

3.2.1.2 *Registration fees*

The registration fee includes document/data review fees, payable to TFRA. It doesn't include the cost for factory inspection, efficacy and safety data generation, and testing for compliance to standards; these payments should be paid directly to the institutions/organizations generating the data and they are not controlled by TFRA. TFRA only specifies the minimum data required; however, the efficacy and quality data should be generated by an institution approved by TFRA. The fee structure applied by TFRA for bio-fertilizers registration is available on request.

3.2.1.3 *Authorized representatives*

To ensure that confidential business information (CBI) is not released to unauthorized individuals, the applicant should provide in writing a list of maximum three persons authorized to request information on the product file when necessary. Details on the individuals including their contact information, physical address, and their relationship with the product proponent should be specified. Any other person who is TFRA-authorized staff and who is not included in the list of the applicant shall not have access to information in the product file or details related to the registration process for the specific bio-fertilizer. The applicant can modify the list at any time in writing. However, TFRA will not be responsible for any damage that may occur during the transition period, i.e. from the initial list to the revised list of authorized individuals. It is the responsibility of the applicant to ensure that TFRA receives the correct and valid information on time. Once the amended list is received TFRA shall immediately implement the change.

3.2.1.4 *Declaration of local agent*

When an applicant is not a citizen of Tanzania, he/she must have a Tanzanian citizen as local representative or agent (also known as country representative). An official letter signed by the product proponent and countersigned by the local agent should be submitted to TFRA. The local agent must be included in the list of authorized representative(s).

3.2.2 **Efficacy requirements**

In addition to the administrative requirements, the application package should include efficacy data generated by an institution/organization approved by TFRA. The efficacy data shall include performance data generated based on the requirements in these registration guidelines. A summary of the efficacy data (maximum 5 pages) should be submitted alongside any other relevant supporting data.

Upon reviewing the nature of guarantees or claims displayed on a product label, TFRA shall determine the type of efficacy data to be submitted. Similarly, if the efficacy of a given use-pattern is not well established TFRA may request efficacy data to substantiate the recommended use-pattern. Stated differently, each usage pattern or direction for use on the product label is treated as a claim, and must be supported by scientifically valid efficacy data. Anecdotal or testimonial evidence will not be accepted. Below are the minimum requirements for efficacy data; however, TFRA reserves its rights to requested additional information when deemed necessary.

3.2.2.1 *Good Quality System Procedures*

It is recommended that efficacy trials be conducted using Laboratory Quality System Procedures (LQSP; also known as Good Experimental Practices or GEP). The primary goal of LQSP (***Annex 3***) is to ensure that all efficacy trials conducted are of high quality and the results derived are reliable enough to support the registration of a bio-fertilizer. This is particularly important in the context of mutual recognition across countries. Hence, only institutions/organizations that can demonstrate adequate LQSP will be approved by TFRA to generate efficacy data for product registration. Importantly, the approval duration of the institutions/organizations and research scientists shall be subjected to renewal to ensure the sustainability of the LQSP.

3.2.2.2 *Location of efficacy testing and site selection*

The location of efficacy testing shall be recommended by TFRA. Hence, TFRA shall determine the minimum number of agro-ecological zones (AEZ) where a given bio-fertilizer should be tested. However, the site selection within the recommended AEZ

is left at the discretion of the approved institutions/organizations. The AEZ choice shall also be based on the agricultural production regions for the intended crop(s). The minimum AEZ number shall also depend on where the applicant wants to sell or distribute the product of interest.

In all instances, the efficacy data shall be generated in an environment relevant for the intended use. For instance, greenhouse trials will not be enough to support the efficacy of a bio-fertilizer intended for field use.

3.2.2.3 *Minimum number of trials*

The minimum number of trials required to support product efficacy will vary, depending for instance on the intended usage pattern, intended crops, and label claims. For example, a product intended for soil application, to be used on a single crop with the claim of increased yield, would generally require a low number of trials. However, when the same product is intended for several crops, and the bio-fertilizer label includes several claims in addition to yield increases, the minimum number of trials may significantly increase. In general, the minimum number of trials/sites is set to 6 when the various claims could be tested at the same time at the 6 sites.

3.2.2.4 *Spatial and temporal distribution of the minimum number of trials*

In general, the minimum number of trials should be conducted during more than one growing/cropping season (temporal variability) and in different AEZ or trial sites (spatial variability). The minimum number of growing seasons shall be determined by TFRA and communicated to the registrant in the feedback letter following the pre-submission meeting.

When agreed upon during the pre-consultation meeting, TFRA may grant a waiver for the temporal variability, but shall improve on the spatial variability (i.e. accelerated trials). As such, the minimum number of trials shall be increased as well as the number of AEZ or trial sites. For instance, when the minimum number of trials

capturing the spatial and temporal variability is 6, then the minimum number of accelerated trials shall be 9 trial-sites in various AEZ.

3.2.2.5 *Bio-fertilizer recommended for several crops*

When a bio-fertilizer is recommended for several crops, the following two options shall be discussed during the pre-consultation meeting to optimize the number of trial sites:

1) Representative crops: In the case where the similarities between crops is supported by scientific evidence in terms of physiology and production patterns, the crops may be grouped together based on similarities and the efficacy testing conducted using representative crops from each group. The grouping shall be approved by TFRA before the beginning of the trials. Grouping will not be considered in the case of few crops (e.g., less than 3 crops).

2) Representative sites: When possible, the effect of the bio-fertilizer on the selected crops shall be evaluated at the same sites keeping the same minimum number of trials for each crop.

TFRA reserves the right to determine the most appropriate option for a given bio-fertilizer and crop(s); the decision will be made on a case-by-case basis.

In all instances, if the bio-fertilizer is tested on a reduced number of crops compared to the list in the product label, the label will have to specify the crop species that were used to generate the efficacy data.

3.2.2.6 *Trial design*

A randomized complete block design in which the treatment plots are randomly distributed within each block is recommended. Other designs such as the completely randomized design/plan may be used for trials conducted in completely homogeneous environments, such as greenhouses or growth chambers. There is a general consensus

that the trials should also be designed in a manner that allows at least 10 degrees of freedom to the error term during the analysis of variance (ANOVA).

3.2.2.7 *Preventing cross-contamination between experimental plots*

Guard rows or border plots to prevent treatment overlap and/or drift of product or treatment from one plot to another are recommended. Guard rows are particularly important when the plot size is small. Plot size will vary depending on the crop of interest, the product, and the method of application of the product. The plot size will be discussed during the pre-consultation meeting.

3.2.2.8 *Treatment structure*

Treatments with the bio-fertilizer intended for registration must be compared to one or more check treatments, including but not limited to (a) an untreated control and (b) appropriate comparative treatments (positive controls; for instance a registered bio-fertilizer intended for the same use and with the same mode of action).

3.2.2.9 *Planting window*

When the product label does not recommend to sow the seeds treated with the bio-fertilizer immediately after treatment, the label should specify the timeframe that is allowed between the treatment and planting. Such a timeframe is known as the planting window. The planting window should be substantiated using scientific data to ensure that the required number of viable cells in the bio-fertilizer of interest can be recovered from the seeds at the end of the planting window. The planting window shall be demonstrated not only based on laboratory data (counting), but also field data obtained when the product is tested at the end of the planting window. A tolerance of one tenth of the recommended planting window will be tolerated; however, the tolerance won't exceed 7 days when the planting window is significantly long.

3.2.2.10 *Equivalence of data*

When data collected in other countries are found to be relevant in Tanzania based on the similarity of the agro-climatic conditions, TFRA will apply the principle of

equivalence data, also known as mutual recognition. In such a case, TFRA will require a reduced number of trials (half of the minimum number of trials generally required and in a single growing season) to confirm the efficacy of the product under the local conditions. The equivalence of data shall be granted based on the merit of the rationale and evidence provided to support the similarity of the agro-climatic conditions.

3.2.2.11 *Expiry date and shelf life for bio-fertilizers*

The active ingredients in bio-fertilizer products are subjected to degradation or loss of viability over time. A bio-fertilizer label shall display an expiry date, i.e. the date after which the required minimum number of viable cells can no longer be guaranteed. Alternatively, the product label shall display the manufacturing date and the shelf life; the shelf life represents the expected storage duration (from the manufacturing date) within which the required minimum number of viable cells can be guaranteed when the bio-fertilizer is stored under the recommended conditions.

3.2.2.12 *Measurable parameters*

When evaluating the efficacy of a bio-fertilizer, data should be collected before planting, during the growing season, and at harvesting. TFRA will discuss with the applicant the minimum measurable parameters required, as this is a critical determinant in the registration process.

a) **Before planting**: To ensure that product efficacy is evaluated in appropriate conditions, the initial soil fertility level should be evaluated prior to the establishment of the trials. Soil analysis prior to treatment should include (but is not limited to): soil texture, pH, cation-exchange capacity, organic matter content, availability of selected plant nutrients, functional microorganisms of interest (in this case of bio-fertilizers), etc. This information should be collected regardless of the label claims.
b) **During the growing season**: After the application of the treatment, minimum weather data including the ambient temperature, humidity, and rainfall should be collected. In addition to the initial soil testing, information on weather conditions could also be used to explain any spatial or temporal variability.

Other measureable parameters shall be based on the label claims, but don't have to be limited to the label claims. Measurable parameters will include, but are not limited to, the following:

1) Visual symptoms of nutrient, abiotic, and biotic stress (when observed)
2) Pod numbers for legumes
3) Uptake of plant nutrients of interest at a specific growth stage
4) Number, weight, and colour of nodules in the case of rhizobium inoculants
5) Intensity of root colonization/infection, and root and hyphal length in the case of mycorrhizal inoculants
6) Root architecture in the case of plant growth promoting rhizobacteria

c) At harvesting: The following measurement parameters should be considered. Crop yield remains by far the most critical parameter.

1) Tissue analysis for nutrient uptake (i.e. major, secondary, and micro-nutrients depending on the product of interest)
2) Crop yields (particularly grain yield when applicable, haulms, husks, etc.)
3) Quality of the crop yields when applicable (based on label claim)

3.2.2.13 *Data analysis*

The data should be statistically analysed, including descriptive statistics and analysis of variance (ANOVA) using accepted software (e.g., SAS, R). The method of statistical analysis should be considered prior to conducting the trial. The level of significance and the mean separation techniques should be the ones that are commonly used in the field of interest (e.g., probability of 5% and the least significant difference i.e. LSD). Anecdotal or testimonial evidence should not be considered as a scientifically valid form of efficacy data, and therefore should not be accepted to support product approval for registration; however, such evidence could be used as background information. Hence, all label claims must be adequately supported by scientific data that has been statistically analysed and demonstrates a statistically significant benefit. The statistical analysis should be consistent across AEZ for the same product and treatments.

3.2.2.14 *Profitability analysis*

Economic evaluation of crop responses to bio-fertilizers is important to assess their profitability, particularly in the context of smallholder farmers. The benefit cost ratio (BCR) is one of the tools used to conduct such an evaluation, particularly when yield is considered. BCR is the ratio of the net value of extra crop produced to the cost of the bio-fertilizer (Eq. 1). In actual practices, a BCR of 2.5 and above is considered to be satisfactory for the adoption of the technology. However, some authors have indicated that a BCR > 1 is already attractive for farmers. Taking into consideration other costs, including credits and risk taken, the higher the BCR the better. For the purpose of bio-fertilizer registration, TFRA shall accept BCR values ≥ 1. Such BCR values shall be shown in at least 60% of the trial sites for a bio-fertilizer to be registered by TFRA.

$$\frac{Value\ of\ additional\ crop\ produced - cost\ of\ the\ biofertilizer}{Cost\ of\ the\ biofertilizer} \qquad \text{(Eq. 1)}$$

3.2.3 **Safety requirements**

A package of safety data should be prepared. In addition to the supporting document(s), a rationale not exceeding 5 pages to substantiate the safety of the bio-fertilizer should be provided. Basically, the applicant shall demonstrate that each ingredient in the product formulation is present at a level expected to be safe to humans, animals, plants, and the environment when used as directed. Also, the safety of the formulation when all the ingredients are mixed together should be demonstrated i.e. mixing the ingredients results in a product equally safe. Equally important, the level of non-guaranteed micro-organisms in the bio-fertilizer product should not be higher than the tolerance prescribed in the quality-control standard-operational-procedure applicable to the specific product. TFRA will keep a database of approved SOPs to be used for quality control of bio-fertilizers sold in Tanzania. No pathogen micro-organism or ingredient will be tolerated in a bio-fertilizer intended for sale in Tanzania. TFRA reserves the right to ask for additional safety information on the bio-fertilizer not only during the registration process, but also during the post-registration period when deemed necessary. The level of contamination of bio-fertilizers will be evaluated by laboratories approved by TFRA.

The requirements to establish the safety of a bio-fertilizer include, but are not limited to, the following:

1. Summary (5 pages maximum) of the technical dossier related to the safety of the product (i.e. bio-safety assurance statement on pathogenicity, gene flow, invasiveness, persistence, and effect on non-target organisms, among others)
2. Evidence (i.e. data and/or biographical references) supporting the safety of the bio-fertilizer
3. Information on the safety of the carrier material (when applicable)
4. Manufacturing process
5. Quality assurance (QA) and quality control (QC) procedures of the manufacturing plant (i.e. company self-evaluation on quality)
6. Information on the strain(s) including the source, identification, and taxonomy
7. Declaration that the bio-fertilizer does not contain GMO ingredients
8. Material safety data sheet (MSDS) of the bio-fertilizer and ingredients (when available)
9. Any additional information and supporting documents or items deemed necessary by the applicant or TFRA

3.2.4 **Labeling and packaging requirements**

3.2.4.1 *Product label*

The applicant should provide a proposed tentative product label to allow correct use of the bio-fertilizer during the efficacy testing and its safe handling. Based on the efficacy and safety data, the label will have to be amended accordingly into a commercial label. The commercial label will also have to include a registration number granted by TFRA as a seal of approval. Equally important, the label of a bio-fertilizer sold in Tanzania shall be at least in both English and Swahili.

Product labels shall not have any incorrect or misleading information, mark, brand, or name that would tend to deceive or mislead the end-user with respect to the composition or benefits of using the product. The approved product label shall be the only commercial label found in the marketplace for the registered bio-fertilizer.

3.2.4.2 *Specific requirements for labelling and packaging*

Any of the items below that is not qualified as optional is by default mandatory.

1. Product name
2. Guarantee analysis: a statement that shows the content (concentration of the active ingredients) of the product, i.e. cfu of active ingredient(s) per gram of finished bio-fertilizer product. TFRA will verify the guarantee analysis using the service of laboratories approved by TFRA for quality control of bio-fertilizers
3. Directions for use: specifying application rates, frequency of application, target crops, application equipment, and method of application, among others (the directions for use should be based on the results of the efficacy trials)
4. Registration number: seal of approval by TFRA
5. Batch number
6. Manufacturing date
7. Expiry date or shelf life
8. Company information: contact address including the physical address of the place of manufacture
9. Net weight using the International System (IS) of units of measure
10. Cautionary statement (safety statement)
11. Planting window or pre-planting treatment period (when applicable)
12. Storage conditions
13. Handling conditions
14. Disposal statement for both the bio-fertilizer and containers
15. Brand name (optional)
16. Net weight in local equivalence of the IS units of measure (optional)
17. Seller's guarantee: warranty statement in case of damage or product failure when product is used as per the direction for use (optional)
18. Label claims (optional)
19. List of ingredients (optional)
20. Website (optional)

3.2.5 **Quality requirements**

Bio-fertilizer quality is one of the most important factors resulting in its success or failure. The SOPs for the quality control of bio-fertilizers in Tanzania (available on request) will provide detailed quality criteria of specific bio-fertilizers. Items considered for the quality of bio-fertilizers sold in Tanzania include, but are not limited to, the following:

1) Viable cell count for bacteria based products (i.e. cfu per gram of finished bio-fertilizer product)
2) Propagules per gram of finished bio-fertilizer product for arbuscular mycorrhizae fungi (AMF) based products
3) Contamination data at a specific dilution level
4) pH of the bio-fertilizer product
5) Efficacy character of the bio-fertilizer (i.e. quick test of the potential efficacy of the product in controlled environment conditions. This shall not be considered as evidence of field performance)
6) Moisture content (Note: limited to solid formulations, i.e. bio-fertilizers in granular or powder form)
7) Particle size (Note: limited to bio-fertilizers in powder form)

When TFRA does not have a specific SOP to verify the quality of a novel bio-fertilizer, the applicant will have to provide the procedure to TFRA. TFRA shall validate it in its approved laboratories before the bio-fertilizer can be registered.

3.2.6 **Sampling requirements for quality control**

Product sample shall be significantly representative of the bio-fertilizer batches. Adequate precautions shall be taken to prevent contamination of the bio-fertilizer during the sampling process.

3.2.6.1 *General requirements for sampling*

1) Precautions and directions must be observed when drawing, preparing, and handling samples intended for quality control
2) To ensure that representative samples are taken, sampling must be carried out by a qualified, trained and experienced inspector
3) For packaged products, unopened packets should be sampled and sent to the laboratory using appropriate equipment to prevent possible contamination of samples during handling
4) Samples must be taken in the presence of the product proponent or his/her authorized representative
5) Collected samples should not show any visible sign of contamination
6) For quality control, samples shall be taken from representative lots in a random manner
7) Adequate and representative samples for testing should be taken. The product proponent shall retain one unit as a representative sample for re-testing in the case of dispute

3.2.6.2 *Drawing samples*

a) The number of sample-packets to be taken from a lot will depend on the size of the lot. The samples should be randomly selected using a well-established randomization procedure. The sample will be considered a legal sample as the result will be used as a proof of the product compliance to the regulatory requirements.
b) The inspector or any other authorized staff shall take 9 sample-packets from a given lot based on the batch number (3 of the samples will be sent to the laboratory approved by TFRA for quality control; 3 will be handed to the product proponent in case he/she may want to send them to a reference laboratory to cross-validate the result from the approved laboratory; and the remaining 3 will be kept in adequate conditions for re-testing in case of conflicting results or dispute). The product proponent or his/her authorized representative shall sign onto the sampling form of the inspector. When analysing samples, each packet should be analysed separately.
c) The inspector or any other authorized staff should carry with him/her appropriate sampling forms on which to consign information about the sample

and the sampling procedures. He/she should ensure to have appropriate sampling tools for taking and transporting samples to the laboratory. Each sample shall be sealed in cloth bags or any approved containers using the inspector seal after having put inside the sampling form filled out by him/herself and signed by the product proponent.

d) The total number of lots to be sampled will depend on how many there are. When the total number of lots is lower than or equal to 5, each of them will be sampled. When it is higher than 5, 5 randomly selected lots will be sampled. The minimum number of samples per lot shall be as shown in the table below:

Packets per lot	Number of samples
≤5,000	03
>5,000 - ≤10,000	04
> 10,000	05

Note: number of randomly selected samples to be drawn from a lot

3.3 **Feedback to the applicant on the registration process**

When the registration process is completed, TFRA will communicate the result in writing to the applicant including a rationale of the decision and information on the post-registration requirements. When all the efficacy and safety data have been received and a commercial label provided, TFRA will make a decision related to the registration of the bio-fertilizer within a period of three months.

3.3.1 **Registration decision**

Based on the evidence provided, TFRA will take one of the 3 potential decisions below:

1) Full registration (FR) of the bio-fertilizer
2) Conditional registration (CR) of the bio-fertilizer (note: the conditions will be specified in the decision letter)

3) Denial of the registration of the bio-fertilizer (note: a rationale will be included in the decision letter)

All registered bio-fertilizer products will be subject to renewal of the registration (the application form will be available on request) as follows.

1) In the case of conditional registration, the registrant will have to fulfil the requirements for full registration within six months. Failure to do so will lead to the registration being denied. There will be no room for renewal of conditional registration. In the case of full registration, upon continued compliance with the registration procedures and regulations, the registrant shall apply for the renewal of the registration every 3 years.

3.3.2 **Documentation of registration decisions**

Once a decision is taken it will be recorded in the official Register. Hence, each bio-fertilizer registered will be assigned a specific registration number. The registration number will have to be included on the registration certificate as well as on the commercial product label. The registration number for conditional registration should include the letters "CR", whereas that of full registration will include "FR". The registration numbers will read as follows:

1) Registration number: TFRA DDMMYYYYBFCRXX or
2) Registration number: TFRA DDMMYYYYBFFRXX

Where DD stand for the day, MM for the month, YYYY for the year, BF for bio-fertilizer, CR for conditional registration, FR for full registration, and XX for a number from 01 to 99 in the precedence order of registration.

The history of a given product registration process should be kept in the Register. The Register of bio-fertilizers will be in electronic form; however, hard copy will be kept for a minimum of 3 years from the date of the registration decision. The renewal of the registration will not affect the registration number; a registered bio-fertilizer will

keep the same registration number during its entire lifetime in the Tanzanian marketplace.

3.3.3 **Certificate of Registration**

When a bio-fertilizer is registered, the registrant shall get a registration certificate including, but not limited to, the following information:

1) Name of the registrant and local representative if it is not the same person
2) Company's name and physical address of the place of manufacturing of the bio-fertilizer
3) Name of the bio-fertilizer
4) Registration number
5) Type of registration (full or conditional; also reflected in the registration number)
6) Period of validity
7) TFRA's seal (i.e. seal of approval)
8) Full name and signature of the CEO of TFRA
9) Date of registration or registration renewal

3.3.4 **Appeal of a registration decision**

When applicant/registrant is not satisfied by a decision made by TFRA regarding the registration status of a bio-fertilizer, he/she has the right to appeal according to the Fertilizer Act of Tanzania. TFRA will provide the applicant with adequate guidance related to the appeal procedures and instances.

4 **Concluding remarks**

The TFRA registration guidelines for bio-fertilizers outline the various requirements for the attention of TFRA staff and product proponents. They allow for a transparent, fair, and timely review of applications for bio-fertilizer registration in Tanzania. All bio-fertilizers intended for sale in the Tanzanian market shall comply with these registration guidelines. Any bio-fertilizer product found in the Tanzanian market without the appropriate registration certificate and the related registration number

shall be subject to enforcement including potential detention. For products that were found in the market prior to the implementation of these registration guidelines, the product proponents are required to contact TFRA to agree on the appropriate actions to make those products compliant to this bio-fertilizer regulatory framework.

Both TFRA staff (including regulatory officers, inspectors, and laboratory staff involved in the quality control of bio-fertilizers) and product proponents are required to familiarize themselves with these guidelines. The quality control requirements (labelling, efficacy, quality, and safety data) are not limited to the registration process, but also apply to post-registration marketplace monitoring. Product proponents are required to ensure that the quality of the bio-fertilizers in the marketplace is up to the standards prescribed in the registration guidelines or applicable standard operational procedures for quality control, which are available on request. Stated differently, if a product in the marketplace no longer meets the quality standards (labelling, efficacy, and safety requirements), it will be subjected to enforcement actions including (but not limited to) detention or cancelation of the registration certificate.

To ensure timely access to innovative technologies by Tanzanian farmers, TFRA will clarify the file review timeframe during the pre-submission meeting. Once all the required items are submitted, TFRA will process the file in a timely manner. To prevent unnecessary delay, applicants are required to provide TFRA with any clarification or item required at their earliest convenience. Hence, the registration process is interactive. Both parties (i.e. TFRA and the applicant) will have to take advantage of it. However, the registrant shall follow up with TFRA for the progress of the registration process only when the timeframe indicated in the feedback of the pre-submission meeting has elapsed.

After the registration of a bio-fertilizer by TFRA, the registrant can commence legal sale of the product in the Tanzanian marketplace. He/she is also responsible for the quality of the product in the marketplace (commercial chain), unless there is significant evidence that the product has not been handled as prescribed on the product label by a third party (e.g., retailer). For instance, the product label shall clearly indicate that bio-fertilizer repackaging by unauthorized persons or adulteration

is prohibited. Importantly, once a bio-fertilizer is registered, the registrant shall not make any modification to the product label or product formulation (ingredients and their proportion in the product) without a written approval from TFRA. Such changes represent a modification and will be reviewed by TFRA to evaluate the impact on the product registration status.

When the validity of a registration is running out and the registrant wishes to continue marketing and selling the product, the registrant has to apply for the renewal of the registration certificate using the recommended application form (available on request). He/she will have to indicate in writing whether he/she has the intention of modifying the product label or formulation. If no change is expected, no additional information will be required except the application form. If changes are expected, the registrant has to provide details of the changes in writing. The information will be reviewed by TFRA. TFRA also reserves the right to require additional information including quality, efficacy, and/or safety data depending on the nature of the changes. Registrants are required to submit the renewal request of the registration certificate at least 3 months prior to the expiry date of the current certificate.

When a bio-fertilizer fails to comply with the regulatory framework after registration, it will be subject to enforcement actions that may include, but are not limited to, product detention or cancelation of the registration certificate. The situation could result either from a contravention by the registrant to a prescribed standard, or emergence of new data on the efficacy, quality, or safety of the bio-fertilizer. When a bio-fertilizer is detained or registration certificate cancelled, TFRA will inform the product proponent or registrant in writing; the letter will include the reasons of the enforcement action and the requirements to address the issues. Detained bio-fertilizers will only be released when all the issues have been addressed. The same applies to the reactivation of the registration certificate; a newly signed registration certificate will have to be granted at his/her charge. If the product proponent or registrant cannot address the issues related to the detention of a product or cancelation of a registration certificate within the timeframe agreed upon with TFRA, the products will be disposed at his/her charge.

As a result of the implementation of the registration guidelines, TFRA has started developing various SOPs intended to provide more details or clarification on the enforcement of the bio-fertilizer regulatory framework, including the fee structure, penalties on violation of regulations and procedures, and dispute settlement. Equally importantly, when a registrant requires clarification on a specific provision of these guidelines, he/she is required to contact TFRA for that effect. This also applies to the appeal process for any decision made by TFRA under the Fertilizer Act.

GROSSARY OF TERMS

Lot: All packets/containers of a product material from the same batch of manufacture in a consignment. Collection of the same materials of the size and style which have been processed under the same condition.

Batch - Specific quantity of materials (inoculant/ bio-fertilizer) manufactured in a single operation

Batch number – a combination of numerals and/or letters used to identify material pertaining to a particular batch and serving to distinguish it from all other batches of like materials

Bio-fertilizer: a substance which contains living microorganisms which colonize the rhizosphere or the interior of the plant and promote growth by increasing the supply or availability of primary nutrient and/or growth stimulus to the target crop, when applied to seed, plant surfaces, or soil.

Active ingredient: an ingredient in a bio-fertilizer to which plant growth activity is attributed.

Genetically-modified organism: any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

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Annex 1: Checklist accompanying the application form for bio-fertilizer registration in Tanzania

Checklist to verify the completeness of an application package submitted to TFRA to seek for the registration of a bio-fertilizer		
Item	Included (Tick with √ when applicable)	
	Yes	No
Application form		
Letter of intention		
Checklist		
Registration fees (a proof of payments from the bank)		
List of authorized representatives		
Declaration of a local agent		
Efficacy data as agreed upon with TFRA		
Safety data		
Declaration that the bio-fertilizer does not contain genetically-modified organisms		
Quality data as agreed upon with TFRA		
Tentative product label		
Evidence for product registration in other countries or rationale showing why not when the product is not registered elsewhere		

Footnotes:

The applicant shall verify whether all the required information and items have been included in the application package. Any incomplete package won't be processed. The checklist has to be attached to the application form and included in the application package.

TFRA reserves the right to ask for additional information when deemed necessary to verify the labelling statement, as well as the efficacy, quality, and safety data.

Annex 2: Application Form for Bio-fertilizer Registration in Tanzania

<table>
<tr><td colspan="2">Purpose of the application in maximum 20 words (attach letter of intention):</td></tr>
<tr><td>Registrant's contact information (full name, physical address, postal address, e-mail, telephone, mobile phone, fax):</td><td>Contact information of the manufacturing plant (full name, physical address, postal address, e-mail, telephone, mobile phone, fax) (Note: if many plants are involved, list those which are relevant for this registration process):</td></tr>
<tr><td>Local agent's contact information (full name, physical address, postal address, e-mail, telephone, mobile phone, fax) if not the same as the registrant:</td><td>List of maximum 3 authorized representatives with signing authority in the company in addition to the registrant and the local agent when applicable (full name, e-mail, telephone, mobile phone):</td></tr>
<tr><td>Product name:</td><td>Brand name (if any):</td></tr>
<tr><td>Active ingredient(s) in the bio-fertilizer (for each ingredient provide number of cfu/g of finished product):</td><td>Inert ingredients in the bio-fertilizer (all ingredients other than the active ingredients):</td></tr>
<tr><td>Labelling statement (key headings on the product label):</td><td>Safety statement (declaration related to the bio-fertilizer safety; maximum 100 words):</td></tr>
<tr><td>Efficacy statement (declaration related to the bio-fertilizer efficacy; maximum 100 words):</td><td>List of countries where the bio-fertilizer has been registered or approved for use (attach the evidence; maximum of 5 countries):</td></tr>
<tr><td>Quality statement (Declaration related to the bio-fertilizer quality including at least physical characteristics [solid or liquid], guarantee</td><td>If the bio-fertilizer has not been registered elsewhere, provide an adequate, brief rationale (maximum 100 words):</td></tr>
</table>

analysis, level of contamination, pH, efficiency character for all types of bio-fertilizer, as well as moisture content and particle size for bio-fertilizers in solid form; maximum 100 words):	

Declaration: All the information in the application package (as per the attached checklist) including this application package is true to the best of our knowledge and has been prepared by our company or authorized individuals. Our company has full ownership of the bio-fertilizer for which we are seeking for registration. The bio-fertilizer does not contain genetically-modified organisms.

Place, date, full name, and signature of one of the 3 authorized representatives other than the applicant/registrant and local agent:	*Place, date, full name, and signature of the applicant/registrant:*	*Place, date, full name, and signature of the local agent (if different from the applicant/registrant):*

Annex 3: Good Quality System Procedures (GQSP)

The GQSP requirements include (but are not limited to):

- a thorough description of trial site where the experiment will be conducted
- a plan of the trial sites and surrounding areas
- trial conditions of the plot and crop
- validity of choosing trial sites explained
- all trials conducted using the specific formulation and methods of application (i.e. use pattern) which appear on the tentative label
- alternative formulations/methods used at the trial site (reference product)
- complete address and geographical coordinates of trial locations
- appropriate number of trials, using the application rates on the tentative label, in order to adequately demonstrate product efficacy
- quality trial management practices are implemented
- proper trial planning, execution, assessment, record-keeping, and interpretation of data
- qualifications and training of staff conducting the trial and/or analysing the field data
- the use of proper equipment, facilities, protocols, methods of application and data recording
- internal procedures that provide verification of the proper use of GQSP

Annex 6 Bio-fertilizers registration guidelines for Uganda

Ministry of Agriculture, Animal Industry and Fisheries

GUIDELINES FOR REGISTRATION OF BIO-FERTILIZERS IN UGANDA

2015

ACRONYMS AND ABBREVIATIONS

ACB	**Agricultural Chemicals Board**
ANOVA	**Analysis of Variance**
AEZ	**Agro-Ecological Zones**
COMPRO II	**Commercial Products II**
GEP	**Good Experimental Practices**
SOP	**Standard Operational Procedure**
REC	**Regional Economic Community**
SMEs	**Small and Micro Enterprises**
LMO	**Living Modified Organism**
MSDS	Material Safety Data Sheet
QA	Quality Assurance
QC	Quality Control

EXECUTIVE SUMMARY

The production and distribution of biofertilizers in the agro-input markets is on the ascendency in many countries including Uganda. The guidelines for the registration of biofertilizers have been developed by the Department of Crop Protection of the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) to ensure that the circulation of such products for research or commercial purposes has been authorised and that they are safe, efficacious, and effective as per label claims.

The document begins with an introduction of Biofertilizers, the scope and essence of the registration guidelines. The second section outlines details of the registration procedure and the third section provides guidance for the conduct of efficacy trials. The document has annexes of application forms, model certificates of registration and a sample label for biofertilizer products.

It is hoped that these guidelines for registration of biofertilizers in Uganda would increase the competitiveness of the agricultural sector in the country and facilitate farmers' access to innovative biofertilizer products that are safe, efficacious, and properly labelled for the end users.

DEFINITION OF TECHNICAL TERMS

For the purposes of this guideline, the following definitions shall apply;

Active ingredient**: the micro-organism and any associated metabolites in a bio-fertilizer to which plant growth activity is attributed.**

Lot: **All packets/containers of a product material from the same batch of manufacture in a single consignment.**

Specific Lot**: containers/packets of a product material from two or more batches of manufacture in a single consignment.**

Batch: All biofertilizers that are prepared from a batch of fermentor or a group of flasks run at the same time and during the same timeframe.

Batch number: Is a specific number used to distinguish each batch. The number could be combination of symbols including letters and figures. The number should at least include the date of manufacture (dd/mm/yyyy). The number should be printed on each product package.

Biofertilizer: **a substance which contains living microorganisms which colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of primary nutrient(s) and/or growth stimulus to the target crop, when applied to seed, plant surfaces, or soil (tentative or proposed definition).**

Microbial fertilizer: **a biofertilizer in which the sole or main active agent is a microorganism.**

Microbial active agent: **a microorganism (bacterium, alga, fungus, protozoan, virus, mycoplasma, rickettsia) and any associated metabolites, which aid soil health, plant growth, or improve soil fertility but excluding nematodes.**

Indigenous microorganism: **a microorganism originating naturally in the country or region in which the biofertilizer is being registered.**

Non-indigenous microorganism: **a microorganism originating from outside the country or region in which the biofertilizer is being registered.**

Genetically-modified organism/living modified organism: **any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology**

1.0 **INTRODUCTION**

These guidelines are developed for operators in the Ugandan biofertilizer market who wants to register biofertilizer products. Following all the guidelines, and providing all the required information, operators will speed up the registration process.

Appropriate registration process of biofertilizers will enable a better marketplace monitoring to ensure that only products with adequate seal of approval provided by the Department responsible for registration of biofertilizers are legally sold in Uganda. The guidelines enlist details of registration procedures including administrative, safety, quality, efficacy, and labelling requirements.

1.1 Importance of Biofertilizer Registration

A biofertilizer is a substance which contains living microorganisms which colonizes the rhizosphere or the interior of the plant and promotes growth by increasing the supply or availability of primary nutrient(s) and/or growth stimulus to the target crop, when applied to seed, plant surfaces, or soil .

Biofertilizers, as microbial products, act as nutrient suppliers and/or soil conditioners that lower agricultural burden and conserve the environment. Good soil condition is imperative to increased crop production, as well as human and/or animal health welfare. However, materials such as Biofertilizers which contain soil microbes, although is used to sustain good soil condition, are treated as environmental issues. And as such, the circulation of such products for research or commercial purposes can be allowed after it has been proved to be safe, efficacious, and effective and consistent with label claims, and must be registered or certified for use in the country.

1.2 Purpose of This Registration Guideline

The purpose of this registration guideline is to stipulate the procedures for regulating bio-fertilizers and also provide a general framework for the registration of bio fertilizers in Uganda. This will ensure that the Ugandan environment and its population are protected against the potential dangers associated with biofertilizer commercialization and use. It will also safeguard the interest of fertilizer enterprises and the end users.

1.3 Objectives of Biofertilizer Registration

The objectives of biofertilizer registration are as follows;

- **To ensure that only registered biofertilizers are placed on the market and made available for use by farmers.**
- **To ensure that only biofertilizers that are demonstrated to be safe and effective for intended use may be registered.**
- **To ensure that registered biofertilizers are used correctly and safely.**
- **To ensure that registration of a biofertilizer may be re-evaluated if new data becomes available following registration.**
- **Generate a register of approved Biofertilizer products.**
- **To facilitate national, international and inter-regional trade in biofertilizers.**
- **To facilitate post-registration monitoring/surveillance of biofertilizers.**

1.4 Scope of Biofertilizer registration

These guidelines are limited to only Biofertilizers which include;

- **products containing micro-organisms to which plant growth activity is attributed and**
- **products containing microorganisms and any associated metabolite which aid plant growth, soil health or improves soil fertility.**

1.4.1 Biofertilizers from Genetically Modified Organisms (GMOs)

The default position adopted in this guideline document is that there is a separate

regulatory mechanism for approving the production, importation and use of GMOs in Uganda. The Biosafety Bill makes regulatory provisions for GMOs, therefore GMOs are out of the scope of this guideline document.

1.5 Identity and Ownership of Biofertilizers being Registered

1.5. 1 Identity

A registrant should know the identity of the product. Identity of any biofertilizer is determined by its composition. The registrant shall provide the following identity information on the product to be registered:

- **Details(Scientific name, taxonomic grouping) and population of active ingredients/active agents**
- **Details on type of carrier**
- **Details on contaminant(s)**
- **And any other details as determined by regulators usually on a case-by-case basis according to the nature of the biofertilizer proposed for registration.**

1.5.2 Ownership

The owner will be the manufacturer of the product. The applicant will be the local representative who is registered to do business in Uganda. The applicant is responsible for the commercialization of the product when it is registered.

1.6 Confidential Data

Any information submitted to the Department responsible for product registration is classified as confidential. However, the separate submission of data (by secure means electronically or in sealed envelope) should be accompanied by a *Disclosure Declaratio*n.

2.0 BIOFERTILIZER REGISTRATION PROCEDURE

In order to import or sell biofertilizers, registration is required. An applicant must submit an application letter to the Chairperson, ACB and completed application forms (Annexes 1 and 2) for registration to ACB for processing, and if approved the product is registered.

2.1 Types of Registration

There are five types of registration that can be made; they include:

- **Product Registration; entails the registration of biofertilizer products to be manufactured or imported.**
- **Company Registration;**
- **Manufacturing Registration ;**
- **Distributor Registration;**
- **Retail Registration;**

- **After initial registration is done, applicant is permitted to advertise and sell biofertilizers within the stipulated period of time. Renewal of registration may be granted for the various registration types. For renewal of registration, an application for renewal should be submitted to the ACB not later than three months before the registration expires, and renewal of certificate granted before advertisement or sales can be resumed.**

The ACB reserves the right to revoke, suspend or modify registration on its own initiative subject to emergence of post-registration data.

2.2 Pre-submission consultation

In order to facilitate the registration of biofertilizers, intending registrants should request for a Pre-Submission Consultation with the ACB Secretariat prior to making a full and formal

application, to enhance familiarization with the registration procedures. The consultation will allow the registrants to understand the registration process as well as the safety, labelling, and efficacy requirements.

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During this meeting, the following administrative requirements shall be discussed:

- **Application letter to be sent to Chairperson ACB declaring intension to register your company (as a manufacturer or Importer) and the biofertilizer product.**
- **Application forms with checklist.**
- **Certificate of Incorporation and Certificate to Commence Business in Uganda for the local representative or importer.**
- **Acquisition of a TIN with URA**
- **Product Dossier**
- **Draft label of the product.**
- **Proof of ownership of the biofertilizer to be registered.**
- **Submission of sample for laboratory analysis and field trials.**
- **Approved fees to be charged.**

2.3 Submission of Application Letter

An application letter for product and company registration shall be addressed to the Chairperson ACB indicating the intention of the application (Manufacturing or Importing). A product dossier and company registration certificate shall be attached to the application letter. If the product has already been registered elsewhere the registrant shall submit a list of all the countries where the product has already been registered. In the case of a renewal of registration, the previous registration number given shall be provided.

2.4 Completion of Application forms

The registrant will be required to complete application forms as detailed in Annexes 1 and 2

Information required shall include;

- **Date of submission of application form**
- **Type of biofertilizer**
- **product formulation including constituent materials**
- **source of the material**

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- **well-documented physical-chemical-biological properties,**
- **applicant and his/her contact information including the address and location,**
- **Restrictions and cautions**
- **Signature of the registrant**
- **Name and Signature of ACB officer receiving application**
- **Name of manufacturer of active ingredient.**

A checklist at the back of the application form will ensure that registrants provide all the necessary details for registration.

2.5 Product Dossier

The registrant shall attach the dossier to the application letter. The applicant is responsible for the content of the dossier. The dossier must contain the technical information on the bio-fertilizer, and this would include:

- **Information on the strain(s) including the source, identification and taxonomy.**
- **product composition**
- **information on the carrier material and pre-treatment**

- **product formulation**
- **Quality Assurance and Quality Control Procedures**
- **product use (dosage, direction for use)**
- **mode of action**
- **packaging specification**
- **Manufacturing Process**
- **efficacy trial report**
- **Material Safety Data Sheet (MSDS) of the product and ingredients**

2.5.1 Safety requirements

A package of safety information should be prepared in addition to the supporting document, a rationale not exceeding 5 pages to substantiate the safety of the product should be provided. Basically, the product proponent should demonstrate that the micro-organism(s) in the product formulation is/are present at a level expected to be safe to human, animal, plants, and the environment. Also, the safety of the formulation when all the ingredients are mixed together should be demonstrated. The level of non-guaranteed micro-organisms should not be higher than the tolerance level prescribed in this registration guideline.

2.6 Product label

The registrant shall provide a tentative product label that meets the requirements in this guideline (Annex 5). The various sections of the product label shall be reviewed and approved before commercial use. The commercial label will have to include a registration number granted by the ACB as a seal of approval.

2.6.1 Requirements for Labeling and Packaging

Labels must not have any incorrect or misleading information or mark or brand or name that would tend to deceive or mislead a purchaser with respect to the composition or utility

of the product. The approved and registered product label must match the label being used in the marketplace.

The main panel (principal display panel) of the label must display at least the product name, the product weight and the name and address of the registrant or the manufacturer. The label should also as specified by the regulations have a complete address. If an address stated on the label refers to the place of manufacture of the container, this must be clearly indicated (e.g., bags manufactured by;). If the product is packaged outside Uganda, and contains the country's address on the label, and is imported for resale in Uganda, the words "imported by" or "imported for" must precede the country's address, unless the geographic origin of the pre-packaged product is also stated on the label.

All information on the label must be printed conspicuously, legibly and indelibly. All information must be printed in a font size that would be legible from a normal distance without the aid of magnifying devices.

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Summary of requirements for labelling

- **Product name**
- **Brand name**
- **Microbial active agent(s) (active ingredient(s))**
- **Direction for use (application rate, application frequency, rate frequency)**
- **Registration number**
- **Expiry date**
- **Date of manufacture**
- **Company information (manufacturer and local representative/agent, address and physical location)**
- **Units of measure (Use SI units)**
- **Net weight**
- **Guarantee / label claim**

- **Lot number**
- **Cautionary statement**
- **Planting window**
- **List of ingredients**
- **Website (optional)**

2.7 Outcome of submission

The ACB shall inform the registrant of the outcome of the application after assessments and evaluation of data.

Normally, a response will come as follows:

(v) Registration granted with a certificate of registration and a ACB Registration number. The certificate will bear conditions of registration to be complied with, including any mandatory modifications to the intended use, label indications, etc. The certificate will also bear the use category (general use, restricted, severely restricted)

(vi) Registration refused, in which case the ACB shall provide reasons for refusal.

(vii) A request for re-run of laboratory results when the test result(s) is/are not satisfactory.

(viii) Request for field trial to analyse the effect of the product on crops and the environment.

If the registrant is not satisfied with either the conditions of registration or with a refusal to register the product, the registrant may make a complaint to ACB. If the outcome is not satisfactory to the registrant, he can appeal to MAAIF, and perhaps ultimately to the courts.

2.8 Registration fees

Registration fees are charged for the under listed items;

g) Company Registration

h) Manufacturing Registration

i) **Fertilizer Product Registration**

j) **Distributor Registration**

k) **Retail Registration**

l) **Application Forms**

The registration fees is subject to annual review. Fees for registration shall be paid to ACB. Fees for laboratory and field testing shall be paid through the ACB to the approved institution.

2.9 Certificate of Registration

Certificates of registration for the product and company shall be awarded to the registrant after approval has been given by the ACB.

2.10 Responsibilities of the Registrant after Registration

The responsibilities of the registrant are stipulated in the registration certificate or as separate conditions for registration. The activities that a registrant would be responsible for include among others to prevent product adulteration along the whole commercialization chain so as to ensure that the quality is maintained. Registrants shall be held responsible when their product in the marketplace is found to be non-compliant to the prescribed standards after registration.

2.11 Modification of Registration Status

The registration status of a biofertilizer product can be modified in the following instances:

2.11.1 Modification of composition or use of a product: **If after initial registration, there is cause to modify composition or modify use of a product, an application to modify the registration status must be made according to the data requirements in the Application Form. The need may arise from data emerging from post-registration monitoring of the use, effectiveness and adverse effects of the biofertilizer or from information coming from other countries where the same or similar products are in use. A modification to the**

registration may therefore be required by ACB based on its dissatisfaction of emerging data or the need may arise from the registrant's own post-registration monitoring.

2.11.2 Revocation of registration: **A situation may arise where ACB as a result of emerging data, may conclude that a given biofertilizer presents too great a risk to continue its use or that the biofertilizer no longer meets the prescribed standards. In these situations registration may be revoked, but ACB would inform the registrant of the reasons for such action. In this case, the biofertilizer will effectively be classified as a prohibited biofertilizer, until the product owner ensures it complies again with the prescribed standards and qualifies for re-registration.**

2.11.3 Renewal of registration: **When the validity of a registration is running out and the registrant wishes to continue marketing the product, an application for renewal should be submitted to the Minister not later than three months before the registration expires. Certificate of renewal must be granted before advertisement or sales can be resumed**. **If for some reason the registration is not renewed, the product will cease to be recognised as registered, and it would be illegal to engage in any regulated activities connected with it, including formulation, transport and distribution, sale and use. The product owner can decide to modify the product composition and use before it is renewed. The data requirements for renewal of registration are indicated in the application form.**

2.12 Register of Biofertilizers

The Register of bio-fertilizers shall be kept on paper or electronic form at the ACB Secretariat.

2.13 Post-registration Surveillance

ACB shall conduct post-registration market surveillance to ensure that the quality standards are maintained throughout the marketing chain of the bio-fertilizers based on

the prescribed specification. If it is discovered that standards have to be modified based on emerging concerns, the registration guidelines would be amended accordingly.

2.14 Product Sampling requirements

Standard operational procedures (SOPs) for sampling are meant to ensure consistency of product sampling including acquisition of representative samples. The following outlines the recommended SOPs for sampling that shall be implemented by the ACB to ensure adequate marketplace monitoring or surveillance of product registration to its lifetime in the marketplace.

2.14.1 General requirements for product sampling

8) **Precautions and directions must be observed when drawing, preparing, and handling samples intended for quality control.**
9) **To ensure that representative samples are taken, sampling must be carried out by an authorized fertilizer inspector.**
10) **For packaged products, unopened packets should be sampled and sent to the laboratory using appropriate equipment and procedure to prevent possible contamination of samples during handling.**
11) **Samples must be taken in the presence of the product proponent and/or his/her authorized representative.**
12) **Collected samples should not show any visible sign of potential contamination or exposure to a well-established contaminant.**
13) **For quality control (ascertaining the conformity), samples should be tested from each lot separately to determine whether a material meets the regulatory requirements with respect to prescribed standards or specifications.**

2.14.2 Drawing samples

f) **The number of sample-packets to be taken from a lot will depend on the size of the lot. The samples should be randomly selected using a well-established randomization tool or software when applicable. The sample will be considered a legal sample since the result will be used as a proof of the product compliance to the regulatory requirements.**
g) **The authorized inspector or any other authorized staff shall take three (3) sample-packets from the same lot. The sample should be taken in the presence of the product proponent or his/her authorized representative; the latter should sign on the sampling form of the inspector. When analysing samples, each packet should be taken separately.**

h) **The authorized inspector or any other authorized staff should carry with him/her appropriate sampling forms on which to document information about the sample**

and the sampling procedures. Hence, each sample should be sealed in cloth bags or any approved containers. The completed sampling form shall be placed in the container and the seal of the authorized inspector appended.

i) When the product proponent or her/his authorized representative wants to send samples to independent laboratory for potential cross-validation of the results; the authorized inspector or the authorized staff should randomly select three (3) additional sample-packets for each independent laboratory. The samples should be handled as described above.

j) When the total number of lots is lower than or equal to 5, each of them will be sampled; when it is higher than 5, 5 randomly selected lots will be sampled.

The minimum number of samples per lot shall be as shown in table 1 below:

Table 1 Number of randomly selected samples to be drawn from a lot

Packets per lot	Number of samples
≤5,000	03
>5,000 - ≤10,000	04
> 10,000	05

2.15 Requirements for Quality

Quality of biofertilizers is one of the most important factors that can result in product success or failure. Quality of a product can lead to its acceptance or rejection by the end-users. Quality is about specifications for physical and chemical properties in quantitative terms for maintaining quality. This includes moisture content, particle size and the permissible limits of contaminants as well as specifications for quality checks of fertilizer samples. Description of quality may contain parameters like the microbial density at the time of manufacture, microbial density at the time of expiry, the expiry period, the permissible contamination, the pH, the moisture, the microbial strain, and the carrier. Quality has to be controlled at various stages of production (during mother culture stage, carrier selection, broth culture stage, mixing of broth and culture, packaging and storage). Quality requirement for the registration of biofertilizers in Uganda are as follows:

Rhizobium, Azobacter, Azospirillium & Phosphorus Solubilizing Bacteria (PSB**)**

- **Base (carrier) in form of moist/dry powder or granules, or liquid based**
- **Viable cell count (CFU minimum 5×10^9 cell/g of powder, granules or carrier material or 1×10^9 cell/ml of liquid) formation.**

- **Contamination level (no contaminant at 10^5 dilution) subject to the method of determining contamination**
- **pH (6.5– 7.5) for rhizobia; and pH (5.0 – 7.5) for PSB**
- **Particle size (all material should pass through 0.150 - 0.212 mm IS sieve) (to be verified)**
- **Moisture percent by weight, maximum in case of carrier based (30 – 40%)**
- **Efficiency character**

Mycorrhizal inoculum

- **Form/Base (carrier) Fine powder/tablets/granules/root biomass mixed with growing substrate**
- **pH (6.0 – 7.5)**
- **Particle size (90% should pass through 250 micron IS sieve powder formulation (60 BSS - British Sieve Size)**
- **Moisture per cent by weight, maximum in case of carrier based (8 – 12%)**
- **Total viable propagules/gm of product, minimum (100/gm of finished product)**
- **Infectivity potential (80 infection points in test root/gm of mycorrhizal inoculum used on a standardized reference crop).**

3.0 Biofertilizer Efficacy Trials

The purpose of the trials is to determine the efficacy of the product prior to registration. The registrant will submit product dossier and safety information to ACB for this purpose.

An efficacy report on the product by an institution or organization in any other country may be attached to the dossier if available. The efficacy report should include quality data (i.e. guarantee analysis, level of biological contaminant(s) at a specified dilution level), and performance data.

3.1 Product Efficacy Trials

ACB shall engage the relevant research institution(s) to carry out the trial on its behalf, while doing the necessary monitoring. It is recommended that efficacy trials be conducted using Good Experimental Practices.

The Good Experimental Practices requirements include, but are not limited to:

- **a thorough description of trial site where the experiment will be conducted**
- **a plan of the trial sites and surrounding areas**
- **description of trial conditions of the plot and crop**
- **conditions supporting the validity of chosen trial sites**
- **all trials should be conducted using the specific formulation and methods of application (i.e. use pattern) which are to appear on the product label**
- **alternative formulations/methods used at the trial site**
- **complete address and geographical coordinates of trial locations**
- **appropriate number of trials, using the application rates to appear on the product label in order to adequately demonstrate product efficacy**
- **quality trial management practices to be implemented**
- **proper trial planning, execution, assessment, record-keeping, and interpretation of data.**
- **qualifications of staff conducting and/or analysing the trials**
- **the use of proper equipment, facilities, protocols, methods of application and data recording**
- **internal procedures that provide verification of the proper use of GEP**

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3.2 Location of Efficacy Trials and Site Selection

Efficacy trials shall be conducted in at least three (3) Agro Ecological Zones (AEZs). The choice of the agro-ecological zones should be based on the agricultural production regions for the intended crop(s).

ACB will select a research institution that will determine the location for the trials.

3.3 Minimum Number of Trials

The minimum number of trials required to support product efficacy will vary depending for instance on the intended usage pattern, intended crops, and label claims. For example, a product intended for soil application, to be used on a single crop with the claim of increased yield would generally require a low number of trials. However, when the same product is also intended for foliar application (on the same product label), and for several crops, and claims yield increases and improved root biomass, the minimum number of trials may significantly increase.

When a product is recommended for crops grown in more than two AEZs, the minimum number of trials is set to 6. However when a product is intended for a crop grown in a single AEZ, the minimum number of trials could be reduced to half (i.e. 3trials) When more than one trial is recommended in the same AEZ, the site selection should show a spatial variability within the AEZ.

3.4 Minimum Number of Trials for Spatial and Temporal Distribution

The minimum number of growing seasons for efficacy trials shall be two. In general, the minimum number of trials should be conducted in more than one growing season (temporal variability) and in different locations (spatial variability).

However when the proponent wants to expedite farmer access to a new technology that may have proven profitable elsewhere, ACB may grant a waiver for the temporal variability, but would require an improvement in the spatial variability. Under such a condition, the "accelerated trials" method will be employed, where the minimum number of trials would be increased from six (6) to nine (9).

3.5 Representative Crops

When several crops are considered for the same biofertilizer the minimum number of trials may increase drastically to the extent that it is no longer affordable or scientifically relevant given the potential similarity across crops. In the case where the similarities between crops are supported by scientific evidence in terms of physiology and production patterns, the crops could be grouped together based on similarities and the efficacy testing conducted using a representative crop from each group.

3.6 Mutual Recognition

When data conducted elsewhere are found to be relevant in another country based on the similarity of the AEZ conditions, ACB may recommend a reduced number of trials to confirm the efficacy of the product in the local conditions. Generally, the required minimum number of trials would be reduced to a half and the temporal variability automatically waived. This mutual recognition would be granted based on the merit of the rationale and evidence provided to support the similarity of the agro-climatic conditions and also based on the existence of precedence.

3.7 Measurable Parameters

During assessment of product efficacy, considerations should be made prior to, after treatment and after harvest as follows:

3.7.1 Prior to treatment

To ensure that product efficacy is evaluated under appropriate conditions, the initial soil fertility level should be evaluated prior to the establishment of the trials. When the product proponent has research and development data, these could inform the need for co-treatment to improve crop response. Soil analysis conducted prior to the treatment should include (but not limited to): soil texture, pH, cation-exchange capacity, organic carbon,

availability of selected plant nutrient and functional microorganisms in the case of microbiological products.

3.7.2After treatment

After the application of the biofertilizer, minimum weather data including the ambient temperature, humidity and rainfall should be collected. In addition to the initial soil testing, information on weather conditions could also be used to explain any spatial or temporal variability. Other measureable parameters would be based on the label claims[1].

3.7.3After harvest

Considerations should be given to tissue analysis for nutrient uptake (i.e. major, secondary and micro- nutrients depending on the product of interest), crop yields (grain yield, haulms, husks, etc), quality of the crop yields when applicable (based on label claim) and functional microorganisms.

3.8 Data Analysis

The data should be statistically analyzed including descriptive statistics and analysis of variance (ANOVA) using accepted software (e.g., SAS). The method of statistical analysis should be considered prior to conducting the trial. The level of significance and the mean separation techniques should be the ones that are commonly used in the field of interest (e.g. 5% and the least significant difference i.e. LSD). Anecdotal or testimonial evidence should not be considered as a scientifically valid form of efficacy data, and therefore should

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[1] To include; plant biomass (shoot and if possible root biomass) at a specific growth stage. Generally the dry biomass will be considered.

- **chlorophyll content,**
- **visual symptoms of nutrient, abiotic, and biotic stress (when observed)**
- **Leaf area for large leaf crops**
- **Pod numbers for legumes**
- **Uptake of plant nutrients of interest at a specific growth stage**
- **Number, weight, and color of nodules in the case of rhizobium inoculants**
- **Intensity of root colonization/infection, root and hyphal length in the case of mycorrhizal inoculants**
- **Root architecture in the case of plant growth promoting rhizobacteria**

not be accepted to support product approval or registration; however, such evidence could be used as background information. Hence, all label claims must be adequately supported by scientific data that has been statistically analyzed and demonstrates a statistically significant benefit. The statistical analysis should be consistent across AEZ for the same product and treatments.

3.8.1 Profitability analysis

Economic evaluation of crop responses to biofertilizer product is important to assess their profitability, particularly in the context of smallholder farmers. The benefit cost ratio (BCR) is one of the tools used to conduct such an evaluation particularly when yield is considered. BCR is the ratio of the net value of extra crop produced to the cost of the product. In actual practices, a BCR of 2.5 and above is considered to be satisfactory for the adoption of the technology. However, other authors have indicated that a BCR > 1 is already attractive for farmers.
Taking into consideration other costs, including credits and risk taken, the higher the BCR the better. Thus the average BCR must be ≥ 1 for product approval or registration. Such a BCR must be shown for at least 60 % of the trials

$$\frac{Value\ of\ additional\ crop\ produced - cost\ of\ COMPRO}{Cost\ of\ COMPRO}$$

3.8.2 Requirements for Establishing Efficacy

Efficacy establishment requirements for the registration of biofertilizers in Uganda are as follows;

- **Good experimental practices**
- **Location of field trials based on production regions**
- **Experimental design (done by accredited facilities)**
- **No. of Trials: at least for two seasons in at least three agro-ecological zones; five locations within each agro-ecological zone.**
- **Planting window (preferably field trials conducted at end of planting window), in accordance with the label claim (batch and date of manufacture) provided by the producer (verifiable).**
- **Laboratory data**

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CFIA (1997). T-4-114 - Sampling Procedures for Fertilizers. Canadian Food Inspection Agency.

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Annex 1a: Application Form for Biofertilizer Registration

AGRICULTURAL CHEMICALS BOARD	FORM B

APPLICATION FORM FOR BIO-FERTILIZER PRODUCT REGISTRATION

(A COMPLETED **FORM A** MUST ACCOMPANY THIS FORM)

PLEASE USE CHECKLIST ON BACK TO ENSURE A COMPLETE APPLICATION		
COMPANY NAME	PFRD ISSUED COMPANY NUMBER	DATE
PRODUCT REGISTRATION NUMBER		
PRODUCTS TO BE REGISTERED		
FOR DEPARTMENTAL USE ONLY		

PRODUCT REGISTRATION FEE

Number of products at GH ¢ 3,000.00 each: _____ products × GH¢ 3,000.00 = GH¢ _____.00

(Fee covers initial two year registration cycle)

Make cheque payable to: The Director, Plant Protection and Regulatory Services Directorate.

TOTAL FEES: GH¢ _____.00

*Cheques returned by the bank will be charged the appropriate handling fee.

Processing of this Form will not be completed without field trial results proving the effectiveness or otherwise of the product.

Fertilizer Product Registration Checklist

BIO FERTILIZER PRODUCT REGISTRATION INSTRUCTIONS FOR FORM B AND FORM B2

A completed **FORM A** is required for registration. An incomplete form may result in the rejection of your application. Complete Product Information and Declared Quality Parameters Form (Form B2) depending on number of products to be registered.

COMPANY INFORMATION

- Company Name: Enter the name of the company as it appears on the Form A.
- ACB Company Number – the company number is assigned by ACB. If you are applying for the first time, leave this box blank. If you already have products registered and are adding additional products, please place your assigned company number in the box. You can find your company number on your current registration certificate.
- Date: Enter the date you prepared the registration form.

- DEPARTMENT USE ONLY: Please do not write in this area.

- **PRODUCT REGISTRATION FEES:**
  The registration fees is subject to annual review.

  Fees for registration shall be paid to ACB. Fees for laboratory and field testing shall be paid through the ACB to the approved institution.

  Current Registration fee is SHS 500,000/= per product for initial two years, thereafter renewable every two years.

- PRODUCT INFORMATION: (FORM B2)
  - Product Name: Enter the complete name found on the product label.
  - Mode of Application and Maximum Rate of Application: Complete this section using the highest rate and maximum number of applications allowed during a growing season.
  - Product label: Attach copy of the product label as prescribed in the Guidelines for Registration of Bio-fertilizers in Uganda.

- DECLARED QUALITY PARAMETERS: (FORM B2)
  - Enter a value for each quality parameter on the product label. The value must match the value on the label. Do not list values for quality parameters not guaranteed on the label.

Annex 1b: Attachment to annex 1a

AGRICULTURAL CHEMICALS BOARD	FORM B2

BIOFERTILIZERS

PRODUCT INFORMATION				
PRODUCT NAME AND GRADE				
MODE OF APPLICATION:			**MAXIMUM APPLICATION RATE:**	
MICROBIAL ACTIVE AGENT(S):				
DECLARED QUALITY PARAMETERS				
Carrier Base			**Infectivity potential / Efficiency character**	
Viable Cell Count			**Contamination level**	
Ph			**Moisture Percent by Weight**	
Particle Size			**Total viable propagules / gm of product**	
DEPARTMENTAL USE ONLY				
LABORATORY ANALYSIS				
Carrier Base			**Infectivity potential / Efficiency character**	
Viable Cell Count			**Contamination level**	
pH			**Moisture Percent by Weight**	
Particle Size			**Total viable propagules / gm of product**	

Annex 2: Company Registration Form

AGRICULTURAL CHEMICALS BOARD	FORM A

APPLICATION FORM FOR COMPANY REGISTRATION

PLEASE USE CHECKLIST ON BACK TO ENSURE A COMPLETE APPLICATION	
INDICATE THE ACTIVITY FOR WHICH YOU ARE APPLYING TO BE REGISTERED (PLEASE TICK) ☐ Importing ☐ Manufacturing/Blending	
BACKGROUND INFORMATION	
FULL LEGAL NAME OF APPLICANT, COMPANY OR BUSINESS	
APPLICATION DATE	
POSTAL ADDRESS	
PHYSICAL LOCATION OF BUSINESS	
EVIDENCE OF REGISTRATION OF BUSINESS(YES/NO) ATTACH REGISTRATION CERTIFICATE IF ANY	
TELEPHONE NUMBER	
FAX	
E-MAIL	WEB SITE ADDRESS
COMPANY REGISTRATION FEE	
MANUFACTURING/BLENDING -	

IMPORTING -

FOR DEPARTMENTAL USE ONLY

DATE OF RECEIPT OF APPLICATION: ISSUED COMPANY NUMBER:

Cheque Amount	Cheque Number	Date Issued	Date Received	Receipt Number (ACB#)

REMARKS:

……..

…… ……

NAME OF OFFICER RECEIVING THE APPLICATION DESIGNATION SIGNATURE

Fertilizer Company Registration Checklist

Submit originals to ACB and keep copies for your file.

Your company will receive an ACB Bio Fertilizer Registration Certificate as confirmation of your company registration.

- **Form A, "Application form for Company Registration" Include company name and address.**
- **Attach Business Registration Certificate.**
- **<u>Company Registration Fee:</u>**

The registration fees can be found in the Fees and Charges Legislative Instrument and is subject to annual review.

- **Current Registration fee of ---------- in case of manufacturers for initial five years renewable after every two years.**
- **Current Registration fee of ---------- in case of importers for initial two years, renewable every two years.**

Annex 5: Model Label for a Biofertilizer

PRODUCT AND COMPANY DETAILS

- **Product name**
- **Brand name**
- **Microbial active agent(s) (active ingredient(s))**
- **Registration number**
- **Date of manufacture**
- **Expiry date**
- **Company information (manufacturer and local representative/agent, address, physical location, Website)**
- **Net weight**
- **Guarantee / label claim**
- **Lot number**

DIRECTION FOR USE

- **Planting window / Mode of Application**
- **Application rate**
- **Application frequency,**
- **Time of Application**
- **Units of measure (Use SI units)**

PRECAUTION AND FIRST AID

- **Cautionary statement and Symbols**
- **First Aid**
- **Storage**
- **Disposal**