Legal Notice No……

PLANT PROTECTION (BIOLOGICAL ARTICLES AND CONTROL AGENTS) REGULATIONS, 2021

IN EXERCISE of the powers conferred by section 61 of the Plant Protection Act, 2021 the Cabinet Secretary for Agriculture makes the following Regulations.

	PART I—PRELIMINARY	
	1. These regulations may be cited as the Plant Protection (Biological Articles and Control Agents) Regulations, 2021	Citation
	2. In these regulations, unless the context otherwise requires— "Beneficial organism" means any organism directly or indirectly advantageous to plants, or plant products; "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; "Bio-pesticide" means a crop protection product derived from natural sources and living organisms used to control pests. "Bio-stimulant" means any substance or microorganism applied to seeds, plants and soil with the aim to enhance nutrition efficiency, abiotic stress tolerance and/or crop quality traits,	Interpretation

	increase plant growth, yield and quality; "Commercialization'" means offering for sale articles within the provision of these regulations; "Committee" means the Kenya Plant Health Technical Committee on Imports and Exports as established in Section 11 of the Plant Protection Act; "Classical biological control" means the intentional introduction and release of an exotic biological control agent for permanent establishment and long-term pest control to an area that the pest has invaded; "Extract" means natural product derived from plant, animal or other organisms in its crude form by use of a solvent or other means with the aim to enhance nutrition efficiency, abiotic stress tolerance and/or crop quality traits, increase plant growth, yield and quality; "Local agent" means a person or entity appointed to act on behalf of an applicant not resident in Kenya; "Organic fertilizer" means fertilizer derived from organic material, including animal, and plant material, produced through the process of drying, heating, combustion, composting, chopping, grinding, fermenting, or other methods and makes a declaration	

	of nutrient value on the label; "Organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids; "Parallel approval" means approval and 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; "Person" means an individual or a registered entity with legal rights and obligations; "Pest" means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products; "Risk assessment" means the 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; "Service" means Kenya Plant Health Inspectorate Service; "Soil amendment" means any substance used for the purpose of promoting plant growth or improving the quality of crops by conditioning soils solely through physical means.	

	3. (1) These regulations cover: a) Risk assessment before introduction of articles as listed in First Schedule (1) (a), (b) and (c). b) Registration for commercialization of articles listed in First schedule 1(b) except bio-pesticides which are covered under the Pest Control Products Act. c) Monitoring release of classical beneficial organisms. d) Approval of facilities multiplying or producing beneficial organisms for commercialization and research.	Scope of application
	4. Without prejudice to the provisions of regulation 3, the purpose of these regulations is to facilitate registration, introduction, production and commercialization of the articles listed in First Schedule (1) (a), (b) and (c) and their products in order to protect human, animal, plant and environment health from potential adverse effects.	Purpose of the regulations
	PART II- RISK ASSESSMENT	
	5. (1) The Kenya Plant Health Technical Committee on Imports and Exports as established in Section 11 of the Plant Protection Act shall oversee risk assessment for articles within the scope of these regulations and determine conditions for importation and use. (2) The Service as the secretariat to the committee shall: - a) Receive and process applications for introduction and use of articles within the scope of these regulations; b) Coordinate risk assessment for the applications received in sub regulation 2(a) above;	The Kenya Plant Health Technical Committee on Imports and Exports

	c) Implement the decisions of the committee; d) Monitor the compliance to the decisions of the committee by the applicants.	
	6. (1) No person shall import into the country or export articles listed under First Schedule 1(a) 1(b) 1(c) of these regulations without approval of the Committee; (2) Any person who intends to import and use articles listed in the First Schedule 1(a), 1(b) and 1(c) shall make an application to the Committee through the Service by filling in the appropriate form; PPBR 1, PPBR 2, PPBR 3 or PPBR 4 where applicable, set out in the Second Schedule. (3) Where an application is made by an applicant who is not resident in Kenya, the applicant shall be required to appoint a local agent who is permanently resident in Kenya. (4) The application shall be accompanied by payment of the prescribed fees as provided in the Third Schedule.	Application for risk assessment
	7. (1) Upon receipt of the application in regulation 6 (1) above, the Service shall:- (a) Review completeness of applications; (b) Distribute the application dossiers to subject matter experts for review. (2) The risk assessment shall be undertaken by the experts, using the Criteria for Risk Assessment as prescribed in form PPBR 5 set out in the Second Schedule within three (3) months; (3) The Service shall collate the risk assessment findings from the experts, for presentation to the Committee in form of a	Evaluation of applications and development of Import requirements

	"summary agenda"; (4) The Service may request for risk assessment information from the relevant authority of the country intending to export to Kenya articles listed in the First Schedule 1 (a), (b) and (c); (5) The applicant shall be invited to make a presentation of their application to the Committee; (6) Upon evaluation of all available and availed information and the risk assessment findings, the Committee shall either approve or reject the application and provide import requirements where approval has been granted. (7) The Service shall communicate the decision of the Committee to the applicant within seven (7) days of the committee meeting; (8) Without prejudice to sub regulation (7), The Service shall refer applications of bio pesticides, upon the Committee approval to the Pest Control Products Board for registration as provided for under the Pest Control Products Act, Cap 346; (9) Where the Committee has not approved an application, it shall inform the applicant of such decision in writing and give reasons for the rejection. (10) Applicants for commercial products whose risk assessment has been undertaken and previously approved by the Committee and/or registered shall not require to fill in the forms	
	8. (1) Any person who has been granted approval by the	Importation, exportation

	Committee and intends to import the articles listed in the First Schedule 1 (a), (b) and (c), shall apply to the Service for a Biological Import Permit through form PPBR 6 set out in the Second Schedule. (2) The Service shall issue a Biological Import Permit in the format provided in form PPBR 7 set out in the Second Schedule (3) Upon importation, the Service shall carry out verification of the identity, quality and safety of articles listed under First Schedule 1 (a), (b) and (c).	and verification
	9. If the applicant disputes the outcome of the risk assessment, he may appeal and provide objective evidence, in accordance with the provisions on dispute resolution as outlined in the Plant Protection Act, 2021	Appeal of risk assessment outcomes
	PART III- EFFICACY TRIALS	
	10. (1) Where the Committee approval for the products of the articles listed in First Schedule 1(b) is subject to efficacy trials, the applicant shall undertake efficacy trials by authorized efficacy institutions before commercialization is considered. (2) The conduct of the efficacy trials shall follow guidelines as provided in form PPBR 8 set out in the Second Schedule. (3) The applicant shall identify the authorized efficacy institution to undertake the trials. (4) The principal investigator of the authorized efficacy institution, together with the applicant shall develop a trial	Conduct of efficacy trials

	protocol specific to the product and submit it to the Service for approval. (5) The applicant shall apply to the Service for a biological import permit as provided for in regulation 8(1) above, indicating the specified quantities of the product as guided by the protocol. (6) The applicant shall import and forward the product to the Service for official release to the authorized efficacy institutions (7) The Service shall monitor the conduct of the trials (8) The authorized efficacy institution shall submit trial findings to the Committee for consideration and subsequent approval, prior to commercialization.	
	11. (1) Any person who intends to be authorized as an efficacy institution for the products of the articles listed under First Schedule 1(b) shall apply to the Committee through the Service, for authorization. (2) Application for authorization of efficacy institutions shall be made in form PPBR 9 set out in the Second Schedule and shall be accompanied by: (a) a certified copy of the certificate of incorporation or business registration certificate; (b) details of the location of the field(s), greenhouse(s) and laboratory (ies); (c) proof of compliance with the physical and operational requirements specific to the type of product whose efficacy will be undertaken as	Authorization of efficacy institution

	provided by the Service; and (d) proof of payment of the prescribed fee as set out in the Third Schedule. (3) Upon receipt of the application, the Service shall assess the applicant's suitability to carry out efficacy trials. (4) During the assessment under sub regulation (3), the Service shall assess — (a) whether the applicant has appropriate physical and operational requirements for the efficacy institution of interest; (b) whether the applicant has documentation and record keeping systems; and (c) any other matter which the Service deems appropriate. (5) The Service shall issue a certificate of authorization as provided for in form PPBR 10 set out in the Second Schedule to an applicant who complies with requirements set out in sub regulation (4). (6) Where an applicant intends to operate more than one efficacy institution of the same nature, each institution shall be assessed independently, and a certificate of authorization shall be issued in respect of each institution. (7) Where the Service rejects to grant a certificate of authorization, it shall inform the applicant of such decision in writing and give reasons for the rejection. (8) A certificate of authorization shall: - (a) be valid for thirty-six (36) months from the date of	

	issuance; (b) not be transferrable. (9) An operator of the authorized efficacy institution may apply for renewal of the certificate of authorization upon its expiry in the format PPBR 8 set out in the Second schedule. (10) On receipt of an application for renewal, the Service shall — (c) follow the procedures outlined under sub regulation (4) above; (d) renew the certificate or notify the operator that his application is rejected. (11) The Service shall keep a register of approved authorized efficacy institutions. (12) If, the authorized efficacy institution fails to comply to the prescribed guidelines set out in sub regulation (4) the Service shall give the operator seven (7) days to undertake corrective action and submit a status report to the Service.	
	12. (1) Where the operator fails to implement corrective action in regulation 11 (12), The Service shall by notice in writing cancel the certificate of authorization of the efficacy institution. (2) An authorized efficacy institution operator who intends to terminate his operations shall notify the Service thirty days before the termination of operations. (3) Upon receipt of the notice under sub-regulation 2, the	Cancellation of certificate for an efficacy institution

	Service shall cancel the authorization of the efficacy institution. (4) An authorized efficacy institution operator who fails to renew the certificate of authorization upon the date of expiry shall be deemed to have terminated his operations.	
	13. The Service may undertake monitoring assessments of the authorized efficacy institutions to ensure that standards of practice are maintained.	Post – authorization monitoring
	PART IV - COMMERCIALISATION OF PRODUCTS	
	14. (1) The Service shall prepare a summary of the trial findings as provided by the authorized efficacy institution in regulation 10 (8) for discussion and consideration by the Committee. (2) The Committee shall approve, or reject the application for commercialization. (3) Where the Committee rejects to grant a certificate of registration, it shall inform the applicant of such decision in writing and give reasons for the rejection. (4) A certificate of registration in the format provided for in Second schedule form PPBR 10 shall be issued by the Service upon approval for commercialization by the Committee.	Approval for Commercialization
	15. (1) No person shall distribute, stock, re-package, or store for sale any of the products for articles listed under First Schedule (b) of these regulations unless that product has been registered, packaged and labelled in accordance with these regulations.	Commercialization of articles

	(2) The applicant shall provide the commercial label of the product for approval by the Service; (3) The registration number of the product shall be set out in the following manner— "REGISTRATION NO. KEPHIS (CR) 0000" Where "CR" means Certificate of Registration for a period of three years and or renewal for a period not exceeding two years at any one time. (5) The certificate of registration shall be valid for a maximum period of three (3) years from the date of issue (6) The certificate of registration shall be renewed upon submission of the current label of the product at least one month before its expiry and payment of the required registration fee (7) Without prejudice to sub regulation (6) above, any person who fails to renew the certificate of registration upon the date of expiry shall be deemed to have terminated his or her commercialization activities. (8) The Service shall maintain a list of all approved and registered articles.	
	16. (1) The Committee shall review and determine the application for parallel approval in cases where a similar article listed under First Schedule 1 (b) of the regulation had been approved. (2) Application for parallel approval shall be accompanied by a	Parallel approval

	letter of access from the manufacturer and a letter of no objection from the local agent.	
	17. (1) Any person who adulterates or counterfeits, or is found in possession of adulterated or counterfeit of the products for articles listed under First Schedule 1 (b) of these regulations shall be guilty of an offence and shall, on conviction, be liable to a fine not exceeding five hundred thousand Kenya shillings or to serve imprisonment of a period not exceeding one year or both; (2) Not withstanding sub regulation (1) above, a product shall be deemed to be sub-standard – (e) if it contains any deleterious or harmful substance in sufficient amount to render it injurious to plant life, animals, humans, aquatic life, soil, or water when applied in accordance with directions for use on the label, or if adequate warning statements or directions for use which may be necessary to protect plant life, animals, humans, aquatic life, soil, or water are not shown upon the label; (f) if its composition falls below or differs from that which it is purported to possess by its label; or (g) if it contains foreign material. (3) Without prejudice to 1 above, all articles listed under First Schedule 1 (b) of these regulations shall comply with the Anti-Counterfeit Act, No 13, 2008.	Control of counterfeit or non-conforming products
	18. (1) All articles listed under First Schedule 1 (b) of these regulations shall comply to the labelling requirements as	Labelling

	provided in the relevant Kenya Standards; (2) Every lot, parcel, or package of articles listed in First Schedule 1 (b) of these regulations distributed into or within the territory of Kenya shall have attached to it a label as required by the Service; (3) The name of the products for articles listed under First Schedule 1(b) of these regulations shall be descriptive of the physical form and the purpose or claims of the product and shall include the common name of its active ingredients and may include a distinctive brand or trade mark; (4) As evidence of proof, the labelling statements and claims made of the product shall rely on efficacy data furnished by the authorized efficacy institution that undertook the efficacy trials for the said product; (5) The information on every label shall be printed in both English and Kiswahili languages; (6) All information shown on the label shall be printed in a manner that is conspicuous, legible and indelible; (7) All units of measures shown on the label of products for articles listed under First Schedule 1 (b) shall be expressed in accordance with the requirements of the Weights and Measures Act, Cap. 513; (8) A statement directing the user to read the label which statement shall be in the following form – "READ THE LABEL BEFORE USE" (9) A guarantee statement shall be on the label in the following manner—	

	(a) the word in capital letters "GUARANTEE" followed by; (b) a colon; followed by; (c) the common name of the active ingredient of the product or where a common name has not been designated, the Scientific name or other name of the active ingredient; followed by; (d) the contents of the active ingredient expressed — (10) Any person who fails to comply with this regulation commits an offence and shall upon conviction be liable to pay a fine not exceeding one million Kenya shillings or to serve imprisonment of a period not exceeding two years or both.	
	19. All products for articles listed under the First Schedule 1(b) of these regulations shall be stored and displayed in accordance with the conditions shown on the label	Storage and display
	20. Packages for products listed under the First Schedule 1 (b) of these regulations shall be durable so as to contain the product safety under practical conditions of storage, display and distribution.	Packaging
	21. (1) No person shall distribute or offer for sale misbranded articles listed under First Schedule 1 (b) of these regulations (2) A product shall be deemed to be misbranded – (a) if its label is false or misleading in any manner; (b) if it is distributed or offered for sale under the name of another similar already registered	Misbranding

	product; (c) if it is not labeled as prescribed by the regulations enacted under the Act; or (3) Any person who fails to comply with sub regulation (1) commits an offence and shall upon conviction be liable to pay a fine not exceeding five hundred thousand Kenya shillings or to serve imprisonment of a period not exceeding one year or both.	
	22. (1) The Service shall have the authority to issue and enforce a "stop sale, use, or removal" orders to the owner or custodian of any lot of the products for articles under First schedule 1 (b) (2) Without prejudice to sub regulation (1), The Service shall hold the impounded consignment at a designated place when the said articles are being offered for sale in violation of any provisions under these regulations, at the product owner's cost. (3) The Service shall lift "stop sale, use, or removal" orders on impounded articles when the requirements of these regulations have been complied with and all costs incurred have been paid.	Stop Sale Order
	23. (1) Articles listed under First Schedule (b) of these regulations imported into Kenya without the approval of the Committee shall be intercepted, destroyed or sent back to the exporting country at the cost of the importer. (2) Producing, formulating, distributing, stocking, re-packaging, retailing or storing any articles listed under First	Non-compliance

	Schedule (b) without the approval of the Committee is prohibited; (3) Any person who fails to comply with sub regulation (1) and (2) commits an offence and shall upon conviction be liable to pay a fine not exceeding five hundred thousand Kenya shillings or to serve imprisonment of a period not exceeding three months or both. (4) The Service shall undertake periodic market surveillance to assess compliance of articles listed under First Schedule 1 (b);	
	24. The Service shall maintain a list of approved articles listed in First Schedule 1 (b) and (c) which are handled under the provisions of these regulations	List of approved products
	25. (1) No person shall dispose off any product for articles listed under First Schedule (b) or their containers in a manner that shall be detrimental to man, animal, plants and the environment (2) All product for articles listed under First Schedule 1(b) or their containers shall be disposed off in accordance with the requirements of the Environmental Management and Co-ordination Act (Cap 387).	Disposal of articles under First Schedule (b)
	PART V- LOCAL PRODUCTION	
	26. (1) Any person who intends to multiply, produce or formulate for commercial use articles listed under First Schedule 1 (a), (b) and (c) in Kenya shall apply to the Service for registration of the production, multiplication or formulation facility using form PPBR 11 as provided in the Second Schedule and shall	Application to produce locally

	be accompanied by; (a) A certified copy of the certificate of incorporation or business registration certificate; (b) Details of the location of the facility (ies); and (c) Proof of payment of the prescribed fee as set out in the Third Schedule.	
	27. (1) Upon receipt of the application made in regulation (26) above, the Service shall undertake assessment to evaluate the physical and operational requirements to determine: - (a) whether the applicant has appropriate physical and operational requirements to guarantee safety and quality of the product of interest; (b) whether the applicant has documentation and record keeping systems; and (c) any other matter which the Service deems appropriate. (2) Compliant facility owners shall be issued with a Certificate of Registration as provided for in form PPCR 12 set out in the Second schedule (3) Where an applicant intends to operate more than one facility of the same nature, each facility shall be assessed independently, and a certificate of registration shall be issued in respect of each facility (4) Where the Service rejects to grant a certificate of registration, it shall inform the applicant of such decision in writing stating reasons for the rejection. (5) A certificate of Registration shall: - (a) be valid for twelve (12) months from the date of	Approval of local production and multiplication facilities

	issuance; (b) not be transferrable. (6) The Service shall keep a register of approved local production facilities. (7) An operator of a registered facility may apply for renewal of the certificate of registration at least one month before its expiry as provided for in form PPCR 10 set out in the Second schedule (8) On receipt of an application for renewal, the Service shall: - (a) reevaluate the physical and operational requirements; (b) renew the certificate or (c) reject the application and notify the operator. (9) where the authorized local producer fails to comply with the prescribed guidelines set out in sub regulation (1), the Service shall give the operator seven (7) days to undertake corrective action and submit a status report to the Service.	
	28. (1) Where the operator fails to implement corrective action in sub regulation (27), The Service shall by notice in writing cancel the local facility production certificate. (2) A local facility production operator who intends to terminate his operations shall notify the Service thirty days before the termination of operations. (3) Upon receipt of the notice under sub-regulation (2), the Service shall cancel the authorization local production facility. (4) For purposes of this paragraph, a local production facility	Cancellation of local facility production certificate

	operator who fails to renew the certificate of authorization upon the date of expiry shall be deemed to have terminated his operations.	
	29. (1) Where the registered facility is no longer in operation, the operator shall notify the Service in writing of their status and surrender their certificate of registration. (2) Upon receipt of the certificate of registration, the Service shall cancel the validity of the certificate.	Surrender of certificate of registration
	30. (1) The approved production facilities and products produced therein shall be monitored periodically by the Service in collaboration with the County Executive Committee Member of the respective Counties for compliance to physical and operational requirements and the products integrity, quality and safety. (2) The Service may collect samples of the products at the production and multiplication facility for further testing, where applicable, at the cost of the owner. (3) Where the operator of the facility produces products that fail to meet the integrity, quality and safety requirements, the operator commits an offence and shall upon conviction be liable to pay a fine not exceeding one million or to serve imprisonment of a period not exceeding two years or both.	Monitoring and evaluation of products and production facilities
	31. Where during monitoring of the production facilities, the facilities and the products contained therein fail to meet set requirements, The Service shall revoke the registration certificate.	Revocation of registration certificate

	PART VI- RELEASE OF BENEFICIAL ORGANISMS	
	32. (1) No person shall release any articles listed under First Schedule 1 (c) of these regulations without approval of the Committee; (2) Any person who intends to release into the environment articles listed under First Schedule 1 (c) in Kenya shall apply to the Service as provided for in regulation 6 for approval to release the article and shall be accompanied by; (a) a certified copy of the certificate of incorporation or business registration certificate; (b) details of the location of the project and project plan; and (c) Support letter from a public institution that is legally recognized by the Government	Application for approval of classical release of beneficial organism's release
	33. (1) Where after risk assessment provided for in regulation 7, the Committee considers the introduction of classical biological control agents and beneficial organisms to be safe for release to the environment, the committee shall recommend to the Service the approval of the release. (2) Where the Committee finds that the biological control agent is not safe for release into the environment, it shall recommend to the service not to approve the release and may upon receipt of further information reconsider the application. (3) Without prejudice to the provisions of sub regulation (1) above, the Committee shall not consider applications by individuals;	Approval for classical release

	34. (1) The Service shall issue a written approval indicating the type of release, the target area and conditions of release; provided that: (a) prior to release, The Service shall carry out verification of the identification of the organism under the First Schedule (c) and (b) ensure culturing for at least two generations, where applicable, to ascertain purity of the culture or colony and freedom from other hyper-parasites and pathogens or associated pests. (c) together with the applicant, develop a post-release plan for monitoring and management of any unforeseen occurrences. (2) Without prejudice to sub regulation (1), The Service shall where applicable prescribe the type and measures for release and for: - (a) controlled release, delineate areas of release and targets; (b) uncontrolled release, allow biological control agents and beneficial organisms to be passed directly for release provided that there is adequate experience or information of safe release elsewhere.	Conditions for release of the classical biological control organism
	35. (1) The Service shall monitor the release of the classical biological control agents and beneficial organisms at the cost of the applicant; (2) The applicant shall collaborate with relevant government institutions to undertake the release;	Monitoring of the released biological control agent

	(3) The Service may determine whether classical biological control agents and beneficial organisms to be naturalized after effective post release monitoring hereby not needing further regulation and follow up; (4) Any person who fails to comply with the part VII commits an offence and shall upon conviction be liable to pay a fine not exceeding five million Kenya shillings or to serve imprisonment of a period not exceeding three years or both.	
	PART VII– MISCELLANEOUS	
	36. The Service shall provide returns to the Committee on activities undertaken.	Returns of the Committee
	37. In case of a dispute arising from the implementation of this regulation arbitration shall be conducted as described in the Plant Protection Act.	Resolution of complaints
	38. Any person who contravenes the provisions of these regulations shall be liable, on conviction, to a fine or a term of imprisonment or both as prescribed in Plant Protection Regulations, 2021.	Offences and penalties
	39. The Service will periodically publish a list of prohibited articles under these regulations.	Prohibitions
	40. The Committee or the Secretariat may cooperate and enter into agreements with other agencies of Kenya in order to carry out the purpose and provisions of other Acts and regulations that may have some relation to importation, exportation, production, distribution and use of articles within the scope of these regulations.	Cooperation with Other Entities

	41. (1) All approvals and decisions previously made by the Kenya Technical Committee on Imports and Exports shall be deemed valid under the Committee established by these regulations and the articles shall be assigned a registration/authorization number, where applicable; (2) Any application which had been made prior to establishment of these regulations shall continue under the initial procedures of application.	Transitional Clauses

SCHEDULE ONE

Schedule 1a

1. Biopesticides (microbials, macrobials)

Schedule 1b

1. Live organisms except biopesticides regulated under PCP Act.
2. Bio-fertilizers
3. Organic soil conditioners
4. Bio-stimulants
5. Soil and plant growth media based on organic material
6. Organic fertilizers
7. Plant extracts except those regulated under PCP Act

Schedule 1c

1. Beneficial organisms for classical release

SCHEDULE TWO

Form PPBR1 Application form for bio-fertilizers (R.6(2))

Information for applicants

1. The applicant is responsible for the information submitted.
2. The application shall be submitted in 4 hard copies, separately bound.
3. All parts shall be filled by summarising the required information in the spaces provided and referenced to clearly labelled annexes.
4. A cover letter addressed to the Service (Managing Director KEPHIS) shall accompany this application form.
5. In case of more than one product, the applicant shall fill a separate form for each product.
6. All confidential business information shall be submitted in a separate and sealed file and clearly marked as `CBI`.
7. An applicant who is not a resident in Kenya shall appoint an authorised local agent permanently residing in Kenya. An original letter of appointment must accompany this application.
8. Additional information relating to the application shall be provided if required.
9. The use of genetically modified organisms (GMOs) shall be cleared by the National Biosafety Authority before an application is made.

PART A: GENERAL INFORMATION	
1. Name of applicant	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent where applicable (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
5. Name of Manufacturer	
6. Address of the Manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided	
7. Purpose of introduction/multiplication (Tick where appropriate): a) Research b) Commercial	

c) Personal use d) Other (Specify)_____	
8. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment g) Other (specify)	
9. Quantity 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 (Tick where appropriate) a) Bacteria b) Protozoa c) Virus d) Fungus e) Nematode f) Other (Specify)_____	
4. Are the organisms live or deactivated? If deactivated describe the process used (*Attach evidence)*	
5. Biology of the organism (*attach annexes including peer reviewed publications*)	
6. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (*Detailed descriptions; attach analysis and quality control reports*)	
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. Target plant species and environment	
12. Information on efficacy of the organism	
13. Description of any negative effects caused by the organism	
14. Stability of the organism in the environment	
15. Environmental requirements of the organism	

16. Effect of the organism on availability of soil nutrients and water	
17. Impact of the organism in its area of distribution	
18. List of countries where the organism is in use *(attach evidence*)	

PART C: IDENTITY AND INFORMATION OF FORMULATED PRODUCTS	
1. Trade/commercial name	
2. Purpose of introduction (Tick where appropriate) a) Research b) Commercial c) Personal use d) Other (specify)	
3. Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
4. Details of trademark owner (Names, Postal address, Physical address)	
5. Origin of the Product (*country and state/district)*	
6. Product function (e.g. nitrogen fixing, phosphate solubilizing etc.)	
7. Intended use: (Tick appropriately) a) Agriculture b) Forestry c) Veterinary b) Public health c) Industrial f) Other (Specify)	
8. **Formulation Details**	
8.1 Physical state of formulation: (solid, liquid, etc.)	

8.2 Declare full composition of formulation(s) (active organisms) (Information may be attached in a sealed envelope)	
Active organism(s): (Common name/s)	Minimum count of active organism

8.3 Identification of contaminants	Maximum count of contaminants (CFU)
8.4 Is the product registered in the country of origin? (Provide copy of certificate of registration, approval for use or exemption from registration)	Yes ☐ No ☐ If no give reasons

8.5 Is the product registered in other countries?	Yes ☐ No ☐ State the countries
8.6 Certificate of analysis from the country of origin	Available ☐ Not available ☐
8.7 Specify other physical and chemical characteristics of the product such as grade, matrix etc.	
9. **Production**	
9.1 Describe the production method	
9.2 Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	
9.3 Shelf life (attach reports)	
9.4 Copy of approved Market label for the country of origin *(Attach as annex)*	
10. **Information on product use**	
10.1. Mode of application	
10.2. Area of application a) Green house b) Open field c) Other (Specify)	
10.3. Dosage rates and frequency of application	
11. Mode of action *(Attach supporting scientific publications)*	
12. Description of benefits *(Attach supporting scientific publications)*	
13. Effect on availability of soil nutrients and water	
14. Environmental requirements *(Attach supporting scientific publications)*	
15. Information on tank mixing (combined use/compatibility) (attach reports)	
16. Information on efficacy of the product	
17. **Packaging**	
17.1 Type of Packaging material / container	
17.2 Pack size (s)	
17.3 Describe the disposal of packaging material	
18. Describe decontamination procedures	

19.The proposed point of entry into the country	
20.The proposed final disposition of the product (e.g. incineration, burying, treatment etc)	

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 (tick appropriately)	Skin irritation	Eye irritation	
	None ☐ Mild ☐	Moderate ☐	Severe ☐
1.3 Skin Sensitization in guinea pig (tick appropriately)	None ☐ Mild ☐	Moderate ☐	Severe ☐
1.4 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets			
Material Safety data (Attach MSDS)			

1.5 Summary of Eco toxicological effects	
1.5.1 Toxicity to bees	
1.5.2 Toxicity to fish and other aquatic organisms	
1.5.3 Toxicity to birds	
1.5.4 Toxicity to earthworms	
1.5.5 Toxicity to soil micro-organisms	
1.5.6 Toxicity to other non-target organisms	
1.5.7 Toxicity to other non-target plants	
1.5.8 Fate in the environment (persistent, biodegradable)	
1.5.9 Other effects: Specify	

PART E: PROJECT PLAN (Where applicable)	

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(s) where the activities will be conducted. The site may include for example, an entire facility, a laboratory, a growth chamber or a field	

Any 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) …… Official Title	…… Signed : Date:
Official Stamp of Applicant / Company	**FOR OFFICIAL USE** Remarks …… Signed : Date:

Form PPBR2 **(R. 6(2))**

Application form for soil conditioners and organic fertilizers

Information for applicants

1. The applicant is responsible for the information submitted.
2. The application shall be submitted in 4 hard copies, separately bound.
3. All parts shall be filled by summarising the required information in the spaces provided and referenced to clearly labelled annexes.
4. A cover letter addressed to the Service (Managing Director KEPHIS) shall accompany this application form.
5. In case of more than one product, the applicant shall fill a separate form for each product.
6. All confidential business information shall be submitted in a separate and sealed file and clearly marked as `CBI`.
7. An applicant who is not a resident in Kenya shall appoint an authorised local agent permanently residing in Kenya. An original letter of appointment must accompany this application.
8. Additional information relating to the application shall be provided if required. The use of genetically modified organisms (GMOs) shall be cleared by the National Biosafety Authority before an application is made

PART A: GENERAL INFORMATION	
1. Name of applicant	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent where applicable (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
5. Name of Manufacturer	
6. Address of the Manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided	
7. Purpose of introduction/multiplication (Tick where appropriate): e) Research f) Commercial g) Personal use	

h) Other (Specify)_____	
8. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment g) Other (specify)	
9. Quantity proposed for importation	

PART B: ORGANIC ACTIVE INGREDIENTS	
Details of the Organic Source	
1. The scientific name(s) of the plant/animal/other where the product was derived (Genus, species, strain/variety) *All must be provided*	
2. Common Name of the active ingredient	
3. Does the product have live organisms or are these deactivated? If deactivated describe the process used (*Attach evidence)*	
4. Biology of the organic source (*attach annexes including peer reviewed publications*)	
5. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (*Detailed descriptions; attach analysis and quality control reports*)	
6. Description of benefit	
7. Details of invasiveness of the organic source used	
8. Effect of the organic source used on availability of soil nutrients and water	

PART C: IDENTITY AND INFORMATION OF PRODUCT	
1. Trade/commercial name	
2. Purpose of introduction (Tick where appropriate) a) Research b) Commercial c) Personal use d) Other (Specify)	
3. Origin of the product (*country and state/district)*	
4. Product function (e.g. water retention, aeration, enhanced organic matter etc)	

5. Intended use: (Tick appropriately) a) Agriculture b) Forestry c) Veterinary d) Public health e) Industrial f) Other (Specify)		
6. Formulation Details		
6.1.Type of formulation: (e.g. EC, WP, etc.)		
6.2.Declare full composition of formulation(s) (active organisms) (Information may be attached in a sealed envelope)		
Active ingredient(s): (Common name/s)	Minimum a.i.% purity	a.i. Range %
6.3. Identification of contaminants	Maximum count of contaminants (CFU)	
6.4.Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*		
6.5.Details of trademark owner (Names, Postal address, Physical address)		
7. 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
8. Is the product registered in other countries		Yes ☐ No ☐ If yes state the countries
9. Certificate of analysis from the country of origin		Available ☐ Not available ☐
10. Specify other physical and chemical characteristics of the product such as grade, matrix etc.		
11. Production		
11.1. Describe the production method		
11.2. Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)		
Shelf life (attach reports)		
11.4. Copy of approved Market label for the country of origin		

(Attach as annex)	
12. Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in Section 26 of the regulation)*	
13. Information for product use	
13.1.Mode of application	
13.2.Area of application a) Green house b) Open field c) Other (Specify)	
13.3.Dosage rates and frequency of application	
14. Mode of action *(Attach supporting scientific publications)*	
15. Description of benefits *(Attach supporting scientific publications)*	
16. Effect on availability of soil nutrients and water	
17. Environmental requirements *(Attach all supporting scientific publications)*	
18. Information on tank mixing (combined use/compatibility) (attach reports)	
19. Information on efficacy of the product	
20. Packaging	
20.1Type of Packaging material / container:	
20.2. Pack size(s)	
20.3. Disposal of empty container(s)	
21. Describe decontamination procedures	
22. The proposed point of entry into the country	
23. The proposed final disposition of the product (e.g. incineration, burying, treatment etc)	

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 (tick appropriately)	Skin irritation	Eye irritation	
	None ☐ Mild ☐ Moderate ☐ Severe ☐		
1.3 Skin Sensitization in guinea pig (tick appropriately)	None ☐ Mild ☐ Moderate ☐ Severe ☐		
1.4 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets			
Material Safety data (Attach MSDS)			

1.5 Summary of Eco toxicological effects	
1.5.1 Toxicity to bees	
1.5.2 Toxicity to fish and other aquatic organisms	
1.5.3 Toxicity to birds	
1.5.4 Toxicity to earthworms	
1.5.5 Toxicity to soil micro-organisms	
1.5.6 Toxicity to other non-target organisms	
1.5.7 Toxicity to other non-target plants	
1.5.8 Fate in the environment (persistent, biodegradable)	
1.5.9 Other effects: Specify	

PART E: PROJECT PLAN (Where applicable)	
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(s) where the activities will be conducted. The site may include for example, an entire facility, a laboratory, a growth chamber or a field	

Any additional information that will be useful to support the evaluation process will be accepted.
PART F: DECLARATION
For and on behalf of.....

<table>
<tr><td colspan="2">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.</td></tr>
<tr><td>……
Name in full (Printed)
……
Official Title</td><td>

……
Signed : Date:</td></tr>
<tr><td>Official Stamp
of Applicant / Company</td><td>FOR OFFICIAL USE
Remarks
……
Signed : Date:</td></tr>
</table>

Form PPBR 3 **(R. 6 (2))**

Application form for introduction of bio-pesticides and beneficial organisms

Information for applicants

1. The applicant is responsible for the information submitted.
2. The application shall be submitted in 4 hard copies, separately bound.
3. All parts shall be filled by summarising the required information in the spaces provided and referenced to clearly labelled annexes.
4. A cover letter addressed to the Service (Managing Director KEPHIS) shall accompany this application form.
5. In case of more than one product, the applicant shall fill a separate form for each product.
6. All confidential business information shall be submitted in a separate and sealed file and clearly marked as `CBI`.
7. An applicant who is not a resident in Kenya shall appoint an authorised local agent permanently residing in Kenya. An original letter of appointment must accompany this application.
8. Additional information relating to the application shall be provided if required. The use of genetically modified organisms (GMOs) shall be cleared by the National Biosafety Authority before an application is made
9. For commercial biopesticide preparations, registration will be in accordance with the Pest Control Products Act

PART A: GENERAL INFORMATION	
1. Name of applicant	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent where applicable (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
5. Name of Manufacturer	
6. Address of the Manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided	
7. Purpose of introduction/multiplication (Tick where appropriate):	

a) Research b) Commercial c) Personal use d) Other (Specify)_____	
8. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment g) Other (specify)	
9. Quantity 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 (Tick appropriately) a) Bacteria, b) Virus c) Fungus d) Nematode e) Insect f) Mite g) Other (specify))	
4. Category of organism (Tick appropriately) a) Macrobial b) Microbial c) Other (specify)	
5. Methods of identification, enumeration and bioassay (attach detailed methodology and report)	
6. Biology of the organism (*attach annexes including peer reviewed publications)*	
7. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism *(Detailed descriptions)*	
8. Any relationship to known plant, animal and human parasites/pathogens	
9. Mode of dispersal/ spread, invasiveness, and/or colonization ability	

of the organism	
10. Mode of action of the organism	
11. Natural occurrence (Ecosystem where it is found naturally)	
12. Origin of organism and world distribution	
13. Uses of the organism	
14. Host range of the organism	
15. Specificity to targets	
16. Description of benefit of the organism *(Provide evidence)*	
17. Effect of the organism to non-target organisms	
18. Genetic stability of the organism in the environment	
19. Environmental requirements of the organism	
20. Impact of the organism in its area of distribution	
21. List of countries where the organism/product is in use (*attach evidence)*	

PART C: IDENTITY AND INFORMATION OF PRODUCT		
1. Trade/commercial name		
2. Origin of the Product (*country and state/district)*		
3. Product function (e.g. control of disease, control of insect, pollinator e.t.c.)		
4. Target pest and host		
5. **Formulation Details**		
5.1. Type of formulation: (e.g. EC, WP, other (specify)		
5.2. Declare full composition of the product (Active agent (s) and inert material) (Detailed information on formulation may be provided separately in a sealed envelope)		
Active agent (s): (Common name/s)	Minimum Active agent purity	Active agent Range
5.3. Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*		
5.4. Details of Trademark Owner (Names, Postal address, Physical address)		
6. Is the product registered in the country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration		Yes ☐ No ☐ If no give reasons

7. Is the product registered in other countries	Yes ☐ No ☐ State the countries
8. Certificate of analysis from the country of origin.	Available ☐ Not available ☐ Give reasons
9. Physical and chemical characteristics of the product	
10. **Production**	
10.1.Describe production method	
10.2.Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports	
11. Shelf life (attach reports)	
12. Copy of approved Market label for the country of origin *(Attach as annex)*	
13. Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in Section 26 of the regulation)*	
14. **Information for product use**	
14.1. Mode of application	
14.2.Area of application a) Green house b) Open field c) Other (Specify)	
14.3.Dosage rates and frequency of application	
15. Mode of action *(Attach supporting scientific publications)*	
16. Description of benefits *(Attach supporting scientific publications)*	
17. Environmental requirements *(Attach supporting scientific publications)*	
18. Information on tank mixing (combined use/compatibility) (attach reports)	
19. Information on efficacy of the product	
20. **Packaging**	
20.1.Type of packaging material / container	

20.2. Pack size (s)	
20.3. Disposal of empty container(s)	
21. Describe decontamination procedures	
22. The proposed point of entry into the country	

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				
1.6. SUMMARY OF ECOTOXICOLOGICAL EFFECTS (For microbial products only)				
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 and their identity				
1.6.9. Other effects (Specify)				

PART E: PROJECT PLAN (Where applicable)	
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(s) where the activities will be conducted. The site may include for example, an entire facility, a laboratory, a growth chamber or a field	

Any 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) …… Official Title	…… Signed : Date:
Official Stamp of Applicant / Company	**FOR OFFICIAL USE** Remarks …… Signed : Date:

Form PPBR 4 **(R.6 (2))**

Application form for introduction of Bio-stimulants

Information for applicants

1. The applicant is responsible for the information submitted.
2. The application shall be submitted in 4 hard copies, separately bound.
3. All parts shall be filled by summarising the required information in the spaces provided and referenced to clearly labelled annexes.
4. A cover letter addressed to the Service (Managing Director KEPHIS) shall accompany this application form.
5. In case of more than one product, the applicant shall fill a separate form for each product.
6. All confidential business information shall be submitted in a separate and sealed file and clearly marked as `CBI`.
7. An applicant who is not a resident in Kenya shall appoint an authorised local agent permanently residing in Kenya. An original letter of appointment must accompany this application.
8. Additional information relating to the application shall be provided if required. The use of genetically modified organisms (GMOs) shall be cleared by the National Biosafety Authority before an application is made

PART A: GENERAL INFORMATION	
1. Name of applicant	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent where applicable (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
5. Name of Manufacturer	
6. Address of the Manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided	
7. Purpose of introduction/multiplication (Tick where appropriate): e) Research f) Commercial	

g) Personal use h) Other (Specify)_____	
8. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment g) Other (specify)	
9. Quantity proposed for importation	

PART B: BIOSTIMULANT AND PLANT GROWTH REGULATOR ACTIVE COMPONENTS	
Details of the Organic Source	
1. The scientific name(s) of the organic source where the product was derived (Genus, species, strain/variety) *All must be provided*	
2. Common Name of the organic source	
3. Biology of the organic source (*attach annexes and acceptable and peer reviewed publications*)	
Contaminants, pathogens, pests or weeds likely to be associated with the organic source (*Provide detailed descriptions*).	
4. Description of benefit	
5. Origin of organic source and world distribution	
6. Natural occurrence (Ecosystem where it is found naturally)	
7. Relationship of the organic source to known plant and animal pathogens	

Part C: Identity and Information of Product	
19. Trade/commercial name	
20. Origin of Product (*country and state/district)*	
21. Product function	
22. **Formulation Details**	
22.1 Type of formulation: (e.g. EC, WP, other (specify)	

<table>
<tr><td colspan="3">22.2 Declare full composition of the product (Active agent (s) and inert ingredients) (Detailed information on formulation may be provided separately in a sealed envelope)</td></tr>
<tr><td>Active agents(s):
(Common name/s)</td><td>Minimum Active agent purity</td><td>Active agent Range</td></tr>
<tr><td colspan="2">22.3 Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided</td><td></td></tr>
<tr><td colspan="2">22.4 Details of trademark owner (Names, Postal address, Physical address)</td><td></td></tr>
<tr><td colspan="2">22.5 Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)</td><td>Yes ☐
No ☐ If no give reasons</td></tr>
<tr><td colspan="2">22.6 Is the product registered in other countries</td><td>Yes ☐
No ☐
State the countries</td></tr>
<tr><td colspan="2">22.7 Certificate of analysis from the Country of origin.</td><td>Available ☐
Not available ☐ Give reasons</td></tr>
<tr><td colspan="2">22.8 Specify other Physical and chemical characteristics of the product such as grade, matrix etc.</td><td></td></tr>
<tr><td colspan="3">23. Production</td></tr>
<tr><td colspan="2">23.1 Describe production method</td><td></td></tr>
<tr><td colspan="2">23.2 Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)</td><td></td></tr>
<tr><td colspan="2">23.3 Shelf life (attach reports)</td><td></td></tr>
<tr><td colspan="2">23.4 Copy of approved market label for the country of origin (Attach as annex)</td><td></td></tr>
<tr><td colspan="2">23.5 Proposed market label (Attach as annex) A Tentative product label that meets the requirements of labeling as indicated in Section 26 of the regulation)</td><td></td></tr>
<tr><td colspan="2">24. Usage information</td><td></td></tr>
</table>

24.1. Mode of application	
24.2. Area of application (Greenhouse/ open field)	
24.3 Stage of the crop	
24.4. Dosage rates and frequency of application	
25. Mode of action. *(Attach supporting evidence)*	
26. Description of benefits *(Attach supporting scientific publications)*	
27. Environmental requirements. *(Attach supporting scientific publications)*	
28. Information on tank mixing (combined use/compatibility) (attach reports)	
29. Information on efficacy of the product	
30. **Packaging**	
30.1 Type of Packaging material / container:	
30.2 Pack size(s):	
30.3 Disposal of empty container(s):	
31. The proposed point of entry into the country where applicable	
32. Decontamination procedures	

2. TOXICOLOGY (Formulated product) For microbial products only			
a. Rat:	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
b. Rabbit	Skin irritation	Eye irritation	
	None ☐ Mild ☐ Moderate ☐ Severe ☐		
c. Skin Sensitization in guinea pig:(tick)	None ☐ Mild ☐ Moderate ☐ Severe		

d. WHO classification:	Ia	Ib	II	III
e. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets				
f. Summary of environmental effects				

i. Toxicity to bees	
ii. Toxicity to fish and other aquatic organisms	
iii. Toxicity to birds	
iv. Toxicity to earthworms and soil micro-organisms	
v. Toxicity to other non-target organisms	
vi. Toxicity to other non-target plants	
vii. Persistence in environment	
viii. Metabolites and their identity	
ix. Other effects (Specify)	

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

Any 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) …… Official Title	…… Signed : Date:
Official Stamp of Applicant / Company	**FOR OFFICIAL USE** Remarks …… Signed : Date:

PPBR 5 **(R 7(2))**

Criteria for risk assessment/ review of applications

No.	Item	Yes	No
A.	**DETAILS OF THE APPLICATION**		
	Name of applicant: _____ Product name*: _____ Active live ingredient: _____ Active organic ingredient: _____ Source of material (country) _____ Specific area in the country mentioned above _____ * *if formulated*		
B.	**RISK ASSESSMENT FOR BIOLOGICAL MATERIAL**		
	1) Potential to be a pest, vector or invasive species a) Does the biological material have the ability to be injurious to non-target plants, plant products or environment?		
	Brief information on the harmful effect on the environment or its biological diversity. Immediate effect _____ Long-term effect _____		
	b) Does the biological material have potential to transmit disease?		
	Brief information on mode of transmission of the named agents, disease caused and symptoms_____		
	c) Does the biological material have the ability to persist in the environment?		
	Provide brief description _____		
	d) Does the biological material have the ability to out-compete indigenous non-target species?		
	Provide brief description _____		
	e) Does the biological material have the ability to take over new environments and threaten biological diversity?		
	Provide brief description _____		
	2) Potential to be infective f) Does the biological material have the ability to be infective to		

	humans?		
	g) Does the biological material have the ability to be infective to animals?		
	h) Does the biological material have the ability to cause disease to humans?		
	i) Does the biological material have the ability to cause disease to animals?		
	Brief description on infectiveness_____		
	3) Presence of contaminants Does the biological and carrier material contain any contaminants (unintended organisms, heavy metals, seeds, re-growths e.t.c.)		
	Provide a brief description_____		
	4) 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 hypersensitivity_____		
	5) 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_____		
	6) 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_____		
	7) Behaviour in the environment i.e. mobility in soil, water or air Does the biological material have risk-posing spread characteristics?		
	Brief description_____		
	8) Genetic stability Is the product genetically stable?		
	Provide a brief description_____		
	9) Environmental stability Is the product environmentally stable?		

	Provide a brief description_____		
	10) Uncertainties What are the uncertainties? _____		
C.	**RISK ASSESSMENT FOR ORGANIC BASED MATERIAL**		
D.	**Presence of contaminants** Does the organic and carrier material contain any contaminating organisms?		
	Provide a brief description_____		
	Does the organic and carrier material have potential to contain any heavy metals?		
	Provide a brief description_____		
	Does the organic and carrier material contain any seeds and plant growths?		
C.	**Any other comment/information** _____		
E.	**Recommendation** _____		
F.	**DETAILS OF REVIEWER**		
	Name of reviewer		
	Institution		
	Contacts (Postal & physical address, Email, Mobile)		
	Signature	Date	

REFERENCES AND CITATIONS

PPBR 6 **(R 8(1))**

Biological Importation Permit Application Form

Date:	
Name and address of applicant:	
Name and address of agent in exporting country	
Classification of material(e.g. bio-control, biofertiliser, organic fertiliser, soil amendment)	
Source of material (country)	
Country of origin of organism	
Country exporting into Kenya	
Purpose for importation	
Quantity	

NB: Attach document/letter of authorization from KPHTCIE Committee

PPBR 7 **(R. 9 (3))**

Date: **30/10/2019**

MINISTRY OF AGRICULTURE

KENYA PLANT HEALTH INSPECTORATE SERVICE

BIOLOGICAL IMPORTATION PERMIT

(Plant Protection Act Cap 324)

Permit No:

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:

To import from:

The organism described below:

1. Genus, Species, *Author**: 265 LITRES OF QUICKSOL***
2. Type of Parasit**e: None**
   Predator of weed: **N/A**…---.

   Predator of insect: **N/A**
3. Stage(s) shipped:
4. Dates originally field collected**:**
5. Location (Nearest Town, province/ State, Country: **TANZANIA**
6. Original host (Genus, Species, Author) **N/A**
7. Stage/part attacked **N/A**
8. a) Intended host if different from original... **N/A**
   b) Other alternative hosts **N/A**
9. Laboratory host (If different from original host) … **N/A**
10. Host plant of host pest: **N/A**

Intended use	Intended Host	Type of release study
A. Immediate field Release	**N/A**	***EFFICACY TRIAL***
B. Lab. Culture with Eventual field release	**N/A**	**N/A**
C. Lab. Culture with Study of evaluation only	**N/A**	**N/A**

11. A statement of where similar product has already been used and the degree of success attained……
    Importation of the product is subject to the following conditions:
12. Condition of Release
    i) The supplier must provide documents endorsing that an authorised officer of the plant protection service examined the shipment of the product 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 importation shall be restricted to …See 11. Above
13. 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**

Signed

Official stamp

……

For: Director of Agriculture

* Permission hereby granted is additional to any permission or licence required under any other law

PPBR 8 **(R 10(2))**

Guidelines for evaluating performance of articles for products listed under First Schedule 1 (b)

Instructions

1. All trial institutions must be authorised by the Committee
2. All trials must be authorized by the Committee.
3. It is recommended that the Committee, the Principal investigator/institution and the applicant liaise closely throughout the trial period.

1.1 Cover page

Name and address of applicant.....
Title of trial.....
Principal investigator.....
Name and Address of Institution.....
Physical location.....
Tel: .....
E-mail: .....
Date trial was approved (Permit Ref. for Kenya Plant Health Technical Committee on Imports and Exports approval): .....

1.2 Background on the application

A background on the application shall be given with an overview of the product composition, claims attached to the product, other approvals granted elsewhere, when it was approved by the Committee etc.

1.3 Study Plan

The applicant shall provide a detailed study plan of introducing the product to Kenya.

2. Objectives

State clearly the type of product being evaluated, claims attached to the product(s) and objectives of the evaluation.

3. Materials and Methods

3.1 Plot size

Guidelines on plot size and method of evaluation will depend on the specific crop and the agricultural practices concerned. However they must be internationally or nationally acceptable. The plot size should be sufficiently large to allow for periodic sampling and evaluation.

3.3. Trial site selection

- Trials shall be conducted as directed by the Committee either in the field or glasshouse/greenhouse experiments or both.
- The site(s) shall be as level and uniform as possible and representative of the conditions where commercial use is anticipated.
- When selecting a site, the history of the site may be considered e.g. the preceding crop situation, previous applications.
- Sites at field edges or near ditches, trees, hedges or other obstacles shall be avoided, as they are subject to interfering "edge" effects from those obstacles.

3.4. Experimental set-up

3.4.1 Experimental design

- The design of a trial intended for performance evaluation should permit a statistical evaluation. The treatment shall include; the product(s) to be evaluated, the reference registered (standard) product and the control (a non-treated plot).

3.5. Choice of reference product

The reference product is sometimes referred to as a **standard** or positive control. The reference product chosen shall be **approved** for use in Kenya and shall have the same, or similar, mode of action or active ingredient or claims as that of the test product.

4. Data collection and analysis

Data to be collected shall include but not limited to the following**;**

4.1. Performance assessment

The parameters to be evaluated for performance assessment shall be outlined in the trial methodology. Parameters shall be chosen properly to demonstrate and confirm claims associated with the product and shall be scored using internationally acceptable methods.

4.2 Measure of side effects

Any detrimental effects of the product including phytotoxity and effects on non-targets shall also be assessed.

4.3 Meteorological data

Around the time of application, precipitation (type and daily amount in mm), temperature (daily average, maximum and minimum in ^{o}C) shall be recorded on the field trial site or obtained from a nearby meteorological station. Extreme weather conditions such as severe and prolonged drought, storms, hail, etc, which are likely to influence the effect of the product(s) shall also be recorded. For glasshouse trials, temperature and humidity shall be recorded throughout the trial period.

4.5. Data analysis

- Data collected shall be analysed statistically by use of appropriate scientific statistical method.
- The results shall be fully described in relation to the stated objective(s).

5. Reporting

5.1 Results and discussion

- Results should outline the main findings and how the findings relate to the stated objectives
- Any inferences made
- Any variations or other factors that may have influenced the performance of the product under investigation should also be outlined.
- Any other observations

5. Recommendations

- State whether the product should be approved for the stated uses based on research findings.
- Recommend:-
    - Application rates
    - Time of application
    - Frequency of application
    - Any other

PPBR 9 **(R 11(2))**

Application for Registration/ or Renewal of an Efficacy Trial Institution

1.Name and Address of the Applicant Telephone & E-mail	2. Application Date:	
3. Type of Facility:	( ) Field; ( ) greenhouse; ( ) Laboratory ( ) others :_____(specify) (*Tick where appropriate*)	
4. Type of application	( ) New ( ) Renewal (*Tick where appropriate*)	
5. Location and physical address of Institution (County/Town/Ward/Road		
7. Size of Facility (acreage or No. of production units)		
9. A brief description of facility (Enclose the diagrammatic sketch/plan of the facility). Use separate sheet		
10. Date on which the Facility was approved (for renewal)		
11.Any Additions/Modifications carried out to the existing Facility. If 'Yes' give brief account of additions/modifications	Yes/No	
12.Availability of procedures for operation of the facility *(Tick where appropriate)*	Standard operating procedures (SOPs)	Record keeping
	Yes/No	Yes/No
	Sanitation practices	Pest monitoring
	Yes/No	Yes/No
13. Trained staff operating the Facility	Yes/No	

<table>
<tr><td>14. Any additional information</td><td colspan="2"></td></tr>
<tr><td colspan="3">Declaration
I hereby declare that the information given above is complete and correct to the best of my knowledge.

Name:_____ Official stamp Signature:_____
Date:_____</td></tr>
<tr><td colspan="3">For Official Use</td></tr>
<tr><td>Check list</td><td colspan="2">Status</td></tr>
<tr><td>Application Complete</td><td>Yes</td><td>No</td></tr>
<tr><td>Application details appropriate</td><td>Yes</td><td>No</td></tr>
<tr><td>Final Action Taken:
( ) recommended for assessment
( ) not recommended for assessment</td><td colspan="2">Scrutinized by:
_____
(Signature/Name/Designation)
Date:
_____</td></tr>
</table>

PPBR 10 **(R 11(5))**

REPUBLIC OF KENYA

KENYA PLANT HEALTH INSPECTORATE SERVICE

(KEPHIS)

CERTIFICATE OF AUTHORIZATION FOR AN EFFICACY TRIAL INSTITUTION

This is to certify that.....

Located at .....

Whose facility has been assessed and found to comply with requirements for ..... an efficacy trial institution.

Is hereby approved for a period of three (3) years

Commencing on .....

Certificate No. KEPHIS/..... ***Date of Issue***.....

.....

MANAGING DIRECTOR

**** Renewal is subject to assessment by KEPHIS and Conformity to the physical and operational requirements. Non-conformity will lead to suspension or cancellation of the certificate.***

PPBR 10 **(R 14(4))**

REPUBLIC OF KENYA

KENYA PLANT HEALTH INSPECTORATE SERVICE

(KEPHIS)

CERTIFICATE OF REGISTRATION

This is to certify that product.....

Whose registrant is .....

Is hereby approved for a period of three (3) years

Commencing on .....

Certificate No. KEPHIS/.....

Date of Issue.....

.....

MANAGING DIRECTOR

**** Renewal is subject to assessment by KEPHIS and Conformity to the physical and operational requirements. Non-conformity will lead to suspension or cancellation of the certificate.***

PPBR 11 **(R 26(1))**

Application for Approval as a Local Production Facility

<table>
<tr><td>1.Name/Address of the Applicant

Telephone & E-mail</td><td colspan="2">2. Application Date:</td></tr>
<tr><td>3. Type of facility:</td><td colspan="2">( ) Factory; ( ) greenhouse; ( ) Laboratory
( ) others :_____(specify)</td></tr>
<tr><td>4. Type of application</td><td colspan="2">( ) New
( ) Renewal</td></tr>
<tr><td>5. Location and physical address of Facility (County/Town/Ward/Road</td><td colspan="2"></td></tr>
<tr><td>6. Size of Facility (acreage or No. of production units)</td><td colspan="2"></td></tr>
<tr><td colspan="3">9. A brief description of facility (Enclose the diagrammatic sketch/plan of the facility). Use separate sheet</td></tr>
<tr><td>10. Date on which the Facility was approved (for renewal)</td><td colspan="2"></td></tr>
<tr><td>11.Any modifications carried out to the existing Facility. If ‘Yes’ give brief account of additions/modifications</td><td colspan="2">Yes/No</td></tr>
<tr><td rowspan="4">12.Availability of procedures for operation of the facility (Tick where appropriate)</td><td>Standard operating procedures (SOPs)</td><td>Record keeping</td></tr>
<tr><td>Yes/No</td><td>Yes/No</td></tr>
<tr><td>Sanitation practices</td><td>Pest monitoring</td></tr>
<tr><td>Yes/No</td><td>Yes/No</td></tr>
</table>

13. Trained staff operating the Facility	Yes/No	
14.Any additional information		
Declaration I hereby declare that the information given above is complete and correct to the best of my knowledge Name:_____ Official stamp Signature:_____ Date:_____		
For Official Use		
Check list	**Status**	
Application Complete	Yes	No
Application details appropriate	Yes	No
Final Action Taken: ( ) recommended for assessment ( ) not recommended for assessment	**Scrutinized by:** **_____** **(Signature/Name/Designation)** **Date:** **_____**	

PPBR 12 **(R 27(2))**

REPUBLIC OF KENYA

KENYA PLANT HEALTH INSPECTORATE SERVICE

(KEPHIS)

CERTIFICATE OF AUTHORIZATION FOR A LOCAL PRODUCTION FACILITY

This is to certify that.....

Located at .....

Whose facility has been assessed and found to comply with requirements for a local production facility.

Is hereby approved for a period of one (1) year

Certificate No. KEPHIS/.....

Date of Issue.....

.....

MANAGING DIRECTOR

**** Renewal is subject to assessment by KEPHIS and Conformity to the physical and operational requirements. Non-conformity will lead to suspension or cancellation of the certificate.***

SCHEDULE THREE

FEES AND CHARGES

Item	Proposed Charges (Ksh.)
Application and risk assessment for Import of biocontrol agent and other regulated articles	30,000
Biological Import Permit	1,000
Replacement of Biological Import Permit	1,000
Phytosanitary certificate	1,000
Search fee for documents	1,000
Re-export phytosanitary certificate	1,000
Amendment/Replacement of phytosanitary documents before export	1,000
Amendment/Replacement of phytosanitary documents after export	10,000
Certification of phytosanitary documents	500
Inspection of efficacy trial inspection ((excluding charge of transport (and subsistence allowance where applicable))	5,000
Inspection/ audit of efficacy trial institution ((excluding charge of transport (and subsistence allowance where applicable))	5,000
Transport (Based on prevailing AA rates)	Prevailing AA rate
Subsistence allowance (Based on prevailing SRC rates per day)	Prevailing SRC rate
Inspection of quarantine facility including greenhouse and laboratory (upto 1 ha)	6,000
Additional charges for quarantine facilities for additional hectare above (j) above	500
Inspection of biological production facilities ((excluding charge of transport (and subsistence allowance where applicable))	5,000
Commercial registration of articles under Schedule 1(b)	5,000

Renewal of registration of articles under Schedule 1(b)	5,000
Monitoring of released articles under schedule 1(c) ((excluding charge of transport (and subsistence allowance where applicable))	5,000