Legal Notice No……

PLANT PROTECTION (BIOLOGICAL ARTICLES AND CONTROL AGENTS) REGULATIONS, 2020

IN EXERCISE of the powers conferred by section 53 of the Plant Protection Act, 2020 the Cabinet Secretary for Agriculture Livestock, Fisheries and Cooperatives makes the following Regulations.

	PART I—PRELIMINARY	
	1. These regulations may be cited as the Plant Protection (Biological Articles and Control Agents) Regulations, 2020	Citation
	2. In these regulations, unless the context otherwise requires— "applicant" means any person/entity making an application or request for consideration of the provisions of these regulations; "application" means the request for consideration by an applicant of the provisions of these regulations; "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 used to control pests, pathogens and weeds by a variety of means; "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, increase plant growth, yield and quality;	Interpretation

	"commercialisation'" means offering for sale articles within the provision of these regulations; "committee" means the Kenya Plant Health Technical Committee on Imports and Exports; `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; "export/import" means intentional trans-boundary movement from one country to another; "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; "institution" means an established organization legally operating in Kenya and competent to undertake efficacy trials under this regulation; "local agent" means a person/entity registered and legally operating in Kenya to act on behalf of the applicant; "manufacturer" means any person/entity that produces articles within the scope of these regulations; "monitoring" means an official ongoing process to verify phytosanitary situations; `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 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; "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; "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; "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 listed in Schedule (1) (a) (b) (c). b) Registration for commercialization of articles listed in schedule 1(b) except biopesticides covered under the	Scope of application

	Pest Control Products Act. c) Certification and release of classical beneficial organisms d) Certification of commercial facilities multiplying/producing beneficial organisms	
	4. Without prejudice to the provisions of section 3, the purpose of these regulations is to facilitate mitigation of risks associated with introduction, production and use of the organisms and products in order to protect human, animal, plant and environment health from potential adverse effects.	Purpose of the regulations
	PART II- THE KENYA PLANT HEALTH TECHNICAL COMMITTEE ON IMPORTS AND EXPORTS	
	5. The Committee shall: (1) Consider and decide on applications relating to introduction and use of articles covered in schedule 1(a), (b) and (c) for the purpose of mitigating risks associated with introduction and use of these material. (2) Develop import conditions for articles covered in schedule 1(a), (b) and (c). (3) Develop, verify and/or recommend procedures to guard against adverse effects that may come as a result of introduction and use of articles provided for in schedule 1(a), (b) and (c). (4) Develop, verify and/or recommend procedures to guard against adverse effects that may come as a result of release, multiplication, production and sale, of articles covered in schedule 1(b) (c). (5) Provide risk assessment information upon request by a relevant authority of the country intending to import articles listed in schedule 1(a) and (b) (c) from Kenya.	Functions of the committee
	6. (1) The membership of the Kenya Plant Health Technical Committee on Imports and Exports as established by section 17 of the Plant Protection Act 2020 shall consist of: a The chair shall be the Director responsible for Crop Development in the Ministry of Agriculture b Managing Director, Kenya Plant Health Inspectorate Service or their representative;	Membership of the committee

	c Director General, Kenya Agricultural and Livestock Research Organization or their representative; d Chief Executive Officer, Pest Control Products Board or their representative; e Director, Directorate of Veterinary Services or their representative; f Director General, National Environment Management Authority or their representative; g Director General, National Museums of Kenya or their representative; h Director, Directorate of Public Health and Sanitation or their representative; i Managing Director, Kenya Bureau of Standards or their representative; j One representative from institutions of higher learning k One representative of relevant private sector l One representative from the County Governments (2) The chairperson appointed under sub regulation 6(1) (a) above shall have relevant competence to these regulations. (3) Member(s) under sub regulation 6(1) (b) to (i) shall be appointed by name by their respective institutions or departments taking into consideration the technical nature of the committee. (4) Member under sub regulation 6 (1) (k) shall be nominated by the relevant private sector associations or umbrella body or institution taking into consideration the technical nature of the committee (5) Member under sub regulation 6 (1) (l) shall be nominated by the Council of Governors taking into consideration the technical nature of the committee (6) The Cabinet Secretary shall by gazette notice appoint the Members to the committee. (7) 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 determination of an application before it.	

	(8) The Committee may create as necessary subcommittees for execution of specialized tasks. (9) KEPHIS shall be the Secretariat to the committee.	
	7. (1) The Committee shall hold a minimum of four meetings in a year, being once every three (3) months, or at the request of at least six (6) members. (2) the Service in consultation with the Chairperson shall convene the Committee meetings. (3) The Committee shall establish appropriate procedures to carry out the activities provided in these regulations (4) The Committee shall treat application information provided as confidential business information appropriately except when ordered to release such information by a court of law. (5) Notwithstanding the provisions of sub regulation 4 above, the Committee shall release information under this regulation only after notifying the applicant.	Conduct of business
	PART III- APPLICATION FOR IMPORTATION AND RISK ASSESSMENT	
	8. (1) Any person who intends to import and/or use articles listed in schedule 1(a) and (b) (c) shall make an application to the Committee through the Service by filling in the appropriate forms PPCR 1 - PPCR 4 set out in the Second Schedule. (2) Notwithstanding the sub-regulation 1 above, any further commercial import applications following the initial approval shall be done by the service. (2) Without prejudice to the provisions of 1 above, risk assessment for importation and/use of locally produced/multiplied products under schedule 1(a) and (b) (c) shall be done once by the committee. (3) Where an application is made by an applicant who is not resident in Kenya, the applicant shall be required to appoint an 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
	9. (1) Upon receipt of the application in regulation 8 (1) above, the Service shall coordinate on behalf of the committee to conduct risk assessment of the articles listed in schedule 1(a) (b) and (c) within 3 months.	Risk Assessment and Import Conditions

	(2) the Service may request for risk assessment information from the relevant authority of the country intending to export to Kenya articles listed in schedule 1(a) (b) and (c) (3) The risk assessment shall be undertaken using the Criteria for Risk Assessment as prescribed in form PPCR 5 set out in the Second Schedule. (4) the Service shall collate the risk assessment findings for presentation to the Committee in the form of a summary agenda for deliberation; (5) The applicant shall be invited to make a presentation to the committee when called upon; (6) Upon evaluation of all available and availed information and risk assessment findings, the Committee shall either approve or reject the application based on the risk assessment; (7) The Committee shall provide import conditions specific to the application which shall be subjected to the articles listed in schedule 1(a) and (b) (c); (8) The Service shall communicate the decision of the Committee to the applicant within 7 days of the committee meeting; (9) For applications for articles listed in schedule 1(a), upon decision as provided in sub-regulation 7 and 8, the Service shall provide a referral letter for further processing under the Pest Control Products Act; (10) The decision in sub regulation 7 may be reconsidered upon receipt of new information for determining the risk assessment (11) The Service shall implement the decisions of the Committee (12) The Service shall provide returns to the Committee on activities undertaken on behalf of the Committee	
	10. (1) Any person who has been granted approval by the Committee and intends to import the articles listed in schedule 1(a) (b) (c), shall apply for an import permit in a manner set out in the Plant Protection Regulations, 2020.	Importation and exportation
	11. If the applicant disputes the outcome of the risk assessment and with objective evidence, he may appeal in accordance with the provisions on dispute resolution as outlined in the	Rejection

	Plant Protection Act, 2020	
	PART IV- LOCAL PRODUCTION	
	12. (1) Any person who intends to locally multiply or produce for commercial use articles listed under schedule 1 (a) (b) (c) shall apply for registration of the facility to the Service through form PPCR 10 as provided in the second schedule and shall pay the prescribed fees as provided in the Third Schedule (2) Licensing by the County Government and other relevant competent authorities shall be a prerequisite for registration	Application to produce locally
	13. (1) The Committee shall determine the physical and operational requirements for a local production/multiplication facility (2) The Committee shall undertake evaluation to determine that the facility meets the physical and operational requirements to ascertain safety and quality of the products for articles listed under schedule 1(a) (b) (c). (3) Compliant facility owners shall be issued with a Certificate of Registration as provided for in form PPCR 12 set out in the second schedule and be valid for 1 year from the date of issuance	Approval of local production/multiplication facilities
	14. (4) The Committee may cancel the registration of a facility registered under regulation 13 (3) if the person has contravened the requirements set in regulation 13 (1) or any other provisions under these Regulations.	Revocation of registration
	15. (1) Where the registered facility is no longer in operation, they shall be required to notify the Committee in writing of their intention to do so and surrender their Certificate of Registration issued under Regulation 13 (3) (2) Upon receipt of the Certificate of Registration, the Service shall cancel the validity of the certificate.	Surrender of certificate of registration
	16. (1) Products under a local production/multiplication facility shall be periodically monitored by the Service in consultation with the County Executive Committee Member responsible for agriculture in the respective county from time to time to evaluate the integrity, quality and safety of the products destined for general release.	Monitoring and evaluation of production facilities

	(2) The Committee may collect samples of the products at the production/multiplication facility for further testing, where necessary, at the cost of the owner.	
	17. (1) The facility shall be de-registered where the requirements have been contravened or the where the facility owner officially withdraws the registration. (2) The Committee may cancel the approval of the facility registered under regulation 14 (3) if the person has contravened the requirements set in regulation 14 (1).	De-registration of production facilities
	18. Any person who fails to comply with part IV 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.	Offences and penalties
	PART V- EFFICACY REGISTRATION TRIALS	
	18. (1) Where the approval by the committee for articles listed in schedule 1(b) is subject to efficacy trials, the applicant shall undertake efficacy registration trials in view of commercialization by authorized efficacy trial institutions. (2) The conduct of the efficacy trials shall follow a protocol in the prescribed format as provided in form PPCR 6 set out in the Second Schedule. (3) The applicant shall identify the institution to undertake the trials of the approved product (4) The principal investigator within the institution, together with the applicant shall develop a trial protocol to be used during the trials (5) The authorized institution shall submit the trial protocol to the Service for approval (6) The applicant shall import and forward the product to the authorized efficacy trial institution (7) the Service shall monitor the conduct of the trials (8) The institution shall submit trial findings to the Committee for consideration in view of commercialization	Efficacy trials
	19. Any person who intends to be authorized as an efficacy trial institution for the articles listed under schedule 1(b) shall apply to the Committee through the Service for authorization.	Efficacy trial institution

	20. (1) An application under regulation 19 above shall be in form PPCR 7 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); and c the prescribed fee as set out in the Third Schedule. (2) All applicants shall ensure that they comply with the physical and operational requirements specific to the type of efficacy institution as provided by the Service. (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) If satisfied that the applicant's efficacy institution complies with the physical and operational requirements to competently undertake the efficacy trial, the Service shall issue a Certificate of Authorization to the applicant in the format PPCR 8 set out in the Second Schedule. (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 months from the date of issuance;	Authorization of efficacy institution

	b not be transferrable. (9) An operator of an efficacy institution may apply for renewal of the certificate of authorization at least one month before its expiry in format PPCR 8 set out in the Second schedule. (10) On receipt of an application for renewal, the Service shall — a follow the procedures outlined under sub regulation 4 above; b renew the certificate or notify the operator that his application is rejected. (11) If, in the opinion of the Service, an operator — a does not properly carry out the efficacy trials; b does not comply with any provision of this sub-regulation 4 the Secretariat shall give the operator seven days to correct the deficiency. (12) If the operator fails to correct the deficiency within the period stipulated in sub regulation 11, the Service shall, by notice in writing, suspend or cancel the operator's certificate with immediate effect. (13) An operator who intends to terminate his operations shall notify the Secretariat thirty days before the termination of operations. (14) Upon receipt of the notice under sub-regulation 13, the Secretariat shall cancel the authorization of the operator. (15) For purposes of this paragraph, an operator who fails to renew a certificate of authorization within thirty days from the date of expiry shall be deemed to have terminated his operations. (16) the Service shall keep a register of approved operators. (17) A person who contravenes any provision of this section commits an offence and shall be liable, upon conviction to a fine not exceeding five hundred thousand Shillings or to imprisonment to a term not exceeding one year or both.	

	21. the Service and or Committee may undertake monitoring assessments and other routine assessments on the efficacy institutions to ensure that standards of practice are maintained or to investigate complaints made against authorized efficacy institutions on matters relating to their authorization.	Post – authorization monitoring
	PART VI- COMMERCIALISATION OF PRODUCTS	
	22. (1) Any person who intends to sell articles listed under schedule 1(b) in Kenya shall do so under and in accordance with the terms and conditions of a certificate of registration as provided for in form PPCR 9 set out in the Second Schedule. (2) the Service shall prepare a summary of the trial findings as provided by the efficacy institution in regulation 18 (8) for discussion and consideration by the Committee (3) The Committee shall approve, or reject the application for commercialization (4) 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. (5) A certificate of registration shall be issued by the Service upon approval by the Committee (6) The applicant shall provide the commercial label of the product for approval (7) The certificate of registration shall, unless suspended or canceled, be valid for a maximum period of three (3) years from the date of issue. (8) The certificate of registration shall be renewed upon submission of the current label of the product and payment of the required registration fee. (9) the Service shall maintain a list of registered articles approved under subregulation 3 and 5 above.	Commercialization of articles within the scope of these regulations
	23. (1) The Committee shall review and determine the application for parallel approval in cases where a similar article listed under schedule 1(b) of the First Schedule has already been approved. (2) Such an application should have:	Parallel approval

	(i) Letter of access from the manufacturer (ii) Letter of no objection from the local agent	
	24. All articles listed under schedule 1b shall comply with the Weights and Measures Act Chapter 513 (year)of the Laws of Kenya	Weights and measures
	25. All articles listed under schedule 1b shall comply with the Anti-Counterfeit Act, No 13, 2008	Counterfeits
	26. (1) All articles listed under schedule 1(b) of the second schedule shall comply to the labelling requirements as provided in the relevant Kenya standards. (2) Every lot, parcel, or package of articles listed in schedule 1(b) distributed into or within the territory of Kenya shall have attached to it a label as required by the Committee. (3) the Service shall require proof of labelling statements and claims made for any of the articles. (4) As evidence of proof, the Committee shall rely on efficacy data furnished by the efficacy institutions. (5) Any person who fails to comply with part VI 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.	Labelling
	27. (1) No person shall distribute or offer for sale misbranded articles listed under schedule 1(b) of the first schedule (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 product; (c) if it is not labeled as prescribed by the regulations enacted under the Act; or (d) if it falsely purports to be or is represented as an articles listed under schedule 1(b) of the second schedule unless such product conforms to the definition of identity. (3) Any person who fails to comply with subsection (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 three months or both.	Misbranding

	28. (1) No person shall distribute an adulterated article listed under schedule 1(b) of the First Schedule. (2) Not withstanding (1) above, a product shall be deemed to be sub-standard – a if it contains any deleterious or harmful substance in sufficient amount to render it injurious to beneficial 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; b if its composition falls below or differs from that which it is purported to possess by its label; or c if it contains foreign material. (2) Any person who fails to comply with subsection (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 three months or both.	Non-conforming articles
	29. (1) the Service shall have the authority to issue and enforce a written or printed "stop sale, use, or removal" order to the owner or custodian of any lot of the articles under schedule 1(b) of the first schedule and hold it at a designated place when the Service finds the said articles as being offered for sale in violation of any provisions of the regulations enacted under the Act. (2) the Service shall release the held articles when the requirements of the Act or regulations enacted under the Act have been complied with and all costs and expenses incurred in connection with the "stop sale, use, or removal" order have been paid.	Stop Sale Order
	30. (1) Articles listed under schedule 1(b) of the first schedule found within the territory of Kenya that are not approved by the Committee for importation and/or commercialization shall be intercepted, destroyed or sent back to country of import or	Non-compliance

	origin by the Service at the cost of the person importing, producing, formulating, distributing, stocking, re-packaging, retailing or storing; (2) Notwithstanding the provisions of sub regulation 1 above, the Service shall undertake periodic market surveillance; (3) Any person who fails to comply with subsection (1) commits an offence and shall upon conviction be liable to pay a fine not exceeding fifty thousand Kenya shillings or to serve imprisonment of a period not exceeding three months or both.	
	PART VII- RELEASE OF BENEFICIAL ORGANISMS	
	31. (1) Where after risk assessment, the Committee considers the introduction of classical biological control agents and beneficial organisms to be safe for release to the environment :- a) The Secretariat shall issue a written approval indicating the type of release, the target and conditions of release; b) The Secretariat shall ensure culturing for at least two generations, where applicable, to ascertain purity of the culture and freedom from other hyper-parasites and pathogens or associated pests. (2) There shall be different type of releases as follows; a) Controlled release - the Service shall prescribe measures to delineate areas of release and targets b) Uncontrolled release - the Service may 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. (3) The committee together with the institution shall develop a post-release plan for monitoring and management of any unforeseen occurrences (4) the Service shall monitor the release of the classical biological control agents and beneficial organisms at the cost of the applicant (5) The applicant shall be an institution legally recognized	Release of classical biological control agents and beneficial organisms

	by the Government. The committee shall not consider applications by individuals; (6) The applicant shall collaborate with relevant government institutions to undertake the release; (7) The Committee may determine whether classical biological control agents and beneficial organisms to be naturalised after effective post release monitoring hereby not needing further regulation and follow up; (8) 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 IX – MISCELLANEOUS	
	32. (1) A person shall not import, export, articles listed under schedule 1(a) 1(b) 1(c) of the first schedule under these regulations without approval of the Committee; (2) A person shall not produce, formulate, distribute, stock, re-package, or store for sale any of the products or articles listed under schedule 1(b) of the First Schedule under these regulations without approval of the Committee; (3) A person shall not release any articles listed under schedule 1(c) of the first schedule under these regulations without approval of the Committee; (4) Any person who contravenes the provisions of these regulations shall be liable on conviction to a fine as prescribed in Plant Protection Regulations, 2020.	Offences and penalties
	33. (1) The Service shall carry out verification of the identification and quality and safety of articles listed in schedule 1(a)(b)(c) where applicable. (2) the Service shall maintain a list of articles listed in schedule 1(a)(b)(c) which are handled under the provisions of these regulations	Verification of identification, quality and safety
	34. The Committee will periodically publish a list of prohibited articles under these regulations.	Prohibitions
	35. (1) The Committee may cooperate and enter into agreements with other agencies of Kenya in order to carry	Cooperation with Other Entities

	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. (2)The Secretariat may cooperate with other agencies of Kenya in order to carry out the purpose and provisions of other and regulations that may have some relation to importation exportation, production, distribution, and use of articles within the scope of these regulations.	
	36. (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/authorisation 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 and 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 PPCR1 Application form for bio-fertilizers (R.8(1))

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	Skin irritation	Eye irritation	

appropriately)	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 PPCR2 **(R. 8(1))**

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	
20.1 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	
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..... 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 PPCR 3 **(R. 8 (1))**

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	

<table>
<tr><td colspan="2">Any additional information that will be useful to support the evaluation process will be accepted.</td></tr>
<tr><td colspan="2">PART F: DECLARATION</td></tr>
<tr><td colspan="2">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.</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 PPCR 4 **(R.8 (1))**

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 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)		
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)		
Active agents(s): (Common name/s)	Minimum Active agent purity	Active agent Range

22.3 Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
22.4 Details of trademark owner (Names, Postal address, Physical address)	
22.5 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
22.6 Is the product registered in other countries	Yes ☐ No ☐ State the countries
22.7 Certificate of analysis from the Country of origin.	Available ☐ Not available ☐ Give reasons
22.8 Specify other Physical and chemical characteristics of the product such as grade, matrix etc.	
23. **Production**	
23.1 Describe production method	
23.2 Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	
23.3 Shelf life (attach reports)	
23.4 Copy of approved market label for the country of origin *(Attach as annex)*	
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)*	
24. **Usage information**	
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:

PPCR 5 **(R 9(3))**

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

PPCR 6 **(R 18(2))**

Guidelines for evaluating performance of products

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

PPCR 7 **(R 20(1))**

Application for Registration/ or Renewal of an Efficacy Trial Institution

<table>
<tr><td>1.Name and 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">( ) Field; ( ) greenhouse; ( ) Laboratory ( ) others :_____(specify) (Tick where appropriate)</td></tr>
<tr><td>4. Type of application</td><td colspan="2">( ) New
( ) Renewal
(Tick where appropriate)</td></tr>
<tr><td>5. Location and physical address of Institution (County/Town/Ward/Road</td><td colspan="2"></td></tr>
<tr><td>7. 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 Additions/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>
<tr><td>13. Trained staff operating the Facility</td><td colspan="2">Yes/No</td></tr>
<tr><td>14. Any additional information</td><td colspan="2"></td></tr>
</table>

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:** _____	

PPCR 8 **(R 20(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.***

PPCR 9 **(R 22(1))**

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.***

PPCR 10 **(R 12(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>
<tr><td>13. Trained staff operating the Facility</td><td colspan="2">Yes/No</td></tr>
<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</td></tr>
</table>

<table>
<tr><td colspan="3">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>

PPCR 12 **(R 13(3))**

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