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

## KENYA STANDING TECHNICAL COMMITTEE ON IMPORTS AND EXPORTS

Version 2

## PREFACE

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

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

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

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

**Esther Kimani, PhD**

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**Esther Kimani, PhD**

**Acronyms and Abbreviations**

| | |
|---|---|
| BCA | Biological Control Agent |
| CBI | Confidential Business Information |
| CFU | Colony Forming Unit |
| CITES | Convention on International Trade in Endangered Species of Wild Fauna and Flora |
| EMP | Environmental Management Plan |
| GMO | Genetically Modified Organisms |
| KEPHIS | Kenya Plant Health Inspectorate Service |
| KSTCIE | Kenya Standing Technical Committee on Imports and Exports |
| MOALF | Ministry of Agriculture, Livestock and Fisheries |
| MSDS | Material Safety Data Sheet |
| SOP | Standard Operating Procedure |
| LMO | Living Modified Organisms |
| WHO | World Health Organization |
| PRA | Pest Risk Analysis |
| IOBC | International Organization for Biological Control |
| IPPC | International Plant Protection Convention |
| ISPM | International Standards for Phytosanitary Measures |
| NPPO | National Plant Protection Organization |

**Contents**

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| **Interpretations** | In these guidelines, unless the context otherwise requires- |
| **"Beneficial organism"** | means any organism directly or indirectly advantageous to plants, or plant products, including biological control agents; |
| "**Bio product"** | means a biological agricultural chemical product where the constituents comprises or is derived from biological sources, renewable sources, living organism (plant and plant residues, animal or microorganism) with or without modification. These include many products commonly referred to as botanicals, organics or herbals. They include biological chemicals (plant hormones, plant growth regulators, bio stimulants, enzymes and vitamins), Extracts (plant and animal extracts), Wastes (plant, animal and human wastes), Microbial agents (bacteria, fungi, mycorrhiza, viruses, nematodes, protozoans) and other living organisms (arthropods, plants and animals). |
| **"Bio fertilizer"** | means a preparation or substance containing living organisms which colonize or are intended to colonize the rhizosphere or the interior of the plant that helps or enhances plants to take up nutrients or solubilize or mobilize soil nutrients; |
| **"Biological control agent"** | means a natural enemy, antagonist or competitor or other organism used for pest control; |
| "**Bio-pesticide"** | means a generic term generally applied to a biological control agent, or formulation and applied in a manner similar to a chemical pesticide and normally used for the reduction of a pest population and usually derived from such natural material as animals, plants, fungi, bacteria, other microorganisms and certain minerals. They are classified as microbial and macrobial pesticides, plant incorporated protectants (pesticidal substances that are produced by plants from genetic materials added to the plants) and biochemical pesticides (naturally occurring substances that control pests). |
| **"Committee"** | means the Kenya Standing Technical Committee on Imports and |

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

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| **"National Plant Protection Organization"** | means official service established by a government to discharge the functions specified by the International Plant Protection Convention; |
| **"Natural enemy"** | means an organism which lives at the expense of another organism in its area of origin and which may help to limit the population of that organism. This includes parasitoids, parasites, predators, phytophagous organisms and pathogens; |
| **"Organism"** | means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids |
| **"Parallel registration"** | means registration of a trade name based on the strength of an existing fully registered product from the same manufacturer and source and with authorization from the person holding the registration; |
| **"Parasitoid"** | means an insect parasitic only in its immature stages, killing its host in the process of its development, and free living as an adult; |
| "**Pest**" | means any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products |
| **"Phytosanitary measure"** | means any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non- quarantine pests; |
| **"Quarantine"** | means official confinement of regulated articles for observation and research or for further inspection, testing or treatment; |
| **"Quarantine pest"** | means a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled; |

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| "**Regulated article**" | means any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests, deemed to require phytosanitary measures, particularly where international transportation is involved |
| **"Release (into the environment)"** | means intentional liberation of an organism into the environment; |
| **"Risk assessment"** | means the qualitative identification, evaluation and estimation of the levels of risk involved in a situation, their comparison against benchmarks or standards, and determination of an acceptable level of risk |
| **"Screening for completeness"** | means ensuring that all mandatory fields in the application form have been filled. Where information is not available the non-mandatory fields shall be indicated as such. |

**2. Scope**

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

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

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

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

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

**3. Communication**

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

**4. The Kenya Standing Technical Committee on Imports and Exports (KSTCIE)**

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

(1) The membership of the committee shall consist of:

(a) A Chairperson appointed by the Cabinet Secretary;

(b) Representative, State Department of Agriculture;

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

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

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

(f) Representative of Director, State Department of Veterinary Services;

(g) Representative of Director, National Environment Management Authority;

(h) Representative of Director, National Museums of Kenya;

(i) Representative from relevant institution of higher learning;

(j) Two representatives of relevant private sector players.

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

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

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

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

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

(4) The Committee shall perform the following functions-

i. Consider and determine applications relating to introduction of items covered by the scope of this regulation for the purpose of essential scientific research, experiment, education or commercial production;

ii. To develop and recommend systems and approaches designed to guard against the introduction of organisms that may be harmful to plant, animal, human health and environment;

iii. Determine suitability of facilities, firms or institutions and processes producing biological organisms, bio-products and matters regulated herein and generation of data for purpose of export of the plants, products or organisms.;

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

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

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

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

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

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

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

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

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

**6. Role of the Secretariat**

The secretariat shall perform the following functions:-

(1) Receive applications on behalf of the Committee;

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

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

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

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

(6) Conduct internal risk assessment of the applications;

(7) Receive comments and recommendations from review experts;

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

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

(10) Implement the decisions of the Committee;

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

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

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

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

**7. Role of Expert Reviewers**

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

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

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

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

(4) Participate in Committee meetings when called upon.

**8. Role of the Applicant**

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

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

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

(4) Make required payments.

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

**9. Handling of Applications**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iii) A performance trial report where relevant or available

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

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

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

(c) Upon inspection a report shall be availed by the Secretariat to

the Committee for purposes of facility registration;

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

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

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

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

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

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

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

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

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

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

(ix) The Committee may revoke, suspend or modify an approval subject to emergence of new information that affects the current approval status.

**10. Registration of Approved Products and Articles**

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

(2) The registration certificate shall be issued upon payment of a fee

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

(4) Registration shall be renewable every three years based on post registration monitoring, and payment of a fee

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

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

**10. Non-Compliant Products and Articles**

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

**11. Parallel Registration**

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

(1) The applicant shall:

(i) Fill the application form;

(ii) Provide letter of access from the manufacturer;

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

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

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

(3) If approved, the product shall be registered upon payment

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

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

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

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

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

(9) If new uses are intended, then performance trials shall be undertaken as in label extensions. In case of parallel

registration where label extension is required, the extension shall apply to all other parallel products and the original registered product;

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

**12. Label Extension**

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

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

(3) Once the label extension is granted the use applies to all parallel registrations as well as the original registration;

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

**13. Import of Products and Articles**

(1) Import of samples for trials or research:

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

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

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

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

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

(3)

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

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

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

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

a) The registration number where applicable

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

c) Statement of compliance with import conditions

d) Country of origin or export

**14. Export and Re-Export of Products and Articles**

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

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

**15. Commercialization**

(1) Imported consignments intended for distribution shall be stored in facilities that have been approved and licensed by the Committee;

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

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

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

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

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

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

(ii) Retailer

**16. Release of Biological Control Agents**

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

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

(ii) The Committee will ensure culturing for at least one generation, where applicable, to ascertain purity of the culture and freedom from other hyper-parasites and pathogens or associated pests, notwithstanding regulation 8 (9).

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

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

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

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

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

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

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

**17. Prohibited BCAs**

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

**18. Transition Clauses**

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

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

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

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

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

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

## ANNEXES

### Annex 1a: Application form for Biofertilisers

**Information for applicants**

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

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

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| 7. Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other) | |
| 8. Intended use: (Veterinary, public health, industrial, agriculture, forestry,etc) | |
| 9. Quantity/ Amount proposed for importation | |

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

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| 17. Environmental requirements | |
| 18. Effect on availability of soil nutrients and water. | |
| 19. Impact in its area of distribution | |
| 20. List of countries where the organism/product is introduced. *(attach evidence*) | |
| 21. Details of trials done elsewhere and results.(*Attach annexes)* | |

| **PART C: IDENTITY AND INFORMATION OF PRODUCT FOR STATED ORGANISM** | | |
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| 1. Trade/commercial name | | |
| 2. Purpose of introduction (i.e. Research, commercial, personal use, other) | | |
| 3. Origin of Product (*country and state/district)* | | |
| 4. Product Type/ function (e.g. Soil amendment, soil inoculant etc.) | | |
| 5. Intended use: (Veterinary, public health, industrial, agriculture, forestry,etc | | |
| 6. Formulation Details | | |
| 6.1 Type of formulation: (Peat, liquid, etc.) | | |
| 6.2 Declare full composition of Active organism(s) (a.o) (Information on a.o may be attached in sealed envelope) | | |
| Active organism(s): (Common name/s) | Minimum count of a.o | Maximum count of contaminants ( CFU) |
| 6.3 Details of Formulator (Names, Postal address, Physical address) | | |
| 6.4 Details of trademark owner (Names, Postal address, Physical address) | | |

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| 6.5 Is the product registered in country of manufacture? | Yes ☐<br>No ☐ If no give reasons |
| 6.6 Is the product registered in other countries | Yes ☐<br>No ☐<br>State the countries |
| 6.7 Certificate of analysis from the Country of origin. | Available ☐<br>Not available ☐ |
| 6.8 Specify other Physical characteristics of the product such as grade, matrix etc. | |
| 7. Production | |
| 7.1 Describe production method | |
| 7.2 Purification /quality control procedures applied in production and check for contaminants ( Attach separately) | |
| 7.3 Shelf life | |
| 7.4 Market label for the country of manufacture (Attach as annex) | |
| 7.4.1 Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in annex* | |
| 8. **Information on product use** | |
| 8.1. Mode of application | |
| 8.2. Area of application e.g. leaves, roots, seeds | |
| 8.3. Dosage rates and frequency of application | |
| 9. Mode of action.<br>*(Attach all supporting scientific publications)* | |
| 10. Description of benefits *(Attach all supporting scientific publications)* | |
| 11. Effect on availability of soil nutrients and water. | |

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| 12. Environmental requirements. *(Attach all supporting scientific publications)* | |
| 13. Information on Combined use/Compatibility with other crop protection measures | |
| 14. Details of trials done elsewhere and results. *(Attach all supporting scientific publications)* | |
| 15. Packaging | |
| 15.1 Type of Packaging material / container: | |
| 15.2 Pack size(s): | |
| 15.3 Disposal of empty container(s): | |
| 20. The proposed point of entry into the country | |
| 21. The proposed final disposition of the organism such as destruction, treatment or destined for general Release | |

**PART D. SAFETY INFORMATION**

1. TOXICOLOGY (Formulated product)

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

| | | | | |
|---|---|---|---|---|
| 1.4 WHO classification: | Ia | Ib | II | III |
| 1.5 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets | | | | |
| Material Safety data<br>(summarise material safety data sheet information here)<br>(Attach MSDS) | | | | |
| 1.6 Summary of environmental effects | | | | |
| 1.6.1 Toxicity to bees | | | | |
| 1.6.2 Toxicity to fish and other aquatic organisms | | | | |
| 1.6.3 Toxicity to birds | | | | |
| 1.6.4 Toxicity to earthworms and soil micro-organisms | | | | |
| 1.6.5 Toxicity to other non-target organisms | | | | |
| 1.6.6. Toxicity to other non-target plants | | | | |
| 1.6.6 Persistence in environment | | | | |
| 1.6.7 Other effects: Specify | | | | |

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

| **Any necessary additional information that will be useful to support the evaluation process will be accepted.** | |
|---|---|
| **PART F: DECLARATION** | |
| For and on behalf<br>of.....<br>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. | |
| ……<br>Name in full (Printed) | …….<br>Signature |
| ……..……<br>…<br>Official Title | ……..<br>Date |
| Official Stamp<br>of Applicant / Company | FOR OFFICIAL USE<br>Remarks<br>…….....<br>...<br>Signed : Date: |

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

**Information for applicants**

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

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

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

| **PART C: IDENTITY AND INFORMATION OF PRODUCT** | | |
|---|---|---|
| 1. Trade/commercial name | | |
| 2. Purpose of introduction (i.e. Research, commercial, personal use, other) | | |
| 3. Origin of Product (*country and state/district)* | | |
| 4. Product Type/ function | | |
| 5. Intended use: | | |
| 6. Formulation Details | | |
| 7. Type of formulation: (e.g. EC, WP, etc.) | | |
| 8. Declare full composition of Active ingredient(s) (Technical grade/Formulation) (Information on a.i may be attached in sealed envelope) | | |
| Active ingredient(s): (Common name/s) | Minimum a.i.% purity | a.i. Range % |
| 9. Details of Formulator (Names, Postal address, Physical address) | | |
| 10. Details of trademark owner (Names, Postal address, Physical address) | | |
| 11. Is the product registered in country of manufacture? | | Yes ☐<br>No ☐ If no give reasons |
| 12. Is the product registered in other countries | | Yes ☐<br>No ☐<br>State the countries |
| 13. Certificate of analysis from the Country of origin. | | Available ☐<br>Not available ☐ |
| 14. Specify other Physical characteristics of the product such as grade, matrix etc. | | |
| 15. Production | | |
| 15.1 Describe production method | | |
| 15.2 Purification/quality control procedures applied in production | | |

| | |
|---|---|
| 15.3 Shelf life | |
| 15.4 Market label for the country of manufacture (Attach as annex) | |
| 15.5 Proposed market label (Attach as annex) A Tentative product label that meets the requirements of labeling as indicated in annex | |
| 16 Usage information | |
| 16.1 Mode of application | |
| 16.2 Area of application e.g. leaves, roots | |
| 16.3 Dosage rates and frequency of application | |
| 17 Mode of action. *(Attach all supporting scientific publications)* | |
| 17.1 Description of benefits *(Attach all supporting scientific publications)* | |
| 17.2 Effect on availability of soil nutrients and water. | |
| 17.3 Environmental requirements. *(Attach all supporting scientific publications)* | |
| 17.4 Information on Combined use/Compatibility with other crop protection measures | |
| 17.5 Details of trials done elsewhere and results. *(Attach all supporting scientific publications)* | |
| 18 Packaging | |
| 18.1 Type of Packaging material / container: | |
| 18.2 Pack size(s): | |
| 18.3 Disposal of empty container(s): | |
| 18.4 The proposed point of entry into the country | |
| 18.5 The proposed final disposition of the organism such as destruction, treatment or destined for general Release | |
| **PART D. SAFETY INFORMATION** | |
| 1. TOXICOLOGY (Formulated product) | |

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

| | | | | |
|---|---|---|---|---|
| 1.3. Skin Sensitization in guinea pig:(tick) | None ☐ | Mild ☐ | Moderate ☐ | Severe ☐ |

| | | | | |
|---|---|---|---|---|
| 1.4. WHO classification: | Ia | Ib | II | III |

| |
|---|
| 1.5. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets |
| Material Safety data<br>(summarise material safety data sheet information here)<br>(Attach MSDS) |
| 1.6. Summary of environmental effects |

| | |
|---|---|
| 1.6.1. Toxicity to bees | |
| 1.6.2. Toxicity to fish and other aquatic organisms | |
| 1.6.3. Toxicity to birds | |
| 1.6.4. Toxicity to earthworms and soil micro-organisms | |
| 1.6.5. Toxicity to other non-target organisms | |
| 1.6.6. Toxicity to other non-target plants | |
| 1.6.7. Persistence in environment | |
| 1.6.8. Other effects: Specify | |

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

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

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

**Information for applicants**

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

| **PART A: GENERAL INFORMATION** | |
|---|---|
| 1. Name of applicant/ Company | |
| 2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided* | |
| 3. Name of Local agent (if different from applicant) | |
| 4. Address of the local agent (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) **All must be provided* | |
| 5. Name of Manufacturer | |
| 6. Address of the manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided | |
| 7. Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other) | |
| 8. Intended use: (Veterinary, public health, industrial, agriculture, forestry, etc | |
| 9. Quantity/ Amount proposed for importation | |

| **PART B:DETAILS OF THE ORGANISM** | |
|---|---|
| 1. The scientific name(s) of the organism (Genus, species, strain/variety) *All must be provided* | |
| 2. Common Name | |

| | |
|---|---|
| 3. The type of organism/ micro-organism (Bacteria, virus, fungus, nematode, insect, mite etc) | |
| 4. Category (Macrobial, Microbial etc) | |
| 5. Methods of identification | |
| 6. Are the organisms live or dead? If killed describe the process used *(Attach evidence)* | |
| 7. Biology of the organism (*attach annexes and acceptable and peer reviewed publications)* | |
| 8. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism *(Detailed descriptions).* | |
| 9. Relationship to known plant and animal parasites | |
| 10. Mode of dispersal/ spread of the organism, Invasiveness, and colonization ability | |
| 11. Mode of action of the organism | |
| 12. Natural occurrence (Ecosystem where it is found naturally) | |
| 13. Origin of organism and world distribution and uses | |
| *14.* Is the organism genetically modified? *If genetically modified,*<br>*a)Approval from the Kenya Biosafety Authority*<br>*b) Describe.* | |
| 15. Host range | |
| 16. Specificity to target | |
| 17. Description of benefit | |
| 18. Effect to non-target organisms | |
| 19. Stability of the organism in the environment. | |
| 20. Environmental requirements | |

| | |
|---|---|
| 21. Effect on availability of soil nutrients and water. | |
| 22. Impact in its area of distribution | |
| 23. List of countries where the organism/product is introduced. (*attach evidence)* | |

| **PART C: IDENTITY AND INFORMATION OF PRODUCT** | | |
|---|---|---|
| 1. Trade/commercial name | | |
| 2. Origin of Product (*country and state/district)* | | |
| 3. Product Type/ function (e.g. insecticide, fungicide, etc.) | | |
| 4. Target pest and host | | |
| 5. Formulation Details | | |
| 5.1. Type of formulation: (e.g. EC, WP, etc.) | | |
| 5.2. Declare full composition of the product (Active agent (s) and inert ingreadients) (Detailed information on formulation may be provided separately in a sealed envelope) | | |
| Active agent(s): (Common name/s) | Minimum a.i.% purity | a.i. Range % |
| 5.3. Details of Formulator (Names, Postal address, Physical address) | | |
| 5.4. Details of trademark owner (Names, Postal address, Physical address) | | |
| 5.5. Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration) | | Yes ☐<br>No ☐ If no give reasons |

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

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

**PART D. SAFETY INFORMATION**

1. TOXICOLOGY (Formulated product) For microbial products only

| | | | |
|---|---|---|---|
| 1.1. Rat: | Acute Oral (LD 50 mg/kg) | Acute Dermal (LD50 mg/kg) | Inhalation LC 50 (mg/l/hour) |
| | Experimental | Experimental | Experimental |
| | Calculated | Calculated | Calculated |

| | | |
|---|---|---|
| 1.2. Rabbit | Skin irritation | Eye irritation |
| None | | |
| Mild | | |
| Moderate | | |
| Severe | | |

| | | | | |
|---|---|---|---|---|
| 1.3. Skin Sensitization in guinea pig:(tick) | None ☐ | Mild ☐ | Moderate ☐ | Severe ☐ |

| | | | | |
|---|---|---|---|---|
| 1.4. WHO classification: | Ia | Ib | II | III |

| |
|---|
| 1.5. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets |
| **Material Safety data**<br>(summarise material safety data sheet information here)<br>(Attach MSDS) |
| 1.6. Summary of environmental effects |

| | |
|---|---|
| 1.6.1. Toxicity to bees | |
| 1.6.2. Toxicity to fish and other aquatic organisms | |

| | |
|---|---|
| 1.6.3. Toxicity to birds | |
| 1.6.4. Toxicity to earthworms and soil micro-organisms | |
| 1.6.5. Toxicity to other non-target organisms | |
| 1.6.6. Toxicity to other non-target plants | |
| 1.6.7. Persistence in environment | |
| 1.6.8. Metabolites | |
| 1.6.9. Other effects: Specify | |

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

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

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

**Information for applicants**

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

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

| | | |
|---|---|---|
| vi. | Address of the manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website, fax) *All must be provided | |
| vii. | Purpose of introduction/ multiplication (i.e. Research, commercial, personal use, other) | |
| viii. | Intended use: (Veterinary, public health, industrial, agriculture, forestry,etc | |
| ix. | Quantity/ Amount proposed for importation | |

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

| | |
|---|---|
| x. Natural occurrence (Ecosystem where it is found naturally) | |
| xi. Is the plant/animal genetically modified? *If genetically modified, describe.* | |
| xii. Host range | |
| xiii. Specificity to target | |
| xiv. Details of invasiveness of the plant/animal | |
| xv. Effects to non-target organisms | |
| xvi. Environmental requirements for theplant/animal | |
| xvii. Effect of plant/animal on availability of soil nutrients and water | |
| xviii. Impact of plant/animal in its area of distribution | |

| **Part C: Identity and Information of Product** | | |
|---|---|---|
| 16. Trade/commercial name | | |
| 17. Origin of Product (*country and state/district)* | | |
| 18. Product Type/ function (e.g. Soil amendment, soil inoculant, biostimulant etc.) | | |
| 19. Target pest and host | | |
| 20. **Formulation Details** | | |
| 20.1 Type of formulation: (e.g. EC, WP, etc.) | | |
| 20.2 Declare full composition of the product (Active agent (s) and inert ingredients) (Detailed information on formulation may be provided separately in a sealed envelope) | | |
| Active agent(s): (Common name/s) | Minimum a.i.% purity | a.i. Range % |
| 20.3 Details of Formulator (Names, Postal address, Physical address) | | |
| 20.4 Details of trademark owner (Names, Postal address, Physical address) | | |

| | |
|---|---|
| 20.5 Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration) | Yes ☐<br>No ☐ If no give reasons |
| 20.6 Is the product registered in other countries | Yes ☐<br>No ☐<br>State the countries |
| 20.7 Certificate of analysis from the Country of origin. | Available ☐<br>Not available ☐ Give reasons |
| 20.8 Specify other Physical characteristics of the product such as grade, matrix etc. | |
| 21. Production | |
| 7.1 Describe production method | |
| 7.2 Quality control -method | |
| 7.3 Shelf life | |
| 7.4 Market label for the country of manufacture (Attach as annex) | |
| 7.5 Proposed market label (Attach as annex) *A Tentative product label that meets the requirements of labeling as indicated in annex* | |
| 22. **Usage information** | |
| 8.1. Mode of application | |
| 8.2. Area of application (Greenhouse/ open field) | |
| 8.3 Stage of the crop | |
| 8.4. Dosage rates and frequency of application | |
| 23. Mode of action.<br>*(Attach all supporting scientific publications)* | |
| 24. Description of benefits *(Attach all supporting scientific publications)* | |
| 25. Effect on availability of soil nutrients and water. | |

| | |
|---|---|
| 26. Environmental requirements. *(Attach all supporting scientific publications)* | |
| 27. Information on Combined use/Compatibility with other crop protection measures | |
| 28. Efficacy of the product in trials done elsewhere and results. *(Attach all supporting scientific publications)* | |
| 29. Packaging | |
| 15.1 Type of Packaging material / container: | |
| 15.2 Pack size(s): | |
| 15.3 Disposal of empty container(s): | |
| 20. The proposed point of entry into the country | |
| 21. The proposed final disposition of the organism such as destruction, treatment or destined for general release | |

**Part D. Safety Information**

2. TOXICOLOGY (Formulated product)

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

| 1.3 Skin Sensitization in guinea pig:(tick) | None ☐ | Mild ☐ | Moderate ☐ | Severe ☐ |
|---|---|---|---|---|

| | | | | |
|---|---|---|---|---|
| 1.4 WHO classification: | Ia | Ib | II | III |
| 1.5 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets | | | | |
| Material Safety data<br>(summarise material safety data sheet information here)<br>(Attach MSDS) | | | | |
| 2.6 Summary of environmental effects | | | | |

| | |
|---|---|
| 1.6.1 Toxicity to bees | |
| 1.6.2 Toxicity to fish and other aquatic organisms | |
| 1.6.3 Toxicity to birds | |
| 1.6.4 Toxicity to earthworms and soil micro-organisms | |
| 1.6.5 Toxicity to other non-target organisms | |
| 1.6.7. Toxicity to other non-target plants | |
| 1.6.8 Persistence in environment | |
| 1.6.8 Metabolites | |
| 2.6.7 Other effects: Specify | |

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

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

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

**Site information**

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

**Site Requirements**

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

**General Observations**……..

**Recommendations**…….

**Approved** ☐ **Not approved** ☐

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

**Annex 3: Performance Trials guidelines**

## 1. Introduction

(a) Name of the principal researcher and research institution

(b) Location of the trial

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

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

(e) Source of the formulation tested

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

(g) Information on Reference product.

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

(h) Attributes against which tested: Specify……

## 2. Objectives

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

## 3. Materials and methods to include:-

(a) Crops, species , Cultivars and varieties

(b) Plant growth stage at application time.

(c) Period of testing. …….

(d) Soil type …….

(e) Soil conditions. …….

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

(g) Describe Control and untreated areas…….

(h) Provide information on application rates

……..….

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

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

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

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

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

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

**4. Results**

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

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

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

iv. State main findings……..……

v. Clearly state the final recommendations…….

**5. Note**

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

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

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

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

**Annex 4: Registration certificate**

KSTCIE CERTIFICATE(logo)

Certificate No.

Registration No.

FIELD OF ATTENTION:

ISSUED TO:

STANDARD AND OR REGULATION:

VALID UNTIL:

The committee declares to have inspected the unit(s) and or products of the above mentioned applicant and found them compliant with regulations.

This certificate covers the unit(s) and or product(s) as mentioned herein.

This certificate is in force, provided that the above mentioned applicant continues meeting the conditions laid down in the client contact with the KSTCIE.

Date of certification

Place and date of issue On behalf of the Cabinet Secretary

MoALF

Certifier:

***Units covered:***

| **Certificate of Registration of Bio products and or organism** Mode of Registration:<br>**Temporary**<br>**Full**<br>**Provisional**<br>**Experimental use**<br>(Delete as appropriate)<br>**Registration No……..** | **Previous registration No. if applicable**. (See next column.)<br>---------- | **Is this a modified or renewed registration?**<br>☐ Yes ☐ No<br>**The product/organism was previously registered for experimental use only:**<br>☐ Yes ☐ No. |
|---|---|---|

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

**Annex 5a: Import Permit for organic fertilizers, soil conditioners, soil amelioration**

**products and related products**

**STATE DEPARTMENT OF AGRICULTURE**

**KENYA PLANT HEALTH INSPECTORATE SERVICE**

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

(Plant Protection Act Cap 324)

***Serial Number: …….*** ***Date…….***

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

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

Permission is hereby granted

to……..……

of……..……

To import from……

The following …… (Description and quantity)……

**Subject to the following conditions:**

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

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

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

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

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

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

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

**Additional declarations***

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

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

**Official stamp**…… Signed …….

**For: Director of the National Plant Protection Organization.**

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

**STATE DEPARTMENTOF AGRICULTURE**
**KENYA PLANT HEALTH INSPECTORATE SERVICE**
**BIOLOGICAL IMPORTATION PERMIT**

(Plant Protection Act Cap 324)
Serial No: .....
Date.....

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

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

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

To import from: .....

Quantity permitted.....

**The organism/product described below**:

1. **The organism/product**
   a. Genus, Species, Author.....
   b. Type of Parasite: .....
   c. Predator of weed...…….....…
   d. Predator of insect/ arthropod.....
   e. Stage(s) shipped: ……
   f. Dates originally field collected.....
   *g.* State or Country.....
2. **Original host or parent host plant or organism**
   a. (Genus, Species, Author).....
   b. Stage/part…….
   c. Intended host/target if different from original…….……
   *d.* Other hosts .or sources of material.....
   e. Laboratory host (If different from original host) …….
   *f.* To be tested in the lab against.....
   *g.* To be used for (purpose .....
   *h.* Host plant of target pest……

Approval date and reference.

.....

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

A. Immediate field Release

B. Lab. Culture with eventual field release

C. Study of performance only

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

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

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

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

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

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

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

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

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

*Official Stamp*

*Signed.……*

**For Director of the National Plant Protection Organization**

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

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

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

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

**STATE DEPARTMENT OF AGRICULTURE**
**KENYA PLANT HEALTH INSPECTORATE SERVICE**
**Export certificate forbiological control agents and beneficial organisms, bio fertilizers, organic fertilizers and related products**

<table>
<tr><td>1. Name and Address of Exporter</td><td>PHYTOSANITARY CERTIFICATE No.</td></tr>
<tr><td>3. Dealer’s name and address of Consignee</td><td>4. To Plant Protection Organization of</td></tr>
<tr><td>5. Place of origin</td><td>6. Declared means of Conveyance</td></tr>
<tr><td>7. Declared point of Entry</td><td>8. Distinguishing marks</td></tr>
<tr><td>9. Number and description of packages</td><td>10. Name of regulated Article(s)</td></tr>
<tr><td>11. Scientific identity of Regulated Article(s)</td><td>12. Quantity declared</td></tr>
<tr><td colspan="2">13. This is to certify that the Article(s) described above has/have been inspected according to appropriate procedures and are considered to be free from quarantine pests and practically free from other injurious pests in conformity with the current phytosanitary regulations of the importing country.</td></tr>
<tr><td colspan="2">14. Additional declaration:</td></tr>
<tr><td>15. Disinfestation and/or disinfection treatment……..……..<br>16. Chemical (Active ingredient)……..<br>17. Duration and temperature……<br>18. Concentration……...<br>19. Date…….……</td><td rowspan="2">Place of issue<br>Date:…….<br>Name of Inspector……<br>Signature of Authorizing officer….. ……..<br><br>Official Stamp……..</td></tr>
<tr><td>20. Any additional information</td></tr>
</table>

**Annex 8: Format for Environmental Management Plan**

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

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

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

| | |
|---|---|
| Authorized person or firm | |
| Date of authorization | |
| Item authorized | |

**Outline**

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

**Detailed Plan**

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

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

**Annex 9: Criteria for review of applications**

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

| No. | Item | Yes | No |
|---|---|---|---|
| A. | **DETAILS OF THE APPLICATION** | | |
| | **Name of applicant:**_____<br>**Biological Material:** _____<br>**Source of material ( country) etc**) _____ | | |
| B. | **RISK ASSESSMENT** | | |
| | **1) Potential to be a pest, vector or invasive species**<br>Does the biological material have the ability to be injurious to plants or plant products? | | |
| | Brief information (if available) on an immediate or long-term harmful effect on the environment or its biological diversity_____ | | |

| | | | |
|---|---|---|---|
| | Doesthebiological material have Potential to transmit disease? | | |
| | Brief information (if available) on mode of transmission of the named agents, disease caused and symptoms_____ | | |
| | Does thebiological material have the ability to establish itself, persist, out-compete indigenous species, take over new environments and threaten biological diversity? | | |
| | Provide a brief description on invasiveness _____ | | |
| | **2) Potential to be infective**<br>Does the biological material have the ability to cause disease or pose a risk of harm to humans and/or other organisms? | | |
| | Brief description on infectiveness_____ | | |
| | **3) Potential to be allergenic**<br>Doesthe 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)? | | |
| | Briefdescription on specific hypersensitivity_____ | | |
| | **4) Toxicological effects on mammals**<br>Does the biological material produce toxin or biologically active substance which might be present and may pose a hazard to mammals? | | |
| | List the harmful chemical toxins present and Indicate routes of exposure_____ | | |

| | | | |
|---|---|---|---|
| | **5) Eco-toxicological effects on non-targets**<br>Does the biological material produce toxin or biologically active substance which might be present and may pose a hazard to non-targets (e.g. bees, earthworms, fish etc)? | | |
| | Provide a brief description_____ | | |
| | **6) Behavior in the environment i.e. persistence, mobility, in soil, water or air**<br>How does the biological material behave in the environment? | | |
| | Brief description_____ | | |
| | **7) Presence of contaminants in acceptable limits**<br>Does the biological material contain any contaminants? | | |
| | Check and provide acceptable limits_____ | | |
| | **8) Genetic and environmental stability**<br>Is the product genetically and environmentally stable? | | |
| | Provide a brief description_____ | | |
| | **9) Uncertainties**<br>What are the uncertainties?<br>_____ | | |
| **C.** | **Any other comment/information**<br>_____ | | |
| **D.** | **DETAILS OF REVIEWER** | | |
| | Name of reviewer | | |
| | Institution | | |
| | Contacts (Postal & physical address, Email, Mobile) | | |
| | Signature | Date | |

**Annex 10: Confidentiality Agreement Form**

**NON-DISCLOSURE AND CONFIDENTIALITY AGREEMENT**

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

WHEREAS

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

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

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

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

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

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

1. The CBI is a valuable trade secret of Dossier owner/Applicant and that any disclosure or unauthorized use thereof will cause irreparable harm and loss to Dossier owner/Applicant.
2. All CBI shall be and remains the sole and exclusive property of Dossier owner/Applicant and shall be held in the strictest confidence by Receiving Party. However, CBI submitted by Dossier owner shall be retained by the Receiving party herewith referred as KSTCIE Secretariat.
3. Receiving Party shall not copy CBI or any portion thereof without Dossier owner/Applicant prior written consent.
4. Receiving Party shall return to KSTCIE Secretariat the Dossier submitted for review immediately upon completion of the review.
5. Receiving Party shall not, without the prior written consent of Dossier owner/Applicant, through KSTCIE Secretariat, disclose to any person any portion of the CBI.
6. Receiving Party shall submit review comments to KSTCIE Secretariat who shall hold it in utmost confidentiality.
7. The agreement shall be deemed to commence on.....and shall continue until.....

8. The agreement may be terminated by either party upon seven (7) days written notification to the other party. Upon receiving a termination notice from the KSTCIE Secretariat, the Receiving Party shall cease the evaluation and immediately return the Dossier to the Secretariat.

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

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

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

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

**For KSTCIE** **RECEIVING PARTY**

Signed…….....……Signed…….....…

Name…… Name:…….....

Institution……...……..…Institution……....

Postal address……..… Postal address…….

Physical address……...…… Physical address…….....

Mobile No …….....… Mobile No…….....…

Email:…...……..... Email…….....

Date…….....…… Date…….....

Official Stamp…….....

**Annex 11: Application for Registration as a Biological Products` Merchant**

**Name…….....**

**Postal address …….....**

**Telephone Number…….....**

**Location of premise…….....**

**Premise type( Tick where applicable)**

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

The biological products will be kept in a premise where adequate provisions are available to separate the products and where the articles will be kept which could have an adverse effect on the quality of products.

At anytime during official working hours, even without previous appointment, I/we will allow the inspector(s) entry into the premise and thereby provide them with the facilities necessary to carry out the inspection work.

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

Date.....

Signature.....

Stamp.....

**Annex 12a: Check List for Inspection of a Biological Products` Retail Premise**

**Name…….....**

**Postal address …….....**

**Telephone Number…….....**

**Location of premise…….....**

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

Approved ☐ Not approved ☐

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

**Annex 12b: Check List for Inspection of a Biological Products` Warehouse Premise**

**Company Name…….....**

**Postal address …….....**

**Telephone Number…….....**

**Location of premise…….....**

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

| | |
|---|---|
| Overall comment | |
| Recommendation | |

Approved ☐ Not approved ☐

**Date of next inspection**…….....

**Inspectors Name**…….....

**Signed** …….

**Date**……

**Stamp.....**

**Annex 13: Notification of Interception Form**

**Company Name…….....**

**Postal address …….....**

**Telephone Number…….....**

**Location of premise…….....**

Article categorization (e.g. biofertiliser, biostimulants, biological control agent etc)

……

| No | | Product name ( if formulated) | Quantity |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

Production Country ……

Sample inspected Yes ☐ No ☐

Reason for interception

……

……

Action taken……

……

Name and address of dealer

……

……

……

**Place of Interception**……

**Date of next inspection**……

**Inspectors Name**……

**Signed** …… **Date**……

**Stamp.....**



# Kenya Plant Health Inspectorate Service

**Oloolua Ridge, Karen, P.O. Box 49592-00100 Nairobi**

**020-3597201/2/3  3536171/2, 0722516221 / 0723 786779**

**Email: director@kephis.org, www.kephis.org**