GENERAL GUIDE FOR EVALUATING FACILITIES FOR BIO PRODUCTS

1. Resources

I. Personnel

- There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.
- The qualifications and the training of staff must also be defined and documented.
- Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems.
- Personnel shall wear clothing appropriate for the duties they perform

a. Responsibilities

i. Management's responsibilities

Facility management should ensure that the principles of good laboratory and research practices are complied with. It should;

i. Ensure that qualified personnel, appropriate facilities, equipment, and materials are available.
ii. Maintain a record of the qualifications, training, experience and job description for each professional and technical individual.
iii. Ensure that appropriate Standard Operating Procedures (SOPs) are established and followed.
iv. Ensure that personnel are well trained and understand the functions they are to perform.
v. Ensure that health and safety precautions are adhered to as per the OSHA Act and/or other international safety regulations.
vi. Ensure that there is a quality assurance programme with designated personnel.
vii. Ensure trial plans are developed and agreed upon in conjunction with applicant, trial institution and the regulator.

viii. Ensure that amendments to the study plan/protocol are agreed upon by applicant, trial institution and the regulator and documented.
ix. Maintain copies of all study plans/protocols.
x. For each study ensure that a sufficient number of personnel is available for its timely and proper conduct.
xi. Put mechanisms to ensure proper archiving of documents.

a. Study director/principal investigator qualification and responsibilities

Qualification – Must have at least a Masters degree in the relevant subject

The PI will be responsible for planning, coordinating, executing, monitoring and reporting. Including but not limited to;

i. Ensure that the procedures specified in the study plan/protocol are followed, and that authorization for any modification is obtained and documented together with the reasons for them.
ii. Ensure that all data generated are fully documented and recorded.
iii. To put mechanisms in place to ensure safe working conditions and handling of test products.

b. Other personnel responsibilities

Each individual shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

i. Each facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of the study
ii. Personnel should exercise safe working practice.
iii. Handle test products and other inputs with caution.
iv. Ensure that health and safety precautions are adhered to as per the OSHA Act and/or other international safety regulations.

II. Facilities, equipment and consumables

- There should be sufficient facilities and equipment to perform the studies.
- All equipment must be appropriate and in good working condition.
- An updated programme of equipment calibration and maintenance must be adopted.

III. Maintenance and calibration of equipment

Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations.

IV. Test products and consumables

i. All test products and consumables should be stored and handled appropriately (according to manufacturers specifications)
ii. All test products and consumables should be clearly labelled

V. Waste Disposal

- All remnants, expired test products and empty containers of test products should be disposed according to disposal regulations (EMCA and PCP act).
- Test produce should be disposed appropriately

VI. Rules

a. **Protocols and written procedures**

i. General Standard Operating Procedures (SOPs)

Written SOPs approved by management to ensure the quality and integrity of the data generated in the course of the study should be made available. Each procedure should have a specific SOP. Instruction and manuals of all measuring and application equipment must be available

ii. Study Plan/protocol

The main steps of research studies are prescribed in the study plan or protocol.

a. For each study, a plan should exist in a written form prior to initiation of the study.
b. The study plan should follow the guidelines as stipulated in the Annex 3.

VII. Conduct of the study

a. A unique identification should be given to each study. All documentation concerning this study should carry this specific identification for traceability.
b. The study should be conducted in accordance with the approved study plan/study protocol.
c. All data generated during the conduct of the study should be recorded.

2. Results

a. Raw data

The data should be kept in hard and soft copies for a minimum of 5 years.

b. Data analysis

- Use appropriate scientific statistical method.

c. Report

- The report should be presented according to the guidelines for reporting efficacy trials provided in Annex 4.

3. Quality Assurance

Are there systems in place to guarantee quality? Such as;
-Strict adherence to the approved protocols and SOPs
-Prove of peer review mechanisms
-Appropriate record keeping
-Implementation of previous audit recommendations

4. Archives

Storage of records must be at least 5 years

a) Archives should be designed and equipped for the accommodation and the secure storage of the study plans, raw data, final reports.
b) Material in the archives should be indexed for ease of retrieval

Annex 1: Greenhouse Facility Requirements

Introduction:

These requirements shall apply to biological control agents, beneficial organisms, = microorganisms and their products e.g. bio-fertilizer, soil inoculants, soil conditioners etc. under greenhouse trials as per approval conditions by the Kenya Standing Technical Committee on Imports and Exports (KSTCIE).

Inspection visits by KEPHIS inspectors shall be organized regularly during active period of the trials. KEPHIS has the right to inspect the facility without prior NOTICE. Annual review of the facilities shall be conducted by KEPHIS to ensure that requirements are met..
Where the material being handled require containment, quarantine procedure shall apply in addition to provision herein.

Basic Requirements:

1. Infrastructure:

- The facility shall be made from glass, polycarbonate or polythene for containment and/or to prevent adverse effects of environmental factors e.g. splashing from rain water.
- The outer perimeter (buffer zone) may be composed of crushed rock, gravel, grass or covered with weed cloth. The buffer zone should be at least one meter and sloped such that water drains away from the facility.
- The floor should be made of material that allows for easy cleaning and prevents growth of weeds
- Adequate lighting should be provided.
- Clean water should be provided in the site.

2. Facility access:

- The facility should be isolated preferably well fenced and must have a secure gate which must be locked at all times.
- The facility should have only one entrance which shall also serve as an exit and have a double door system with an antennae room and a trough with disinfectant solution. A concrete trough should be constructed to hold the disinfectant solution.
- No unauthorized person should gain access to the facility and the entrance should be labeled “Restricted Entry” and any other appropriate signage
- Nobody should take or carry away any of the products and/or test crops from the quarantine facility without written authority of KEPHIS inspector.

3. **Sanitation:**

- All equipment/implements used shall be disinfected at the end of each trial period. However, those used on day to day operations shall be disinfected before and after use and stored in a designated store.
- The disinfectant solution at the entrance shall be used at all times during entry and exit of the facility.

4. **Labeling:**

Proper labeling should be done to capture the test products under trial, date trials commenced, test crop and any other relevant parameter.

5. **Personal Protective Equipment (PPEs):**

- Protective clothing should be provided before entry into the facility.
- Provide personal protective equipment for the workers at the quarantine facility.

6. **Record Keeping:**

Maintain a hard cover book on the site and record any pests, disease and weeds observed. Any anomaly noted should be reported to KEPHIS inspector immediately.

7. **Safety Requirements:**

- Personnel should be well trained in handling of test products and conversant with safety requirements.

8. **Disposal Procedures:**

All remnants, expired test products and empty containers of test products should be disposed according to disposal regulations (EMCA and PCP act).

Annex 2: Field Facility Requirements

Introduction:

These requirements shall apply to biological control agents, beneficial organisms, microorganisms and their products e.g. bio-fertilizer, soil inoculants, soil conditioners etc. under field trials as per approval conditions by the Kenya Standing Technical Committee on Imports and Exports (KSTCIE).

Inspection visits by KEPHIS inspectors shall be organized regularly during active period of the trials. KEPHIS has the right to inspect the facility without prior NOTICE. Annual review of the facilities shall be conducted by KEPHIS to ensure that requirements are met.

Where the material being handled require containment, quarantine procedure shall apply in addition to provision herein.

Basic Requirements:

1. **Infrastructure and Facility access:**
   - The facility should be isolated preferably well fenced and must have a secure gate which must be locked at all times.
   - The facility should have only one entrance which shall also serve as an exit.
   - No unauthorized person should gain access to the facility and the entrance should be labeled "Restricted Entry".
   - Nobody should take or carry away any of the products and/or test crops from the facility without written authority of KEPHIS inspector.
   - Clean water should be provided in the site.

2. **Sanitation:**
   - All equipment/implements used shall be disinfected at the end of each trial period. However, those used on day to day operations shall be disinfected before and after use and stored in a designated store.
   - The disinfectant solution at the entrance shall be used at all times during entry and exit of the facility.

3. **Labeling:**

Proper labeling should be done to capture the test products under trial, date trials commenced, test crop and any other relevant parameter.

4. Personal Protective Equipment (PPEs):

- Protective clothing should be provided before entry into the facility.
- Provide personal protective equipment for the workers at the quarantine facility.

5. Record Keeping:

Maintain a hard cover book on the site and record any pests, disease and weeds observed. Any anomaly noted should be reported to KEPHIS inspector immediately.

6. Safety Requirements:

Personnel should be well trained in handling of test products and conversant with safety requirements.

7. Disposal Procedures:

All remnants, expired test products and empty containers of test products should be disposed according to disposal regulations (EMCA and PCP act).

Annex 3: Performance Trials guidelines

KSTCIE guidelines for evaluating efficacy of products

Instructions

1. All efficacy institutions must be authorised by the committee
2. All efficacy trials must be authorized by the committee.
3. The conduct of the trials shall be as per the approved trial protocol
    a. In two sites, for two seasons:

        Where there is consistency in results between the two sites in the first season, then results from one site will be required in the second season; where there is no consistency in results between the two sites in the first season, then results from two sites will be required in the second season, *or*

    b. In four sites for one season, *or*
    c. In one site for three seasons.

    This may take into account variations in soils and agro ecological zones.

4. KEPHIS shall monitor the efficacy trials

1.1 Cover page

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

1.2 Background on the application

A background on the application shall be given with an overview of the product name, composition, claims attached to the product, other approvals granted elsewhere. Information on test crop, claims to be investigated and expected benefits. This information shall be provided in tabular form.

2. Objectives

State clearly the general and the specific objectives of the trial.

3. Materials and Methods

3.1. Site selection

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

3.2 Plot size

Guidelines on plot size and method of evaluation will depend on the test crop following good experimental practices.

3.4. Experimental set-up

3.4.1 Experimental design

- The trial shall be undertaken following an appropriate design based on the objective to permit statistical analysis.

3.4.2 Treatments

The treatments shall include;

i. Test product at recommended rate
ii. Test product at recommended rate +25%
iii. Test product at recommended rate -25%
iv. Positive (standard/reference)
v. Negative control (a non-treated plot).

3.5. Choice of reference product

The reference product is sometimes referred to as a **standard** or positive control.

The reference product chosen shall be **approved** for use in Kenya and shall have the same, or similar, mode of action or active ingredient or claims as that of the test product.

4. Data collection and analysis

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

4.1. Performance assessment

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

4.2 Other observations

Any detrimental effects of the product including phytotoxicity and other effect shall be reported.

4.3 Meteorological data

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

4.4 Laboratory analysis

Where the trial requires lab analysis, this should be undertaken in recognized laboratories

4.5. Data analysis

- Data collected shall be analysed by use of appropriate scientific statistical methods.
- The trial institutions to keep raw data for at least 5 years and make it available upon request by the secretariat.

5.0 Results and discussion

- Results should discuss the findings in relation to the stated objectives
- Any other observations

6.0 Conclusion and recommendations

- State whether the product should be approved for the stated uses based on research findings.
- Recommend:-
    - Application rate (s)
    - Time of application
    - Stage of application

- Frequency and interval of application
- Mode of application

7.0 Reporting

- Progress and a final report to be submitted to KSTCIE secretariat.
- The final report shall be submitted in electronic and hard copies.

Annex 5: 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	**For 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 6: Conflict of Interest Statement

A conflict of interest exists when professional judgment concerning a primary interest (such as validity of research) may be influenced by a secondary interest (such as financial gain or personal/ business rivalry).

I (We) certify that there is no conflict of interest with the product proponent regarding the study to be done on the product …….. as per study protocol……

Company Management	**Study Director/ Principal Investigator**
Signed…… …….	Signed…….....……
Name……	Name: …….....…
Postal address……..…	Postal address…….
Mobile No ……..…	Mobile No…….....…
Email: ……...…….....	Email…….....
Date…….....……	Date…….....

Annex 7: Code of Ethics/ Professionalism Declaration

I (We) agree to;

- Act with integrity, competence, diligence, respect and in an ethical manner with the prospective clients, regulators, employees, colleagues in the profession.
- Put the integrity of the evaluating institution profession and the interest of the clients above our own personal interest.
- Use reasonable care and exercise independent professional judgement when conducting studies, making recommendations among other professional activities.
- Promote the integrity of, and uphold the rules governing research for registration purposes.
- Maintain and improve professional competence
- Will not offer, solicit or accept any gift, benefit, compensation, or consideration that reasonably could be expected to compromise the independence and objectivity of the findings.
- Will not knowingly make any misinterpretations relating to the study activity and recommendations
- Will not engage in any professional conduct involving dishonesty, fraud, or deceit or commit any act that reflects adversely on your institutions professional reputation, integrity and competency.

Company Management	**Study Director/ Principal Investigator**
Signed…… …….	Signed…….....……
Name……	Name: …….....…
Postal address……..…	Postal address…….
Mobile No ……..…	Mobile No…….....…
Email: ……...…….....	Email……....
Date…….....……	Date…….....