THE EAST AFRICAN COMMUNITY

TECHNICAL CRITERIA FOR DESIGNATING EFFICACY TRIAL CENTERS –EAST AFRICAN COMMUNITY (EAC)

Approved by 39th Council of Ministers Held on 28th November, 2019

Introduction

This document prescribes the technical requirements for private or public institutions for designation as Efficacy Trial Centers for conducting efficacy studies that support or are intended to support applications for registration of pesticides in the East African Community (EAC). It is intended to ensure the quality and integrity of efficacy study results that are submitted to the EAC or its Partner States in support of pesticides registration or an extension of uses.

Definitions

Batch – means a specific quantity of the control and test substance.
Carrier – means any material (e.g. water, soil, nutrient media, e.t.c) combined with test substance.
Control substance – means any chemical substance or mixture, or any other substance (e.g. microbials) other than the test substance and used for comparison with the test substance.
Efficacy Trial Center – means a private or public institution that meets the technical criteria and so designated by the EAC or its Member Countries.
Experimental start date – means the 1st date that the test substance is applied in the study.
Experimental end date – means the last date on which data is collected from the study.
Quality assurance – means compliance with quality assurance of the studies.
Quality registration control – means the internal process for designated Center to ensure all steps in the study protocols are followed.
Raw data – means all original information collected from the study and necessary for the evaluation of study results.
Specimen – means any study subject (target pest) intended for examination and analysis.
S**ponsor** – means the applicant (registration) that financially supports the study.
Study – means the efficacy trial conducted in a laboratory, greenhouse, or in the field at one or more sites in which the test substance is applied.
Study Director – means the individual responsible for the overall conduct of the study.
Study Personnel – means all individuals involved in the efficacy study.
Study Protocol – means all processes and steps required for testing the test substance and all documentation that is required by the study.
Test substance – means any chemical substance or mixture, or any other substance which is the subject of the efficacy study.

Application Process

Private or public institutions shall formally apply for designation as an EAC Designated Efficacy Trial Centre by the EAC or its Partner States. Application form attached (Annex A) shall be submitted to EAC or designated pesticides regulatory authorities in the Partner States and provide the technical information required by the criteria as explained below. The designated National Regulatory Authority shall accredit a public or private institution to conduct the trials. The duration for which accreditation is valid should be specified.

Inspection of Efficacy Trial Centre

A prospective or an EAC Designated Efficacy Trial Centre shall permit an authorized official of the EAC or its Partner States, at reasonable times and in a reasonable manner, to conduct physical

verification of the information provided through an inspection. Assessment criteria of institutions involved/ to be involved in carrying out efficacy trials on Pest Control Products is attached (Form B).

Technical Requirements for EAC Designation

A. Testing Institution

The Testing Institution shall ensure that:

1) A Study Director is assigned to oversee the execution of an efficacy trial. The Study Director shall be a scientist or a professional with the required education, training, and experience. The Study Director shall have overall responsibility of conducting the trial, ensuring that all steps in the protocol are followed; trained personnel implement the trial; and appropriate tools are available for data collection and documentation.

2) There is a Quality Assurance/Quality Control (QA/QC) Unit, independent of the Study Director. The QA/QC Unit shall be responsible for inspecting and ensuring the quality and integrity of the efficacy trial. It shall periodically inspect the trial steps and report to the institution management. It shall also review all documentation and the final report to ensure that the reported results accurately reflect the raw data of the study.

3) Quality Assurance/Quality Control Unit communicate any deviations or problems to the Study Director and ensure corrective actions are taken.

4) Evaluation of test substances against the control for identity, amount, stability, and effectiveness in accordance with the submitted pesticide label is carried out.

5) They provide personnel, resources, facilities, equipment, materials, and protocols (and methodologies) before commencement of the experiment.

5) personnel have been properly trained and can perform the functions they are to perform in the study.

B. Testing Centre Facility

The Testing Centre shall have:

1) Shall Standard Operating Procedures (SOP) for conducting efficacy trials.

2) Adequate space and infrastructure for effective conduct of the efficacy trial.

3) Indoor, greenhouse or outdoor facilities. Studies conducted in outdoor facilities must be located in suitable locations.

4) Proper isolation of trial sites to prevent drift or contamination on the efficacy trial.

5) Adequate space for storing and handling of samples and equipment and collection facilities for pesticide waste.

B. Efficacy trial Personnel

The personnel to engage in the efficacy trials shall

1) Have the minimum professional competence required to conduct efficacy trial.

2)be knowledgeable of the Study Protocol.

3) be properly trained in the safe use and application of pesticides.

D. Records and Documentation

The Testing Center Facility shall demonstrate the ability to maintain all raw data, protocols, and final reports resulting from the efficacy trials.

Other Criteria

1) Previous experience in conducting pesticide efficacy trials.

2) International accreditations obtained by the Center.

ANNEXES

Form A- Application Form

Form B- Inspection Form

FORM A

APPLICATION FORM FOR INSTITUTIONS INVOLVED/ TO BE INVOLVED IN CARRYING OUT EFFICACY TRIALS ON PEST CONTROL PRODUCTS

1. INFORMATION FOR APPLICANTS

a) The Application Form shall be completed by a duly authorized person.
b) The application shall be submitted in triplicate to:
The Head of Regulatory Authority
P.O. Box:
Code No:
TOWN:
COUNTRY:
Telephone Number:
Email Address:
Web page:
c) Every Application shall be accompanied by application fee as prescribed
d) The Application shall be accompanied by the evidence as per the specific data requirements

2. DETAILS OF APPLICANT

a) Name and Address of institution/researcher: .....
b) Contact person:.....
c) Tel No: .....
d) Email: .....

e) Signature: ……
f) Date:……..

3. AREAS FOR ACCREDITATION

a) Pest Control Products Category (e.g. Herbicides, Insecticides, Fungicides, etc…..): ……..
b) Crops: ……

4. SPECIFIC REQUIREMENTS

During the visit the following items shall be evaluated: Please indicate level of compliance

		Comments on Level of Compliance
A	**GENERAL**	
	Physical facilities	
	Office space	
	Location/accessibility	
	Availability of Transport	
	Equipment maintenance	
	Cost of doing trials	
	Procedures of keeping records and for how long (archiving)	
	Awareness/utilization of EAC trial protocol	
B	**IMPORTANT**	
	Facilities: particularly chemical store, equipment store, other relevant on and off-site facilities)	
	Disposal consideration after testing	
	Workers' safety	
	Mode of assessment (type, time and frequency of assessment, phytotoxicity).	

		Comments on Level of Compliance
	Proposed System of reporting – 1. Individual reports for each season submitted? 2. Subjected to internal Peer Review Committee? 3. Submission by Head of Department?	
C	**CRITICAL**	
	Availability of land/green houses	
	Availability of crops/animals for trials	
	Staff management – (structure and responsibilities)	
D	**VERY CRITICAL**	
	Human Resources: 1. Qualifications 2. Experience in carrying out efficacy trials	
E	**ADDED ADVANTAGE**	
	Any specific internationally recognized testing guidelines to be followed	
	Copies of study plans (Trial Protocols for specific trials)	
	Testing organization accreditation for any other work	
	Standard Operating Procedures	
	Any other uniqueness of the institution/comment	

NOTE:

METHODOLOGY OF ASSESSMENT

Actual visit to the institutions and private researchers shall be undertaken to inspect the facilities and interview staff involved in efficacy trials.

FORM B

Date ..... **FINAL MARKS AWARDED……**

ASSESSMENT CRITERIA OF INSTITUTIONS INVOLVED/ TO BE INVOLVED IN CARRYING OUT EFFICACY TRIALS ON PEST CONTROL PRODUCTS

SCORE SHEET & CRITERIA

1. OBJECTIVES OF THE VISIT

a) To assess the capacity of private/public institutions to carry out efficacy trials on pest control products for registration purposes.
b) To assess the safety of workers involved in efficacy trials and the concerns to the environment.
c) Make recommendations to the Regulatory Authority based on the findings.

2. METHOD OF WORK

Actual visit to the institutions and private researchers, inspecting the facilities and interviewing staff involved in efficacy trials.

a) Name and Address of institution/researcher: .....

b) Contact person:.....
Tel No: .....
Email: .....

3. SPECIFIC INSPECTION REQUIREMENTS

During the visit the following items shall be evaluated: Insert the score for each criteria as indicated below

	Item	**Guidelines**	**Evaluator 1**	**Evaluator 2**	**Evaluator 3**	**Evaluator 4**	**Evaluator 5**	**Total Marks**	**Recommended/ Harmonized marks**
A	**GENERAL**							Possible by Individual assessor	
1	**Physical facilities**								
	Office space	Should have computer, telephone, internet services						1	
	Location/accessibility	Should be easy to locate						1	
	Availability of Transport	Evidence of transport for easy access to trial sites						1	
	Equipment maintenance	Maintenance schedule should be shown (is it reasonable)						1	

	Item	Guidelines	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended/ Harmonized marks
	Cost of doing trials	Approximate costs for various categories should be given						1	
	Procedures of keeping records and for how long (archiving)	Records must be shown						1	
	Awareness/utilization of EAC trial protocol	Evidence should be provided for inspection						10	
	Remarks							**Total (16)**	
B	**IMPORTANT**								
	Facilities: particularly chemical store, equipment store, other relevant on and off-site facilities)	Should be shown						5	
	Disposal consideration after testing							5	
	Workers' safety	Personal protective Equipment must be shown						5	
	Mode of assessment (type, time and frequency of assessment, phytotoxicity).							5	

	Item	Guidelines	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended/ Harmonized marks
	Proposed System of reporting – 4. Individual reports for each season submitted? 5. Subjected to internal Peer Review Committee? 6. Submission by Head of Department?	Evidence of structured reporting system must be provided for inspection						5	
	Remarks							**Total (25)**	
C	**CRITICAL**								
	Availability of land/green houses	If leased documentary proof required						10	
	Availability of crops for trials	Evidence should be shown or lease agreement, as applicable						10	
	Labaratory facilities							5	
	Staff management – (structure and responsibilities)	Responsible officer must be clearly identified						10	
	Remarks							**Total (35)**	
D	**VERY CRITICAL**								

	Item	Guidelines	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended/ Harmonized marks
	Human Resources: 3. Qualifications 4. Experience in carrying out efficacy trials	1. Lead researcher must have minimum of a relevant M.Sc degree *(Masters 10 &PhD 15)* 2. Lead researcher must have practical experience on relevant crop/pest						15 5	
	Remarks							**(Total 20)**	
E	**ADDED ADVANTAGE**								
	Any specific internationally recognized testing guidelines to be followed.							1	
	Copies of study plans (Trial Protocols for specific trials)	Must be provided for inspection						1	
	Testing organization accredited for any other work?							1	
	Standard Operating Procedures	SOP's should be provided for inspection						1	
	Remarks								

	Item	Guidelines	Evaluator 1	Evaluator 2	Evaluator 3	Evaluator 4	Evaluator 5	Total Marks	Recommended/ Harmonized marks
	Sub-total							**4)**	
	TOTAL MARKS							**100**	
	Recommendation								

Pass Mark = 70% but part D is mandatory

Name of Assessor:- ……..

Final Recommendation: Recommended ☐ for……

General remarks:……

Not Recommended ☐

Marks shall be awarded according to the criteria, where the Maximum possible mark is indicated. The categories are as indicated below

General (where max awarded for each = 1	**Important** Where max awarded for each = 5	**Critical** Where max awarded for each = 10	**Very Critical** Where max awarded for each = 10	**Added advantage** max for each = 1
Office space	Chemical store	Land/Greenhouse/ Lease agreement	Human resource	Standard operating procedures
Availability of transport	Disposal consideration	Crops		Study plans
Location	Workers safety	Protocol awareness		Other internationally recognized protocols
Procedures of keeping records	Assessment mode	Staff management structure		Other accreditation

Costs of trials	System of reporting			Other trial sites
Maintenance of equipment				
Sub-total = 16	**Sub-total = 25**	**Sub-total = 35**	**Sub-total = 20**	**Sub-total = 04**

Any other observations