

THE EAST AFRICAN COMMUNITY

SUMMARY OF GUIDELINES FOR TECHNICAL CRITERIA FOR DESIGNATING EFFICACY TRIAL CENTRES – EAST AFRICAN COMMUNITY (EAC)

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PREAMBLE

This document summarises the technical requirements for private or public institutions to be designated as Efficacy Trial Centers for conducting efficacy studies that 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 submitted to the EAC or its Partner States in support of pesticides registration.

DEFINITIONS

Batch – means a specific quantity of the control and test substance.

Carrier – means any material (e.g. water, soil, nutrient media, etc) combined with test substance.

Control substance – means any chemical substance or mixture, or any other substance (e.g. microbials) other than the test substance 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 Centre 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.

Sponsor – 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 assessing 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. The Application Form shall be submitted to EAC or designated pesticides regulatory authorities in the Partner States, providing the technical information required by the criteria as explained below:

Inspection of Efficacy Trial Centre

A prospective or 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.

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.
- 2) There is a Quality Assurance/Quality Control (QA/QC) Unit, independent of the Study Director.
- 3) Quality Assurance/Quality Control Unit communicates 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.
- 6) 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) 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.

C. 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 Protocols.
- 3) Be properly trained in the safe use and application of pesticides.

D. Records and Documentation

The Testing Centre 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 centre.

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