



THE EAST AFRICAN COMMUNITY

**EAC HARMONIZED EFFICACY TRIAL PROTOCOL FOR
EVALUATION OF BOTANICAL PEST CONTROL PRODUCTS FOR
PLANTS**

THE EAST AFRICAN COMMUNITY

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List of abbreviations

GPS	Geographical Positioning System
EAC	East African Community
SCAFS	Sectoral Council on Agriculture and Food Security
TWG	Technical Working Group
GAP	Good Agricultural Practices
GEP	Good Experimental Practices
EPPO	European and Mediterranean Plant Protection Organization
IPM	Integrated Pest Management
FAO	Food and Agriculture Organization of the United Nations

Definition of the terms

Terminology	Definition
Botanical	formulations of pesticides that originate from plants as phytochemicals and eliciting toxic effects on insects and mites.
Efficacy evaluation	assessment of the effectiveness of a plant protection product, against the target pest, which may include an assessment of its agronomic sustainability and economic benefits
Good Experimental Practice (GEP)	measures taken and practices followed with respect to organization, design, conduct, monitoring, recording and reporting of efficacy trials of plant protection products, with the aim to ensure that the trial and its results are reliable, comparable and transparent.
Integrated Pest Management (IPM)	careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms.
Phytotoxicity	capacity of a plant protection product to cause temporary or long-lasting damage to plants.
Product (or pesticide product)	pesticide active ingredient(s) and other components, in the form in which it is packaged and sold.
Protocol	detailed procedure for performing a scientific experiment
Reference product	also referred to as the standard or positive control and should have demonstrated satisfactory control and preferably be registered.
Season	cropping cycle

Preamble

East African Community (EAC) Partner States have prioritized to intensify agricultural production to meet the regional demands for food and agricultural exports. The intensification of agricultural production ultimately necessitates increased reliance on agricultural inputs including pesticides. However, the Partner States have inadequacies and variances when it comes to the pesticide regulatory systems which largely contribute to injudicious control of trade and use of hazardous pesticides that greatly accelerate environmental deterioration, adversely reduces agricultural productivity and impacts on health of consumers as well. Development of an efficient, competitive and sustainable agricultural sector in the region requires strict adherence to standards on production, trade and use of pesticides.

The 7th EAC Sectorial Council on Agriculture and Food Security (SCAFs) ranked farm inputs among the critical factors for improved agricultural production and productivity in the region. The Council subsequently directed the Secretariat to mobilize resources and undertake harmonization of the regulatory framework in the area of farm inputs including agrochemicals and pesticides. Pursuant to the directive, in January 2015, the EAC Secretariat and the Food and Agriculture Organization of the United Nations (FAO) reached an agreement to jointly implement a regional initiative for a harmonized pesticide regulatory system. The main focus of the harmonization is to facilitate sustainable production, trade in and use of pesticides while safe-guarding human and environment health.

The three areas prioritized for harmonization in pesticide regulation is the development of harmonized guidelines for conducting efficacy trials, registration data requirements and conduct of supervised residue trials for conventional pesticides. A technical working group (TWG), comprising of experts nominated from the National Pesticide Regulatory Authorities of the Partner states, was constituted to review, update and elaborate on the three sets of guidelines.

The EAC SCAFs adopted the three sets of guidelines in June 2018. The 38th Extra-ordinary meeting of the Council of Ministers held in January 2019, adopted the guidelines and directed Partner States to domesticate by May, 2020. During the harmonization of conventional pesticide guidelines, the TWG identified a need for development of additional guidelines for the registration of Bio-pesticides and Bio-control agents. The absence of the guidelines for testing and registration of bio pesticides and bio-control agents was seen as a major hindrance for their registration. Subsequently, the TWG was constituted to fast track the development of guidelines for registration of bio pesticides and bio-control agents.

The Guidelines for registration of Microbial, Botanical and Semio-chemicals were developed and validated in July, 2019 and subsequently adopted by the 13th SCAFs in September 2019 and approved by the 39th Council of Ministers in November 2019.

Approval of the guidelines paved way for commencement of pilot trials and registration of efficacious bio-pesticides and bio-control agents which are critical component in integrated pest management. The EAC harmonized guidelines on Bio-pesticides and Bio-control agents for plant protection aim at ensuring harmonized data requirements, evaluations and decision-making for purpose of protecting human, animal health and the environment.

In order to operationalize and facilitate effective implementation of EAC harmonized guidelines for bio pesticide and bio control agents, comprehensive protocols on testing of bio pesticides are critical. The protocols herein developed will facilitate the conduct of field trials and ensure harmonized evaluation procedures by defining elaborate mechanisms for testing Bio-pesticides (Botanical, Microbial and Semio-chemical) and Bio-control agents used for plant protection.

Upon adoption and full implementation by the EAC Partner States, the protocols will achieve the following objectives;

- i) Provide a harmonized framework for conducting of efficacy trials and reporting for Botanical pest control products for plants; and
- ii) Facilitate mutual recognition and sharing of efficacy data for registration of Botanical pest control products for plants

General Provisions

The general provisions as contained in section 3 of the Regional EAC Guidelines for Evaluating and Reporting the Efficacy of Pest Control Products for Plants shall apply.

Introduction

The efficacy test Protocol has been prepared to facilitate the conduct and reporting of field and greenhouse trials in EAC Partner States. This Test Protocol describes the conduct of efficacy trials of Botanical pest control products for plants.

1.0 Trial Objectives

1.1 General Objective

Define the general objective of the trial in relation to the target pest(s) and target crop(s).

1.2 Specific Objectives

State the specific objectives of the trial by highlighting the performance of the test product (positive, negative and yield effects).

2.0 Location of Trial

Specify the location of the trial using geographical positioning system (GPS) coordinates and altitude of the study area. The agro-ecological zone should also be described.

3.0 Experimental Conditions

The procedures outlined below shall be employed when setting up the efficacy trials.

3.1 Target Pest(s)

The pest(s) to be controlled and the crop to be protected should be clearly specified.

3.2 Selection of Crops Cultivars and Varieties

The variety or cultivar used should be specified. The susceptible cultivar or variety commonly used in the agro-ecological zone should be used for the test.

3.3. Trial Conditions

- i. The trial conditions should be favorable for the development of the pest(s).
- ii. The agronomic practices should be uniform in all the test plots and consistent with Good Agricultural Practices (GAP) under local conditions.
- iii. The test should be carried out in areas with high infestation of the pest(s).
- iv. The cropping condition (soil type, fertilizer application, tillage, cultivar, row spacing) should be uniform in all the test plots and consistent with GAP under local conditions.
- v. The cropping history and the pest control products applied in the preceding two seasons must be known; and

- vi. The test should be conducted in similar agro-climatic conditions, preferably in different years or growing seasons.

4.0 Materials and Methods

4.1 Experimental Design

A randomized complete block design or any other statistically suitable design should be used;

4.2 Number of Treatments

- Efficacy trials on the test product should have five treatments distributed as follows:
 - a) Manufacturer recommended rate for the test botanical product under question;
 - b) Rate not more than 25% higher than recommended rate;
 - c) Rate not more than 25% lower than recommended rate;
 - d) Reference standard at the registered rate;
 - e) Untreated control.
- There may be exceptional circumstances where more than five treatments may be required, such as where the test product has more than one active ingredient with different modes of action and >1 positive control may be necessary.

4.3 Choice of Reference Product

- A reference product, which is normally the already registered product, should be included in the trial for comparison with test product. The regulatory authority should be consulted on issues relating to the selection of a reference product for the study. The reference product is sometimes referred to as a standard or positive control. The reference product must have been registered and in use in the country where the test is being done for use on the pest and crop, where possible, the positive control should have the same mode of action as the test product.
- The reference product should preferably be a product available in all Partner States.
- Where the use of an appropriate low risk reference product is not possible, an alternative conventional product may be included.
- Where there is a need to use a reference product other than the one agreed or recommended by the regulatory authority, a justification must be made. **In case no product is registered with the same active substance or similar mode of action, the trial manager can choose a product that is in use for similar group of pests belonging to the same family or order and should liaise with the designated national regulatory authority for guidance.**

4.4 The Non-treated Control

- It is a requirement to include a non-treated control plot in efficacy trials. It is important to note that in some situations, the layout of non-treated plots within the randomized blocks may give rise to disadvantages due to extensive interference between non-treated and treated plots. Examples are efficacy trials for fungicides with preventative action on susceptible cultivars of potatoes, or apples for the control of Late Blight and Apple Scab respectively.

- In order to avoid heavy losses in both the current and subsequent crops, it may sometimes be necessary to discard the non-treated plots from the experiment shortly after the occurrence of the disease becomes obvious. The initial non-treated plots should be sprayed taking due care to avoid drift into treated plots.
- Alternatively, excluded controls, i.e. Control plots located outside the trial area but in an area where conditions are comparable to the trial area, can be used where interference with the treated plots is expected.
- In all cases, the length of the observation time should be appropriate for the botanical product under consideration. Pest or disease levels should be considered together with achieving an economic benefit to the user. For further information on design of efficacy trials refer to EPPO Standard on “Design and analysis of efficacy evaluation trial

4.5 Plot Size

- The choice of plot size will depend on the type of crop/ pest and disease/product under study and location of trial. The minimum net plot size should be at least 10 m². Highly mobile pests might require larger plot sizes for evaluation (e.g. 60-80 m² or larger).
- For perennial trees, a Net plot size of 2-4 trees/plot for big trees and 4-6 trees/plot for small trees to allow for variability between trees should be used.
- Depending on type of the plants/cultivar used; mobility of the target organism, technique of application and type of formulation or application equipment. It may be necessary to take a larger plot size than net plot size. Guard or buffer rows/strips are needed to take in to account pest dispersal and possible drift of pesticides.

4.6 Number of Replications

- Replications should be 4 -5 per treatment provided the error or residual degrees of freedom are at least 12). More replications are recommended, in particular, if one wants to account for an expected higher variability of the negative control plots which might show higher pest/disease pressures and crop damage.
- For further information on statistical analysis on efficacy trials refer to EPPO Standard on “Design and analysis of efficacy evaluation trials”.

4.7 Mode of Application

The test product(s) under investigation should be the named formulated product and applied in accordance to the manufacturers’ recommendation. All applications should comply with good experimental practices. The methods of application e.g. spray, broadcast, soil application, etc. will normally be specified on the product label/leaflet. Different botanical products show different modes of action and require different environmental conditions. Accordingly, there exist specific recommendations for each application.

4.8 Application Equipments

- The type of application equipment should be one that is commonly used and properly calibrated to give intended application rate and droplet spectrum in case of sprays. The

application equipment may be as simple as knapsack sprayer, aerosol can, motorized pump sprayer, electrical driven pump, and power-driven sprayer. It should provide an even distribution of product on the whole plot or accurate directional application where appropriate. Factors which may affect efficacy (such as operating pressure, nozzle type, spray volume, depth of incorporation in soil) should be recorded, together with any deviation in dosage of more than 10%. Other application techniques, different to spraying, will also need proper description.

- It is important to optimize volume application rates, especially when treating foliage.
- Precaution should be taken to avoid drift between plots, where applicable, by holding a screen around the plot being treated.

4.9 Time and Frequency of Application

- The time and frequency of application should be specified on the product label /leaflet.
- The number of applications and the date of each application should be recorded. Additional general information on factors influencing time and frequency of application like growth stage of the crop, threshold levels or development stage of pest or infestation level should be considered.

4.10 Dosage and Volumes

The product should be tested at the dose proposed by manufacturer and should also be used with other doses as indicated in section 4.2 above. The doses will normally be expressed in gram active ingredient(s) per hectare and formulation in terms of litre per hectare or kilogram per hectare. Where applicable the spray volume per hectare should be specified.

4.11 Number of seasons

- a) Where an applicant applies to one Partner State for registration of a product not registered in the region according to this guideline, the product shall be subjected to two (2) successful cropping seasons' trials at two sites in different agro ecological zones. Where a commercial crop is only grown in one agro-ecological zone, data from that one zone will suffice.
- b) Where an applicant applies for registration of a product on the same crop/pest combination, simultaneously to more than one Partner State, two (2) cropping seasons on one site will be required in each of the respective Partner States and all data from the region will be submitted for assessment. Partner States conducting the trials should be required to avail raw data to the other participating Partner State(s) for decision making when necessary. For the purpose of this protocol, simultaneous submission means submissions made within 3 months to different Partner States. A Partner State can decide on product approval on the basis of 4 data sets (of which 2 from local trials) from a simultaneous submission.
- c) Where a trial on product has already been conducted for two cropping seasons at one site within a Partner State in accordance with this guideline, only one season of trials at two sites in different agro-ecological zones would be required in the next Partner State.

- d) Where applications for label extensions (new uses) are submitted in a Partner State, the product will undergo one cropping season of efficacy trials at two sites in different agro-ecological zones in the Partner State.
- e) If an applicant applies to more than one partner state for a label extension, one cropping season's trial shall be conducted at a representative site in each Partner State and all data from the region shall be submitted to the respective Partner States for decision making.
- f) Where an application for a label extension has been approved in one Partner State in accordance with these guidelines, one cropping season's trial shall be conducted at a representative site in each next Partner State and all data shall be submitted to the respective Partner States for decision-making.
- g) The above conditions for label extension apply to specific crop and pest combinations but may be adopted in the context of crop grouping and data extrapolation where a Partner State may have adopted this concept.

4.12 Other pest control products used

Information on other pest control products used in the trial plots should be provided by the scientist involved in the trial.

4.13 Growth stage of the crop and variety used

- The growth stage of the crop at the time of application should be indicated. The last application (pre-harvest interval) should be linked with harvesting time.
- The variety of the crop in use should be specified. The most susceptible variety should be considered for the worst-case scenario, among the available commercial varieties.

4.14 Climatic conditions and edaphic data

- Before, during and after the time of application, precipitation (type and daily amount of rainfall in mm), temperature (daily average, maximum and minimum in °C), insolation should 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) should also be recorded.
- For pest control products applied to the soil pH, soil organic matter, texture and moisture should be recorded. For plants grown under protected environment (glass houses), temperature and humidity should be recorded throughout the trial period.

5.0 Mode of assessment, recordings and measurements

5.1 Characterization of the location

Characteristics of the location should be provided, including coordinates, elevation, climatic zone etc.

5.2 Assessments

5.2.1 Type

Type of assessment depends on the type of the insect-pest(s)/disease(s)/number of weeds under investigation but normally by number of insects on selected plants or by percentage of damage or percentage of infection per unit area of plant parts on selected plants in the trial

5.2.2 Time and Frequency

An assessment of the level of infestation/infection should always be made prior to treatment application. The interval of assessment for the parameters to be measured will depend on type of plant, pest, mode of action of the test product and growth stage of the plant.

5.2.3 Phytotoxic Effects on the Crop

- The crop should be examined for presence or absence of phytotoxic effects on the crop. The type and extent of these effects should be recorded including major symptoms of pesticide phytotoxicity on crops as defined in FAO guidelines for phytotoxicity assessment in protocol FAO/AP/027.
- For products with fungicidal or insecticidal activity, phytotoxicity should be addressed by appropriate observations at each assessment made in the efficacy trials. For products with herbicidal activity, crop safety trials are always required.
- Assessments made in phytotoxicity trials can establish crop safety and provide useful support to reasoned cases addressing succeeding or adjacent crops.

5.2.4 Yield

Yield data (qualitative and quantitative) may be recorded in all efficacy trials where applicable. Quantitative data such as biomass weight, plant height, stem diameter, ear total/number of fruits, grain yield among others may also be recorded.

5.2.5 Residual Effects on Subsequent Crops

The residual effects on subsequent crops is particularly important for herbicides. Information on effects on succeeding crops may be obtained from trials conducted outside EAC, including published data. For further information on the assessment of the risk of effects on succeeding crops consult EPPO Standard on effects on succeeding crops.

5.2.6 Effects on non-target organisms

Observations on any adverse effects on non-target organisms in the treated crop should be made.

5.3 Monitoring of efficacy trials

The testing institution should send to the regulatory authority the study plan and schedule of activities showing critical milestones, including the initiation of the trials, treatment application, data collection and expected date of completion for each season. The regulatory authority shall ensure that a representative sample of trials being conducted in Partner States in accordance with these guidelines, are monitored for compliance. Evidence of peer review should be provided.

5.4 Statistical Analysis of Data

The generated data should be subjected to statistical analysis at a confidence level of 95%. The statistical method(s) used should be indicated. The raw and statistically analyzed data should be held by the trial manager for a minimum period of five years for submission to regulatory authority on request. All data and information should be filed appropriately by the testing institution for easy retrieval. Further information on statistical analysis of efficacy trials may be obtained from EPPO Standard: *Design and analysis of efficacy evaluation trials*.

5.5 Decision on acceptable efficacy

The primary criterion of acceptable efficacy is that the product should show results that are significantly superior to those recorded in the untreated control i.e. that use of the product is better than no use.

6.0 Results (Reporting)

- A progress report should be submitted at the end of each season. The report should undergo internal peer review before being submitted by the head of the institute to the designated regulatory authority. The report should be submitted in both hard copy and electronically.
- The final results should be reported in a systematic form and the report should include an analysis and evaluation and should include a biological dossier containing the individual efficacy trial reports or their summaries, results, discussions and conclusions.

Note: More information on reporting efficacy trials may be obtained from EPPO reporting Standard: Conduct and reporting of efficacy trials including good experimental practice

6.1 Cover Page

The cover page of the report should include the title, author(s), date of reporting and permit reference number. The title should include trade name, common name, target pests/disease, crop(s) and countries of trial. The details of the author(s) should include the name(s), designation, name of institution(s) and any other relevant information.

6.2 Summary

It should summarize the content of the report and the main findings. It should include a brief summary of the place where trial(s) was conducted, time in years, study conditions, statement of the objective(s), general methods (experimental design, replications and treatments), results, conclusions and recommendations.

6.3 Introduction

The introduction should provide briefly statements that are clear for the reader and reviewer. It should include description of the target crop(s) and its importance, effect of target pest(s)/diseases on crop(s), commonly method(s) used by farmers to control pests/diseases. It should also include description of the active ingredient(s) of the test products and their mode of action to target pest(s)/diseases as well as, indicate gap of knowledge and how to bridge the gap of knowledge. In addition, it should provide a brief explanation if the study is introducing a new technology or methods of controlling pest(s)/diseases,

6.4 Objectives of the Study

General and specific objectives of the trial/study should be clear and concise.

6.5 Materials and Methods

It should give a description of methods used and citations of relevant reference methods. The information should include the common and trade names of the candidate product, source of product, formulation, concentration of the active ingredient, test crop/commodity, target pests, experimental design and methods of statistical analysis. The description should include the following:

- i. Experimental Site/Location Description
- ii. Provide adequately explanation on how the trial was conducted
- iii. Experimental Design: Full details of the experimental design, numbers of replicates and plot sizes should be provided for each study.
- iv. Treatments:
 - application rate in terms of product per unit or active constituent per unit
 - carrier volume (L/ha and type (for example, water),
 - type of application equipment used
 - frequency of applications and application intervals
 - other application details, such as nozzle type.
 - date of application
 - crop growth stage at application and crop part treated
 - pest population or developmental stage or infestation level at time of application.
- v. Agronomic practices/Cultivation and Management Practices
 - Agronomic Details (soil type, pH, rainfall, cultivars, etc.).
 - Land Preparation
 - Planting/ Sowing

- Fertilization
 - Plant protection substance application methods
 - Provide description on whether trial(s) conducted during rain fed or under irrigation situation
- vi. Provide relevant meteorological information (rainfall, temperature, humidity, etc.)
 - vii. Phytotoxicity assessment of test plant protection substance on target crop(s) (Provide phytotoxicity rating point scale).

Note: Trial results and the conclusions drawn from them have little value if the report does not adequately explain how the trial was conducted.

6.6 Statistical Analysis

The Research scientist involved in efficacy trials should:

- i. Conduct a statistical analysis of the results whenever relevant or if you are required to demonstrate differences or equivalence between treatments.
- ii. Provide full details of the statistical methods used, including a justification or validation for the method chosen. Include information about how the underlying assumptions of the statistical method have been met in the justification for the method selection.
- iii. Include any reasons for not carrying out a statistical analysis if you have not done one. The results of the statistical analysis (for example, degrees of freedom, F-values and *p* values) should be presented in table format with each study.

Note: Novel statistical analysis submitted to the regulatory authority in support of experimental data should be accompanied by the raw data and the published literature that references the statistical technique

6.7 Results

- The results should be fully described in relation to the stated objective. Tables should contain summaries of statistically analyzed results showing: means, minimum and maximum values for each treatment, coefficient of variation (CV), levels of significance, appropriate mean separation etc.
- The report should summarize results obtained from all the test seasons and describe variations or consistence among seasons.
- All relevant data should be presented and reported.
- When only means, percentages or other presentations of results are given in the results section of a report, all ‘raw’ data should be provided in an appendix.
- Statement that efficacy compare treatments of the test product, reference (standard) product with untreated control should be provided.
- If negative or unusual results have been recorded, they must be included together with a discussion (below) about how or why they may have occurred. This information can help in determining optimal application conditions.
- If a study produces many separate results (for example, from different treatments and assessment times), the data are best presented in a table or matrix format. This allows a quick and easy comparison of results.

- If graphs or other methods of presentation are used, they should be appropriately labeled with measurement details, including the relevant units.
- Original or raw data should be included and may be submitted as an Appendix to the report.

6.8 Discussions

- a) State main findings
- b) Relate findings to stated objectives
- c) Any inferences made
- d) Explain any variations or factors that may have influenced the performance of the product under investigation.
- e) Relate results to previous findings
- f) Each trial should be appropriately analyzed, the results interpreted and a relevant conclusion about the purpose and hypotheses of the study stated.
- g) Research scientist involved in efficacy evaluation should discuss results of efficacy trial and make comparison with findings of the previous studies. Evidence(s) should be provided by inserting reference(s) in the texts of the report. All references in the texts should be seen in the reference section of the report

6.9 Recommendations and Conclusions

- a) It should be stated clearly whether the product is suitable for registration for the stated use based on the findings.
- b) The trial manager should clearly recommend: -
 - i. Application rates expressed as amount of product per ha, amount of active ingredient per ha, amount of product per 20 L of water.
 - ii. Time of application (also in relation to harvesting)
 - iii. Number of applications per season
 - iv. Frequency of application
 - v. Spray volume
 - vi. Any other observations
- c) It should be stated clearly whether the data met the 2/3 consecutive season criteria. The conclusion shall mention the minimum effective dose of the pesticide to suppress the target pests.

Note:

- Any unusual or unexpected results should also be discussed and if possible, explanation on how they occurred.
- Issues such as unusually low or high pest abundance or other confounding factors (e.g. weather effects or soil types) may need to be discussed to allow a proper interpretation of the results.
- The integration of the proposed product with current pest management practices should be discussed.

6.10 Acknowledgement

Pertinent acknowledgement should be included. Statement to acknowledge the funding agent(s) supporting the study, proof-readers, people who provide assistance during the study etc. should be provided.

6.11 Appendix

Appendices may include raw data, detailed statistical analyses and any other details that are important in supporting the report but that are not needed in the body of the report.

6.12 References

The research scientist involved in efficacy trials should provide references in the report if they are used to justify a claim. The listed references should be cited on in texts. They should be logically ordered. The list of references should be included with author, date of publication, title of article, name of journal/source, volume and the first and last page of the document

7.0 References

This protocol was developed based on the following references;

1. Association of South East Asian Nations; Guidelines on regulation, use and trade of bio-control agents (April 2014).
2. Bulletin OEPP/EPPO (2017) 47(3),297-304; PP1/296(1) Principles of efficacy evaluation for low-risk plant protection products;
3. EPPO Guideline 1/214(1) (2000) Principles of acceptable efficacy.
4. FAO International Code of Conduct on the Distribution and Use of Pesticides; Guidelines on Efficacy Evaluation for the Registration of Plant Protection Products (June ,2006)
5. Regional EAC guidelines for evaluating and reporting the efficacy of pest control products for plants (East African Community, January ,2019)
6. Summary of UK efficacy evaluation process and requirements for biological products. (S.M. Mattock, Pesticides Safety Directorate, United Kingdom)
7. Treaty for the establishment of the East African Community (1999)