THE EAST AFRICAN COMMUNITY

EAC HARMONIZED EFFICACY TRIAL PROTOCOL FOR EVALUATION OF SEMIO-CHEMICALS FOR PEST MANAGEMENT IN PLANTS

THE EAST AFRICAN COMMUNITY

Arusha, Tanzania

September, 2021

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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**
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
Semiochemicals	substances or mixtures of substances emitted by plants, animals, and other organisms that evoke a behavioral or physiological response in other individuals of the same or other species.

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 Semiochemicals 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 Semiochemical) 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 semiochemicals for pest monitoring and control in plants; and

ii) Facilitate mutual recognition and sharing of efficacy data for registration of semiochemicals for pest monitoring and control in 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 of field trials for registration of semiochemicals in EAC Partner States. The protocol describes the processes and requirements for conducting efficacy trials of semiochemicals for plant pest monitoring and control.

The protocol covers attracting, repelling and mating disrupting pheromones.

1.0 Trial Objectives

1.1 General Objective

State clearly the purpose of the evaluation of the semiochemical product including target pest(s), the product being evaluated, etc.

1.2 Specific Objectives

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

1.3 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. For semio-chemical field trials it is advisable to lay the trials over very large areas with discrete plots because of likely interference arising from their highly volatile nature. For example, 0.5 – 10 Ha for one plot for one treatment separated by about 200 m from the next plot.

1.4 Trials on Greenhouse Crops

In the green house, the same general principles apply. Being volatile, semiochemicals should be tested in separate greenhouses or greenhouse compartments for each treatment.

2.0 Experimental Conditions

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

2.1 Target Pest(s)

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

2.2 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.

2.3 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.

3.0 Materials and Methods

3.1 Experimental Design

The design of the efficacy trial should permit a statistical evaluation. It should however be simple but compatible with the immediate objective of the test. Multi-factorial designs should be avoided considering the large size of the plots and the distance between the treatment. The design and layout of the plots, number, size and shape of plots and any additional remarks should be provided.

The problem of interference, both between treated plots and also with untreated plots, means that plots need to be separated by a minimum distance. The distance required will depend on the manufacturers recommendation based on prior test results, the nature of the semiochemical being tested, flight activity, movement of the individual species and prevailing wind direction.

The distance between the traps are normally large. Plots do not necessarily need to be located in separate sites but could be spatially separated within a larger block as much as possible.

Description of design and layout of the plots like type of experimental design, number, size and shape of plots and any additional remarks should be provided.

3.2 Site Maps

A site map may be useful to compare trial sites and put levels of control achieved into context. Together with knowledge of pest biology, it can also identify likely immigration hotspots, which aids both placement of monitoring traps and dispensers and application of any appropriate insect barrier treatment. Site maps are particularly useful when the adult flight activity can take place over wide areas. The test product treatments will depend on nature of the product, pest and site.

3.3 Number of treatments

Number of treatments used for assessment varies with the purpose of the semiochemical, such as pheromones for monitoring, semiochemicals for mass trapping/mating disruption and repellent semiochemicals

3.3.1 Semiochemical products for monitoring

It should be noted that other factors that can influence the trap catches such as colour of the trap, trap design should be kept uniform. Efficacy trials on the new semiochemical products used for monitoring should have at least three (3) treatments as follows:

a. Manufacturer recommended semiochemical product and trap design;
b. Reference standard at the registered rate with the same trap design
c. Similar traps without the semiochemicals (untreated control)

3.3.2 Semiochemical products for mass trapping/mating disruption

The following factors should be considered;

i. Number of pheromone dispensers per given area to control insect pests as per the manufacturer's guideline
ii. Plot size/Area to be used for evaluation of disrupting semiochemicals should be specified
iii. Reference products (with similar application technique) if available should be indicated
iv. Untreated control should be included
v. Conventional insecticides may be included where necessary

In such an efficacy trial, five (5) treatments as detailed below may be adopted.

a. Manufacturer recommended semiochemical product and trap design/formulation/number of traps per unit area;
b. A higher dosage of semiochemical product in similar traps as applicable – this could be concentration of the semiochemical/ number of traps per unit area;
c. A lower dosage of semiochemical product in similar traps as applicable – this could be concentration of the semiochemical/ number of traps per unit area;
d. Reference standard at the registered rate with the same trap design; and
e. Untreated control (traps without semiochemical or untreated plots)

Note:
Other factors such as trap design, colour of traps and application technique should be uniform.

3.4 Choice of Reference Product

The reference product is sometimes referred to as a standard or positive control should be included in the trial for comparison with test product. The reference product must be registered and in use in the country where the test is being done for use on the pest and crop. It should

preferably be a product available in all Partner State and should have shown satisfactory results in practice. The registration authority must be consulted on issues relating to the selection of a reference product for the study. Where possible, the positive control should have the same mode of action as the test product.

Where the type of pesticide product or its use is new, comparison with a reference product may sometimes be impossible or inappropriate. Where the use of an appropriate low risk reference product is not possible, an alternative conventional product may be included. In this case, the product under study should show a consistent well-defined benefit. The pesticide to be introduced should be able to bring and/or keep the pest population and the damage to which it gives rise below an economic threshold level, where this is known.

Where a there is the need to use a reference product other than the one recommended by the registration authority, a justification must be provided. In case no product is registered with the same active substance or similar mode of action, the trial manager should liaise with the designated national authority for guidance.

3.5 The Non-Treated Control

A non-treated control plot or treatments with traps without semiochemicals should be included in efficacy trials. 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. Hence, it is advisable that the non-treated control plots should be widely spaced from other treatments. For instance, this could be 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. Excluded controls provide information on the level of pest infestation to be included in the statistical analysis.

In all cases, the length of the observation time should be appropriate for the semiochemical product under consideration and as per manufacturers guidelines. Pest and disease levels should be considered together with achieving an economic benefit to the user.

For further information on design of efficacy trials refer to EAC testing protocol and/or EPPO Standard on “Design and analysis of efficacy evaluation trials” and a close consultation between the manufacturers, regulatory authorities and the semiochemical experts might be considered.

3.6 Plot Size

Efficacy of semiochemicals require large plots with the actual size and separations dependent on the target species, the nature of the semiochemical, the crop-pest combination in question and typical migration distance. The minimum plot size could be 0.5 Ha for all types of crops. The untreated controls and the reference product treatments should, where possible and practical have comparable population densities.

Factors that may influence plot size include lateral spread of treatments, the available equipment for spraying or other mode of treatment, and harvesting method. The plot size

should be sufficiently large to allow for periodic sampling and evaluation of the crop yield at harvest.

The number of traps and distance between traps in an area should be specified. In some cases, individual traps in pheromone efficacy trials are treated as experimental units or plots and should be separated with enough distance as recommended by the manufacturer to avoid interference.

3.7 Number of Replications

This should be determined by the likely magnitude of experimental variance and the number of treatments. It is advisable to have a significantly large number of replicates to cater for variability that might arise with large plot experiments. Three (3) to five (5) replications may be acceptable (e.g., in greenhouse trials where separate greenhouses or compartments need to be used). On the other hand, a greater number of replications will be required when there is an erratic distribution of pest over the experimental area.

When crop yield is not being evaluated (e.g. Efficacy trials for monitoring purpose), replications should be sufficient in number and the plot size large enough to offset the variability. Whilst replication and crop yield are necessary in trials for testing semiochemicals for purpose of control, large scale trials may be replicated but a suitable number of trials should be conducted to allow appropriate support of product claims.

3.8 Application of Treatments

The test product(s) under investigation should be the named formulated product(s). All applications should comply with good experimental practices. The method of application will normally be specified on the product label/leaflet. The distribution of pests within a crop may not be uniform across the site and therefore the dispenser placement should reflect this.

A site map will indicate likely immigration points and determine where a higher number of dispensers (and monitoring) may be required. The edges of the plots may be particularly vulnerable because for example, female Lepidoptera tend to lay eggs in the first suitable location. A significant proportion of crop damage may occur close to these areas thus buffer zones or discard areas may be useful to ensure results from the net plot are not compromised by such events. Alternatively, spatial separating plots to isolated crop areas may be more practical. Persistence of effect, particularly whether a second placement of dispensers will be required later in the season, should also be examined.

Placing of both monitoring traps and dispensers within the crop should also consider the pest biology, for example where flight activity is concentrated within the crop. Pests caught in traps are sometimes the objects of ants' attack. Interference from ants can be prevented by application of grease or any other ant repellent product on the stem or string. Such repellent should not cause a significant interference with the treatment.

3.9 Type of Equipment Used

The type of equipment (e.g., Traps) used and the distribution of the pest control product (Note: Use of similar pest control product in various treatment plots is necessary) over the plot should be stated. It should, as much as possible, be similar to what is used in practice. The techniques of presenting the product are very specialized and may include traps and manually placed dispensers.

3.10 Time, Dosage and Frequency of Application

The time, dosage and frequency of the semiochemical application will be as proposed by the applicant on the label/leaflet. Precautions should be taken to ensure minimum interference with the adjacent plots. The number of applications and the date of each application should be recorded. 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 provided.

3.11 Management of Non-target Pests

A barrier treatment may be necessary to control non-target pests which are capable of causing misleading interpretation of plant or fruit damage. In these cases, the product chosen should have no impact on the particular target pest. Site maps and reference to monitoring information can be used to identify the likely areas of immigration where barrier treatments may be required and the timing of such treatments.

3.12 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.

3.13 Other Pest Control Products Used

Information on other pest control products used in the trial plots should definitely be provided and it should be uniform in all treatment plots.

3.14 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 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.

3.15 Climatic Conditions and Edaphic Data

During the test period, meteorological data such as precipitation (type and daily amount in mm), temperature (daily average, maximum and minimum in ^{o}C) and 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 greenhouse trials, temperature and humidity should be recorded throughout the trial period.

4.0 Mode of Assessment, Recording and Measurements

4.1 Assessment-Monitoring and Estimating Population Densities

Monitoring pest populations has two purposes. The first is to determine the appropriate timing for any necessary treatments by providing information on adult/migration activity and an indication of local population levels. Second, in the mating disruption plots, the monitoring data may additionally be used as an indication of the product effectiveness. Monitoring adult/migration activity should be based on traps located in the plots or in margins of the experimental field (away from the treated buffer areas).

The use of pheromone traps in the mating disruption plots, as the sole determinate of effectiveness or pest population density, should be avoided. The numbers caught in these monitoring traps can be misleading because if the test pheromone disruption product is

working effectively, the males may not be able to locate the monitoring traps. As such, numbers in monitoring traps cannot be used for decision making on for instance, the necessity or timing of treatments. Alternatively, the monitoring traps could include other standard semiochemicals that are not based on sex pheromones, including kairomone lure traps (e.g., fruit extracts such as acetic acid) or light traps. Data from these traps can be useful because they are not affected by high concentrations of the sex pheromones, delivered by the test product, interfering with the males' ability to locate the monitoring trap. Such traps may attract both males and females and may not be species specific, therefore it is important to record the presence of other species. Light traps may also be used as an alternative monitoring tool and again are not sex/species specific. Regional monitoring data if available, should also be provided because it also provides an indication of general pest pressure during the season.

4.2 Assessing effectiveness

4.2.1 Crop damage

The principal assessment is based on crop damage, whether qualitative or quantitative because of difficulties of using population levels as an indication of product effectiveness. Mating disruption techniques are generally species specific hence should be established that the crop damage relates to the particular target and not confuse it with other crop damage.

4.2.2 Other indicators of effectiveness

The information on crop damage can be very usefully supported by other assessments. For instance, use of mating tables with tethered virgin females to estimate reduction in mating can be a particularly useful indication of the success of the technique. Assessment of population reservoir at the end of the trials can be useful if data from the previous year is available for comparison. Also, the content of pheromones in the dispenser (weight loss due to evaporation of the active substance) at the end of the trials may be of interest (for dispenser-based products) as an indicator of dispenser efficiency over the season. Number of male adult insect pests capture with 20 traps/day should be established as the level of control in treated and untreated plots.

Effectiveness of mating disruption is indicated by calculating the mating interruption index (MII), MII = (M-P/P) *100, where M is the average number of males captured per trap in mating disruption plots and P is the number of captures in the conventional pesticide plots. Compare the total average number of insects captured per trap in the mating disruption plots, after installation of mating disruption, with that obtained in untreated control plots (Or plots treated with insecticides). Calculate Mating Disrupting pheromones field efficiency period from the reduction in mating interruption index for each sample over time.

Damage caused by the insect pests should be evaluated/assessed using ranking scale at intervals after application of pheromones. It is accepted that these techniques (other than spray applications) are unlikely to cause significant crop damage. However, they do result in localized high concentrations of pheromones, possibly in combination with release of other formulation components. Some types of dispensers are based on impregnated powder, with possibility of spillage or 'puffer" release packs. There is evidence with the latter that these can sometimes

cause localized limited symptoms of damage. It is therefore considered appropriate to make visual assessments of phytotoxicity symptoms on leaves and effects on russeting where appropriate, in all local areas where dispensers are placed.

4.3 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.

4.4 Effects on Non-Target Organisms

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

4.5 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.

4.6 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.*

4.7 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.

5.0. 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

5.1 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.

5.2 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.

5.3 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,

5.4 Objectives of the Study

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

5.5 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.

5.6 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

5.7 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.

5.8 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

5.9 Recommendations and Conclusions

a) State 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 number of traps/dispensers per unit area;
   ii. Timing of application in relation to growth stage of the crop;
   iii. Number of applications (replacement of lure/repellant/trap) per season;
   iv. Use limitations; and
   vi. Any other observations
c) State clearly whether the data met the required number of seasons.

5.10 Acknowledgement

Pertinent acknowledgement should be included.

5.11 References

A 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.

6.0 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 (2019)0(0)1-4; PP1/264(2) Principles of efficacy evaluation for mating disruption pheromones;

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)