THE EAST AFRICAN COMMUNITY

REGIONAL EAC GUIDELINES FOR EVALUATING AND REPORTING THE EFFICACY OF PEST CONTROL PRODUCTS FOR PLANTS

EAC SECRETARIAT

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PROCEDURES FOR EVALUATING AND REPORTING THE EFFICACY OF PEST CONTROL PRODUCTS FOR PLANTS

Preamble

East African Community (EAC) Partner States is in the process of intensifying its agriculture to meet the Regional demands for food and to increase Agricultural exports. In a bid to intensify agricultural production, the Partner States foresee an increased reliance on use of pesticides. However, inadequate and varied pesticide regulatory systems within the Region can result in environmental deterioration, reductions in agricultural productivity and adverse impacts on health of consumers and the surrounding community as well. Development of an efficient, competitive and sustainable agricultural sector in the Region requires strict standards on use of pesticides. During the 7th EAC Sectoral Council on Agriculture and Food security (SCAFs), the Council observed that farm inputs are critical for improved production in the region. The Council directed the Secretariat to mobilize resources and undertake harmonization 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 implement a joint regional work plan on pesticide management. The main focus of the harmonized pesticide regulation programme is to reduce risks associated with pesticides, improve trade, safe guard crops, environment, human and animal health.

One of the three focal areas prioritized to kick-start harmonization of pesticide regulation is regional collaboration for harmonization of efficacy trials. To carry the work forward a technical working group was constituted to review, update and elaborate guidelines for the regional harmonization of efficacy trials. The Technical Working Group comprised National experts nominated by EAC Partner States, working under the guidance of an international expert. These procedures are developed pursuant to article 108(e) of the Treaty for the establishment of the EAC (Treaty for the establishment of the East African Community, 1999). The procedure outlined below shall be employed by the Partner States in efficacy evaluation of pest control products for plants. The procedures set out guidelines for carrying out the efficacy trials on plants as well as the presentation of research findings from efficacy trials.

The first version of this document was approved by EAC in 2006. A revised version was produced during the first meeting of the Technical Working Groups on Regional Collaboration for Pesticide Registration in the EAC and Introduction to Risk Reduction and prevention of Highly Hazardous Pesticides (HHPs) in Nairobi, Kenya from 26-29th September 2016 and later reviewed in two subsequent meetings held in Kampala from 28th to 3rd March 2017 and Dar es Salaam from October 11th to 13th, 2017. EAC Secretariat convened national validation workshops in November/December 2017. The main objective of the workshops was to give national stakeholders the opportunity to review the draft EAC Pesticides Management Guidelines and provide feedback/ inputs for improving the final documents prior to regional validation. A regional multi-stakeholder consultation was held in March, 2018 to validate and make final contributions to the draft guidelines.

1. Introduction

Efficacy evaluation of a pest control product is important because it enables the registration authorities to evaluate the benefits to be gained from new pest control products or new uses of existing pest control products to weigh their **benefits** against potential **hazards** due to their introduction. Reports of efficacy trials in the region are not uniform. These guidelines have been developed for trial managers carrying out the efficacy trials with a view to harmonizing the procedure of conducting and reporting of efficacy trials. This will improve the evaluation process for the registration of new pest control products in the region.

All trials must be authorized by the designated national registration authority. The trial manager is obliged to liaise closely with the designated national registration authority throughout the trial period.

This guideline borrows largely from existing national guidelines in the partner states and the EPPO (European and Mediterranean Plant Protection Organization) guidelines on efficacy trials.

2. Objectives

- To harmonize the procedures of carrying out efficacy trials and reporting system on new pest control products in the region.
- To promote mutual recognition of efficacy trial data and reports within the EAC

3. General Provisions

3.1 All EAC Partner States shall ensure that all new pest control products or new uses of existing pest control products are subjected to a thorough efficacy evaluation before they are authorized for any use.

3.2 All efficacy trials involving pesticides shall be approved by the national pesticide regulatory authority of the partner state.

3.3 Samples of the pest control product must be sent to the regulatory authority for forwarding to the testing institution.

3.4 (a) All trials must be carried out by institutions and/or individuals accredited by the respective national pesticide regulatory authority.

(b) In case there is no accredited scientist or institution within a partner state, the national authority may engage a technical expert in the subject area to conduct the efficacy trials in line with the guidelines.

(c) The criteria for accreditation shall be clearly indicated to guarantee standards of efficacy trials.

3.5 Applicant intending to register product(s) in more than one partner states shall ensure that a common crop/ pest specific study plan is developed in line with this guideline and the EAC efficacy trial protocol in consultation with the testing institutions in the region. The applicant shall ensure the study plans are complied with.

3.6 The efficacy test report should be submitted in hard (duplicate) and soft copies to the respective regulatory authority in the Partner States, with a copy to the applicant.

3.7 The cost of trial authorized by the registration authority will be incurred by the applicant

3.8 New information on ineffectiveness of already registered products will be relayed by the designated registration authority to the Partner States without delay for immediate follow up.

3.9 Where the provisions of the European and Mediterranean Plant Protection Organization (EPPO) guidelines conflict with these guidelines, the provision of these guideline shall prevail.

4. Scope

The procedures laid out in this document shall be applied to, pest control products used to control harmful organisms (insects, pathogens, weeds etc.) on plants, plant products, products applied to soil and regulated articles. The procedures shall also be applied to plant growth regulators. This guideline covers all plants.

5. Conducting efficacy trials

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

5.1 Objectives of the trials

The pest control product to be evaluated and the target crop/plant, the target pest(s) and other objectives must be stated clearly.

5.2 Materials and Methods

The trial manager should refer to this guideline and regional testing protocols when available. If not available, internationally acceptable guidelines should be used, e.g. the EPPO standards that are freely available on the EPPO website (http://archives.eppo.int/EPPOStandards/efficacy.htm)

5.2.1. Trial site selection

The sites should be as uniform as possible and representative of the conditions where commercial use is anticipated. Sites with irregular soil conditions should be avoided or experiments should be designed to accommodate the minor differences.

The disease, insects, weeds, etc. which forms the object of the efficacy trial should occur in a uniform pattern over the site or should be expected to become uniformly present during the trial period. Before trials are carried out, it is important to assess the infestation levels.

When selecting a site, the history of the site should be considered such as the preceding crop situation and previous infestations. A single preceding crop, on which only uniform treatments were applied, should have been grown over the whole area of the site. As a general rule, sites at field edges, or near ditches, trees, hedges or other obstacles should be avoided, as they are subject to interfering “edge” effects from those obstacles.

The experiment should be sited away from the edges of a normal commercial crop. If the crop has to be treated with a pest control product which may interfere with those under study in the experiment, then a sufficient margin of untreated crop should be left in the immediate vicinity of the experiment. If the trial consists of repeated blocks which follow each other in the direction of drilling, spraying or other treatments of the crop, it may be helpful to have a gap between the blocks to allow for turning on and off the supply of the pest control product, and as well to align the apparatus with the next plot or sub-plot.

5.2.2. Trials on plants grown under protection

Efficacy trials on plants grown under protection should be conducted under conditions comparable to those used in practice. If products with high vapor pressure, fumigants, aerosols or fogs are tested, separate glasshouses or glasshouse compartments should be used for each treatment.

5.2.3 Post harvest pest control products

Post-harvest products should be tested in the laboratory (bioassay) and field facilities that simulates supply chain/storage conditions. Laboratory tests should be based on reference or known test population of the appropriate pest.

Storage duration of the grain before application (or in the case of fresh produce, cold storage conditions) should be specified to establish if there is a relationship between time in storage and prevalence in pest population/disease severity/incidence, and subsequent influence to the trial.

5.2.4. Trial lay-out

The design of a trial intended for efficacy evaluation should permit a statistical evaluation. It should however be simple and compatible with the immediate objective of the test. A randomized complete block design is usually adequate. A very unique design may be used with prior approval by the regulatory authority. 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”.

5.2.5. The non-treated control plot

It is a requirement to include non-treated control plots 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 “preventive” 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 treated plots is expected. Excluded controls provide information on the level of pest infestation but cannot be included in the statistical analysis.

5.2.6. Choice of reference product

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 test is being done for use on the pest and target 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.

In case no product is registered with the same active ingredient or a similar mode of action, the trial manager should liaise with the designated national authority for guidance.

5.2.7. Plot size and shape

This should be determined by the crop-pest combination in question. In narrow row (broadcast sown) crops, minimum net plot size (the part of the plot used for assessment and harvest) should be between 10 and 20 m^2 depending on plant density. Higher density allows for smaller plot size). In row crops net plot size should be two (2) to four (4) rows of 8-10 m depending on plant density. In tree crop trials, it is desirable to have 4-6 trees per net plot to allow for variability between trees.

The minimum plot size in uniform vegetable or flower crops may be smaller, if internal interferences can be avoided. The plot size should be sufficiently large to allow application of treatments, sampling and evaluation of the crop yield at harvest. In some situations, the plot size and separation distance may be required to be larger in order to reduce interferences between treatments e.g. trials on pheromones.

5.2.8. Number of treatments

Efficacy trials on the new product should have a maximum of five treatments distributed as follows: manufacturer recommended rate; rates slightly higher than recommended and slightly lower than recommended for the new product; reference standard at the registered rate; and untreated control. (Lower and higher treatment should not be more than 25% variation above or below the manufactures´ recommended rate).

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.

5.2.9 Number of replications

This will be determined by the likely magnitude of experimental variance and the number of treatments. The fewer the treatments, the more the replications needed to give an acceptable estimate of variance and to give the necessary degrees of freedom. Four to five replications are usually sufficient to give a reasonable estimate of the variation. For further information on statistical analysis on efficacy trials refer to EAC testing protocol and/or EPPO Standard on “Design and analysis of efficacy evaluation trials”.

5.2.10. Number of seasons

a) Where an applicant submits an application 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 submits an application 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 these guidelines, simultaneous submission means submissions made within 3 months to different Partner States. A Partner State can make a decision 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 submits an application 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.

5.2.11. Application of the pest control products

The type of equipment used should be stated. It should, as much as possible, be similar to that currently used in practice, and should give an even distribution of the pest control product over the plot. Other relevant information such as type of nozzles, operating pressure in kilopascal (Kpa) should be provided.

The type (foliar, soil incorporated, seed dressing. etc.), method of application (e.g. drench, spray, etc.), time, dosage and frequency of the pest control products application will be as recommended by the applicant and they should be recorded. Where deviations occur, records should be maintained. Precautions should be taken to ensure minimum interference with the adjacent plots (avoid drift).

5.2.12 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.

5.2.13 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.

5.2.14 Meteorological 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 ^{o}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, soil organic matter, texture and moisture should be recorded. For plants grown under protected environment (glass houses) or grains stored in fumigation sheets or silos, temperature and humidity should be recorded throughout the trial period.

5.2.15 Assessment of efficacy and yield

An assessment of the level of infestation/infection should always be made prior to treatment. The number of assessments after treatment depends on the type of the plant, pest and the growth stage of the plant. Assessment should always be made in the net plot. Objective methods of assessment such as counting, weighing, measuring should be used rather than subjective methods such as visual assessment except for diseases where severity or incidence is the commonly agreed method of assessment.

Parameters that demonstrate direct effects should be measured e.g. disease severity. Where internationally acceptable assessment methods exist, they should be adopted. Time of assessment and sampling method should be recorded. For further information on assessment of efficacy trials refer to EAC testing protocol and/or EPPO Standard on "Principles *of acceptable efficacy"*.

Yield data should be recorded in all the efficacy trials. However, in some crops like pineapples and sugarcane, yield data may be waived due to duration of the cropping season. Raw data and analyzed data should be maintained by the testing institutions and should be readily available to the regulatory authority whenever required.

5.2.16 Phyto-toxicity and other side effects

The type and extent of phyto-toxicity should be described and, where appropriate, recorded according to a recognized scale. Any detrimental effects on wildlife and/or beneficial organisms shall also be recorded. For high value crops such as roses and other flowers, varietal phytotoxicity tests should be carried out on a number of representative varieties. For herbicide and plant growth regulators, data should always be provided from trials on crops/plants where double of the normal dose is applied. Further information on phytotoxicity assessment may be obtained from EAC testing protocol and/or EPPO Standard on *Phytotoxicity assessment*.

5.2.17 Residual effects

The effect of the pest control product on subsequent crop should be documented. This 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 EAC testing protocol and/or EPPO Standard on Effects on succeeding crops. These data are not required for perennial crops such as sugarcane, pineapple, coffee, etc.

5.2.18 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.

5.2.19 Statistical analysis of data

The generated data should be subjected to statistical analysis to establish statistical significance. The statistical method(s) used should be indicated. The raw and statistically analyzed data should be held by the trial manager 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 EAC testing protocol and/or EPPO Standard: *Design and analysis of efficacy evaluation trials*.

6.0 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 regulatory authority. The report should be submitted in both hard copy and electronically. The final report should summarize the results and should be compiled in the following format. More information on reporting efficacy trials may be obtained from EAC reporting standard and/or EPPO Standard: *Conduct and reporting of efficacy trials including good experimental practice*.

6.1 Title

The title should reflect the content of the report.

6.2 Summary

It should summarize the content of the report and the main findings

6.3 Introduction

6.4 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.

6.5 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.

6.6 Discussions

a) State main findings
b) How the findings relate 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

6.7 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 amount 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) State clearly whether the data met the 2/3 consecutive season criteria.

6.8 Acknowledgement

Pertinent acknowledgement should be included.

6.9 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.

7.0 References

Treaty for the establishment of the East African Community (1999).

8.0 Definitions of terms

Disclaimer: the terms specified in the guideline are applicable only to pest control products that shall be registered after the commencement of this guideline.

The guideline shall be piloted for the first three years after approval and ratification by partner states subject to annual reviews. Thereafter, full mutual recognition could be operationalized.