THE EAST AFRICAN COMMUNITY

SUMMARY OF GUIDELINES FOR THE CONDUCT OF SUPERVISED PESTICIDE RESIDUE FIELD TRIALS ON CROPS

Approved by the 38th Extra-Ordinary Council of Ministers held on 30th January, 2019

PREAMBLE

The EAC, with support from the Food and Agriculture Organisation of the United Nations (FAO) and the United States Agency for International Development (USAID), initiated the process of harmonising EAC pesticide management guidelines in September 2016. The main focus was to harmonise pesticide regulation in the region and to reduce the risks associated with their use, improve trade, and safeguard crops, the environment, human and animal health. The process culminated to the approval of the guidelines on efficacy trials, supervised residue trials and data requirements by the Council of Ministers in January 2019.

In January 2015, the EAC Secretariat and the Food and Agriculture Organisation of the United Nations (FAO) agreed to implement a joint regional framework on pesticides management to reduce risks associated with pesticides, improve trade and safeguard human health and the environment.

Pesticide residue trials is one of the three focal areas prioritised to kick-start harmonisation of pesticide regulation. Supervised pesticide residue field trials (SPRFT) aim to ensure safe food and promote fair practices in food trade. They quantify the expected range of residues in crops after their treatment with the pesticides to be registered in the region. The data is used for registration and for setting Maximum Residue Limits (MRLs) on commodities.

This document summarises the guidelines to be used by trial managers, researchers and pesticide manufacturers to provide residue data to support pesticides registration and set both Codex and regional MRL and import tolerance where not available.

OBJECTIVES OF THE GUIDELINES

- Provide a regional framework for carrying out supervised residue field trials on crops, contributing to the establishment of MRLs or import tolerance.
- Promote mutual recognition of the supervised field trial data within the EAC Partner States

GENERAL PROVISIONS

i. EAC Partner States should ensure that all new pest control products or new uses of existing pest control products are subjected to supervised residue field trials where the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) data or such data is unavailable from another region, before they are authorised for use.

ii. The manufacturer shall prepare the study protocol for submission to the responsible authority for approval, upon which the protocol shall be submitted to the authorised testing institution to conduct the supervised residue field trials.

iii. The testing institution shall conduct the supervised residue field trials in accordance with the provisions laid out in the study protocol and in line with provisions of GLP.

iv. Samples of the test substance must be provided by the manufacturer to the testing institution upon approval by the responsible authority for pesticides.

v. All trials must be authorised by the responsible authority in the respective EAC Partner State. It is recommended that the responsible authority liaises closely with the trial scientist/testing institution

and the applicant throughout the trial period.

vi. Field residue trials and laboratory analysis must be carried out by institutions that are officially recognised by the responsible authority in the respective EAC Partner State. In case there is no recognised laboratory, the responsible authority shall recommend accredited reference laboratory.

vii. The report shall be submitted in hard and soft copies to the respective responsible authority in the EAC Partner States and a copy maintained by the applicant/manufacturer.

RESIDUE TRIAL REQUIREMENTS

The trials should reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed.

a) Design

Trials should be designed to cover a range of representative field conditions, typical periods of the year, and common farming practices. If data is sought to support establishment of a maximum residue limit, a number of trials in several geographical areas are required. When a product is applied to a crop near maturity, studies on residue disappearance with time are usually needed to determine acceptable pre-harvest intervals. Such considerations markedly influence the location of the test plots. The size and number of samples that must be taken from each plot determines the size of the experimental plots. Since climatic conditions may have an important influence on the persistence and performance of a chemical, trials shall be carried out in those areas where the product is to be finally used.

In particular, the design of residue trials will consider the following factors:

Zoning: The impact of climatic zones on pesticide residues is small, and residue data derived from similar use patterns and growing conditions may be compared regardless of the geographical location of the trials.

Selection of sites: Trials should be carried out in major areas of cultivation or production and should be sited to cover the range of relevant representative conditions, including different bioclimatic regions, seasons of production, soil characteristics, cropping system, farming practices, and cultivars etc, likely to be met for the intended use of the pesticide.

Number of sites and replication: The number of sites needed depends on the range of conditions to be covered, the uniformity of crops, variation in agricultural practices, and the data already available. As a general rule, a minimum of five trials (for major crops) or a minimum of four trials (for minor crops) are required. The trials sites should be at least 35km apart, to be deemed independent.

Plots: Residue data should not be generated from plots which are too small to be representative. The size of the individual plots will vary between crops but should be large enough, generally at least 10m2 for row crops and typically four trees or eight vines for orchard and vineyard crops respectively. This is in order to apply the pesticide in an accurate and realistic manner; and to provide representative crop samples.
Specific trial protocols (procedures) shall be prepared for specific pesticide / crop combinations based on the type of trials to be conducted.

Crop Variety/Cultivars: The type or variety of crop and the way in which it is grown may influence the residue pattern. Data should be generated on the most commonly used type or variety and on the factors most likely to result in the highest residue levels. If more than one variety of crops is commonly grown, then more than one variety should be used in the trials.

Number and timing of applications and additional pesticides: The number of treatments and the intervals between applications should reflect the latest and maximum use of the product to be recommended. No pesticide in addition to those to be analysed, should be applied to the control or experimental plots before or during the trial period. However, since it is of primary importance that both the untreated and treated plants be healthy, the use of other pesticides may be necessary. In this case only those pesticides that will not interfere with the analysis of the residues of the test compound may be used.

Number of seasons: Residue data from only one season are considered sufficient, provided that crop field trials are located in the typical crop production areas such that a variety of climatic conditions is taken into account. However, if a particular crop is produced commercially in one geographic locality/ climatic area, then

trial sites should be situated at least 35km apart. If this is not possible, trials should be separated by time e.g. done over a minimum of two seasons.

Application rates: Supervised residue field trials should be carried out according to the typical commercial practice in regard to spray volume. The application rate should be expressed in terms of amount of product and/or active ingredient per unit area, and where appropriate, the concentration at which it is applied. Both the growth stage at application (preferably as BBCH code) and PHI should be recorded.

Equipment and Mode of application: Applications should preferably be made with equipment similar to that used in normal commercial practice for the crop. Other forms of applicators may be used, provided the deposition and coverage achieved are similar to what would occur in normal practice.

Equipment calibration: Before application of the test substance, the application equipment must be calibrated for the intended delivery, such as discharge and application speed calibration.

b) Decline studies

Residue decline data is necessary for uses where the pesticide is applied when the edible portion of the crop has formed or it is expected that residues may occur on the food or feed commodities at, or close to, the earliest harvest time. When residue decline data are necessary, up to 50 percent of the residue trials should be decline studies to demonstrate the behaviour of the active ingredient and relevant metabolites close to harvest.

c) Number of crop field trials

Trials should be conducted to represent the typical growing areas of crops. The number of crop field trials conducted at the critical good agricultural practice (cGAP) should be in line with international provision, taking into account the following:

i. Crop production regions, often defined or identified by the crop production practices (e.g., irrigation type; planting densities) and the soils and climatic properties of the region.
ii. Significance of the crop in the country of production, most often determined by the production acreage or volume.
iii. The importance of the crop in the national diet.

SAMPLING AND SAMPLE HANDLING

For raw agricultural commodities (RAC), samples should be taken of the commodity as it is traded. Care should be taken not to remove surface residues or contaminate them during handling, packing or preparation. This includes avoiding damage to or deterioration of the sample, as this might affect residue levels. Control samples are in every way as important as samples from test plots. Therefore, the quality of control samples should be similar to that of the test samples.

Proper labelling of samples is of utmost importance. Sample labels must indicate crop, variety, trial site, active ingredient, pesticide formulation, dosage rate, date of sampling, time of sampling and name of sampler. Samples should be frozen as soon as possible following collection to avoid deterioration and decomposition of the residue(s). Therefore, shipment of frozen samples should be either by freezer truck or packed in dry ice.

Samples should be transported immediately to the laboratory and upon arrival, the pesticide residue laboratory personnel should verify the following:

- Inclusion of a sampling record;
- The conditions of the samples upon arrival;
- Accuracy of the sampling record, especially rate and interval data;
- Completeness of information.

If there are any deviations of any consequence, or the sampling report is not received or is incomplete, the samples should be stored in the simplest form that will preserve the residue and the crop. The trial organiser should then be contacted immediately to determine how to proceed.

The laboratory samples should be prepared for analysis in accordance with the instructions of the Codex Standard on Portion of commodity to which MRLs apply and which is analysed. It is acceptable to sub-sample large commodities (e.g., head cabbage, melons, etc.) with procedures such as quartering and collecting opposing quarters. However, this should be done in a laboratory environment to avoid contamination or degradation of pesticide residues.

Samples should be analysed as quickly as possible after collection before physical and chemical changes occur. If prolonged storage is unavoidable, store the samples at a low temperature, preferably at or below -20 °C. Do not store samples (whole or homogenised) for analysis unless an adequate check has been made on the stability of the residue. Fumigant residue samples need special attention and ideally should be analysed immediately on receipt at the laboratory.

RESIDUE ANALYSIS

Residue analysis shall be done in accordance with the principles of pesticide residue analysis and the requirements of Analytical Quality Assurance (AQA) systems such as ISO 17025 (2005). Pesticide residue laboratories should use the guidelines on good laboratory practice in pesticide residue analysis (CAC/GL 40-1993). Further, the Guidance Document on Pesticide Residue Analytical Methods (2007), published by the OECD, should be used to generate the data for establishing MRLs and to determine processing factors. Method validation should be undertaken in accordance with the principles set out in the said guidelines.

DATA REPORTING

The data obtained from the supervised residue field trials shall be reported using internationally harmonised formats. A detailed outline of how to organise the data is described in the FAO Manual on the Submission and Evaluation of Pesticide Residue Data for the Estimation of Maximum Residue Levels in Food and Feed.

DATA SHARING AND USE

The EAC Partner States shall establish a central data repository that is accessible to all responsible Partner States. The data will comprise, among others, the necessary registration, efficacy and residue data. The central data repository shall be coordinated and facilitated through the EAC Secretariat. The responsible pesticides authorities of EAC Partner States shall meet periodically to share information on new needs for data sharing.

Office of the Deputy Secretary General Productive and Social Sectors

East African Community Secretariat

Afrika Mashariki Road

P.O. Box 1096 Arusha

United Republic of Tanzania

Tel: +255 (0)27 216 2100

Fax: +255 (0)27 216 2190

Email: eac@eachq.org