THE EAST AFRICAN COMMUNITY

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

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ABBREVIATIONS:

ADI	Acceptable Daily Intake
BBCH	"Biologische Bundesanstalt, Bundessortenamt und CHemischeIndustrie": Scale used to identify the phenological development stages of a plant
CAC	Codex Alimentarius Commission
CCPR	Codex Committee on Pesticide Residues
cGAP	Critical Good Agricultural Practice
DP	Dustable powder
EC	Emulsifiable Concentrate
GR	Granules
JMPR	FAO/WHO Joint Meeting on Pesticide Residues
SC	Suspension concentrates
SL	Soluble concentrates
WG	Water dispersible granules
WP	Wettable powder

1.0 PREAMBLE

The East African Community (EAC) is committed to improving its global competitiveness for faster and sustainable economic growth. As the East African Partner States aim to increase agricultural productivity towards both food security and export markets, there is an increasing need for the use of pesticides to reduce pest pressure. However, challenges in the management of agricultural regulatory systems in particular that of pesticides reduce efficiency and competitiveness for a sustainable agricultural sector in East Africa. Chapter Eighteen (18) of the Treaty of the establishment of the East Africa Community outlines comprehensive system of cooperation among the EAC Partner States in the Agriculture Sector, which is deemed as one of the key sectors that will drive regional growth and competitiveness.

The EAC Sectoral Council on Agriculture and Food Security (SCAFs) has taken cognizance of the importance of farm inputs in agricultural development and transformation efforts. The farm inputs include animal feeds, mechanization equipment**,** fertilizers, improved seeds, veterinary drugs, agrochemicals and pesticides. The 7thand 8thEAC (SCAFs) directed the EAC Secretariat to mobilize resources for undertaking harmonization in the area of farm inputs including agricultural chemicals and pesticides.

In 2005, the EAC Secretariat coordinated development of draft instruments for pest control products. Work has been done in elaborating Procedures for Evaluating the Efficacy of Pest Control Products for Plants, Application Forms for Registration of Conventional Pest Control Products and labelling requirements of pest control products.

In January 2015, the EAC Secretariat and the Food and Agriculture Organization of the United Nations (FAO) agreed to implement a joint regional work plan on pesticides management. The main focus of the harmonized pesticide regulation programme is to reduce risks associated with pesticides, improve trade and safeguarding human health and the environment. The three focal areas prioritized to kick-start harmonization of pesticide regulation are regional collaboration for harmonization of efficacy trials, pesticide residue trials and data requirements for pesticide registration. The work to prepare the guidelines commenced in September 2016. The guidelines were developed pursuant to Article 108(e) of the Treaty for the establishment of the East African Community (EAC), and aim at promoting the conduct of trials to ensure safe food and promote trade. One of the focus areas was to develop guidelines on the conduct supervised pesticide residue field trials to ensure safe food and promote fair practices in food trade.

2.0 INTRODUCTION

Supervised pesticide residue field trials (SPRFT) are undertaken to quantify the expected range of residues in crops after their treatment with the pesticides to be registered in the region, the data of which is used for registration and for setting Maximum Residue Limits (MRLs) on commodities. In the EAC, data on SRFT to support pesticide registrations can be submitted from other countries or regions. Where such data is not available, the data can be generated within the EAC region. In some instances however, some research has been conducted to provide information on the behavior of grain storage pesticides used on stored grains in some Partner States, however they have yet to be conducted routinely to provide data for registration of pest control products. Further, no guidelines exist within the legal framework of EAC Partner states on how to conduct the trials.

These guidelines have therefore been developed for trial managers, researchers and pesticide manufacturers to provide residue data to support Pesticide registration and setting both Codex and regional Maximum Residue Limits (MRL) and import tolerance, where it is not available; and to support pesticide registration. This will improve the evaluation process for the registration and harmonization of new pest control products in the region.

3.0 DEFINITIONS

Active ingredient: means the part of the product that provides the pesticidal action [1].
Adjuvant refers to any product added to the spray tank for the purpose of improving the performance of the test substance/active ingredient. Adjuvants can be characterized for example as wetting agents, spreader-stickers, compatibility agents, buffering agents, de-foamers, non-ionic surfactants, crop oil concentrates, etc.[2].
Applicant refers to a company and/or person who applies for a registration, amended registration, reregistration or MRL. Also see *Manufacturer*
Application equipment means any technical aid, equipment, implement or machinery which is used for the application of pesticides [1].
Commodity group: Commodities within a group based on similar residue characteristics and which are deemed to be suitable for setting group MRLs are said to belong to a Commodity group, also known as a Crop group. Commodity groups (e.g., pome fruits, cereal grains) within the Codex Classification for Foods and Feeds are suitable for establishing group MRLs.
Control plot: The plot that is not applied/treated with the test substance, or a substance that has similar chemistry or belongs to the same pesticide class and is part of crop field trials, which could interfere with the trial. The use of other products may be necessary to maintain the health of the treated and untreated (control) plants. In that case, only those pesticides that do not interfere with the residue analysis may be used. The additional products used should be noted and, where possible, advice from the analyst should be sought before use.
Crop Field Trial – see "**Supervised Field Trial**"; these terms are considered synonymous for purposes of this guideline.
Crop field trial site is a geographically defined address/location within a country/region/state of a field, space, greenhouse or other area in/on which a pesticide field trial is conducted. A site may consist of several *plots* (areas with defined boundaries on which a crop is grown), including control and one or more treated plots, each of which receives a specific pesticide application regimen. The trial location for a post-harvest application is defined as the location where the post-harvest treatment takes place (for example treatment room or storage location). Additionally, the trial location for a seed treatment crop field trial is defined as the location where the seed is planted or sown.[2]
Crop Group refers to a group of crops in which the expected residues on the commodities are likely to be similar (from treatment under similar GAP) and where the group or subgroup MRLs can be considered. Crop grouping is based on similarities in appearance, harvestable commodity, edible portions and/or growth habits etc. [2]
End-use product is a product containing *active ingredient(s)* and usually formulants that has been manufactured, packaged, and labelled with instructions for direct pest control use or application in a form that is usable by the consumer.
Extrapolation refers to a system projection of data from one system to another system. In this sense, data received from one formulation can be extrapolated to another formulation under certain circumstances. In some instances, extrapolation of field trial data obtained from one commodity are used to predict the residue behaviour of another similar commodity under described circumstances and thus proposing the same MRLs for both commodities. [2].
Formulation means the combination of various ingredients designed to render the product useful and effective for the purpose claimed and for the envisaged mode of application. [1]
Good Agricultural Practice in the use of pesticides includes the officially recommended or nationally authorized uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable [1].
Critical Good Agricultural Practice (*c*GAP) is the GAP selected to represent the worst-case use scenario within the context of national, regional, or global uses that will be producing the highest

possible field residues on crop commodities. It usually includes the maximum use-rate and number of applications and the minimum re-treatment and pre-harvest intervals.

Good experimental field practice is the formalized process for designing and recording the practices used in the performance of field investigations with pesticides, and which assure the reliability and integrity of the data [3].

Good laboratory practice (GLP) is **t**he formalized process and conditions under which laboratory studies on pesticides are planned, performed, monitored, recorded, reported and audited. Studies performed under GLP are based on the national regulations of a country and are designed to assure the reliability and integrity of the studies and associated data. The U.S. Environmental Protection Agency GLP definition also covers field experiments [3].

Highest residue – The Highest residue (HR) level (expressed as mg/kg) in a composite sample of the edible portion of a food commodity when a pesticide has been used according to the maximum GAP conditions. The HR is estimated as the highest of the residue values (typically, one from each trial) from supervised trials conducted according to maximum GAP conditions, and includes residue components defined by the Joint Meeting on Pesticide Residues (JMPR) for estimation of dietary intake. [4]

Import Tolerance is a MRL set for to facilitate the importation of products to meet the needs of international trade where (a) the use of the active substance in a plant protection product on a given product is not authorised in the East Africa Community for reasons other than public health reasons for the specific product and specific use; or (b) a different level is appropriate because the existing East Africa Community MRL was set for reasons other than public health reasons for the specific product and specific use.

Limit of detection (LOD) The LOD is the lowest concentration of a pesticide residue or contaminant that can be identified and quantitatively measured in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis. (Codex Alimentarius, Vol. 2A), [4]. **Limit of quantitation (LOQ)** The LOQ is the smallest concentration of the analyte that can be quantified. It is commonly defined as the minimum concentration of analyte in the test sample that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test. [5] See Explanatory note[1]

Manufacturer means a corporation or other entity in the public or private sector (including an individual) engaged in the business or function (whether directly or through an agent or entity controlled by or under contract with it) of manufacturing a pesticide active ingredient or preparing its formulation or product [1].

Major crops *see Minor crops*

Codex Maximum Limit for Pesticide Residues (MRL) is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. Codex MRLs, which are primarily intended to apply in international trade, are derived from estimations made by the JMPR following:

(a) toxicological assessment of the pesticide and its residue; and

(b) review of residue data from supervised trials and supervised uses including those reflecting national good agricultural practices.

Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices. Consideration of the various dietary residue intake estimates and determinations both at the national and

[1] Limit of quantification' and 'limit of quantitation' are used synonymously and are abbreviated to LOQ. The FAO Panel estimates the LOQ of an analytical method for residues in specified substrates as being the lowest level where satisfactory recoveries were achieved. JMPR has used LOD (limit of determination) in the past with the same meaning as LOQ.

international level in comparison with the ADI, should indicate that foods complying with Codex MRLs are safe for human consumption. [6]

The **maximum residue level** is estimated by the JMPR as the maximum concentration of residues (expressed as mg/kg) which may occur in a food or feed commodity following Good Agricultural Practices. The estimated maximum residue level is considered by the JMPR to be suitable for establishing Codex MRLs.[4]

Minor Crops are crops for which a use of a pesticide or constituent would not produce sufficient economic return to an applicant for registration of the pesticide to meet the cost of registration of the product. [7]. Major crops would generally be the converse of minor crops. **Pesticide Residue** means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such a conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance. [6]

Pre Harvest Interval (PHI) is the time interval in days between the last application of a pesticide to a crop and harvest to meet the relevant *maximum residue limits* for a particular crop. [3]

Product (or pesticide product) means the formulated product (pesticide active ingredient(s) and co- formulants), in the form in which it is packaged and sold. [1]

Post Harvest Treatment refers to a pesticide application to the harvested crop, which may occur before or during storage.

Raw Agricultural Commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. It includes irradiated primary food commodities and products after removal of certain parts of the plant or parts of animal tissue. The term "raw agricultural commodity (RAC)" means the same as "primary food commodity". [4]

Responsible Authority: Means the government agency or agencies responsible for regulating pesticides and more generally for implementing pesticide legislation [1]. Responsible authority also refers to the regulatory authority responsible for the registration of pesticides

Representative commodities are those designated commodities from which extrapolations of residue levels and resulting MRLs can be made to one or more related commodities or to an entire group of commodities (‘crops’).

Sample is a defined representative amount of individual raw agricultural commodity unit(s) (e.g. specific number of fruits or tubers, a set +weight of grain, etc.) randomly selected from a plot which may be composited for pesticide analysis.

Seed treatment application is made to the seeds of crops prior to planting or sowing, which may occur at a seed treatment facility or in the field immediately prior to planting or sowing. [2]

Supervised field trials are residue field trials conducted on crops, typically according to the principles of Good Laboratory Practice (GLP), in order to assess the magnitude of the residues under the conditions of the critical Good Agricultural Practice(cGAP).

Supervised Trials Median Residue (STMR) is the expected residue level (expressed as mg/kg) in the edible portion of a food commodity when a pesticide has been used according to Maximum Good Agricultural Practice conditions. The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum Good Agricultural Practice conditions [8].

Test Substance is the product or formulation used in a crop field trial for the purpose of generating residue data for a specific crop or commodity [4].

4.0 OBJECTIVES

The objectives of these Guidelines are to:

i) Provide a regional framework for carrying out supervised residue field trials on crops contributing to the establishment of MRLs or import tolerance.
ii) Promote mutual recognition of the supervised field trial data within the East African Community (EAC) Partner States.

5.0 GENERAL PROVISIONS

5.1 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 JMPR data or such data is unavailable from another region before they are authorized for use or where new information from exposure assessment is received that may require a change in the use pattern.

5.2 The manufacturer shall prepare the study protocol for submission to the responsible authority for approval. Upon approval, the study protocol shall be submitted to the authorized testing institution to conduct the supervised residue field trials.

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

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

5.5 All trials must be authorized by the responsible authority in the respective EAC Partner State. It is recommended that the responsible authority liaise closely with the trial scientist/testing institution and the applicant throughout the trial period.

5.6 Field residue trials and laboratory analysis must be carried out by institutions that are officially recognized by the responsible authority in the respective EAC Partner State. In case there is absence of recognized laboratory, the Responsible Authority shall recommend to accredited reference laboratory.

5.7 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.

6.0 RESIDUE TRIAL REQUIREMENTS

In designing a residue trial, early consideration must be given to the intended use of the residue data to be obtained and to the sampling programme and analytical work that this entails. The trials should reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed.

6.1 Design of residue trials

Trials should be designed to cover a range of representative field conditions, typical periods of the year, cropping and farming practices which are commonly encountered. If data are sought to support establishment of a maximum residue limit, results from a number of trials in several geographical areas or during typical periods of the year and farming practices 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.

6.1.1 Zoning

The FAO/WHO Joint Meeting on Pesticide Residues agreed with the conclusion that 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 of the geographical location of the trials [9].

6.1.2 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, cultivars etc.) likely to be met for the intended use of the pesticide.

6.1.3 Number of sites and replication

The number of sites needed depends upon the range of conditions to be covered, the uniformity of crops, variation in agricultural practices, and the data already available. Since the variations in residue levels between replicates at individual sites are small compared with those found in data from different sites, it is usually not necessary to replicate treatments at individual sites [10].
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 thirty five (35) kilometres apart to be deemed independent.

6.1.4 Plots

Residue data should not be generated from plots which are too small to be representative. The size of the individual plots will vary from crop to crop but should be large enough generally at least 10 m^2 for row crops and typically four trees or eight vines for orchard and vineyard crops respectively; in order:
(i) to apply the pesticide in an accurate and realistic manner, preferably under the same conditions as in normal local commercial/production practice; and
(ii) to provide representative crop samples.

A control plot for the supply of untreated samples is necessary to provide the analyst with a sample known to be free from residues of the pesticide under investigation. Where treated and control plots are in close proximity, measures should be taken to avoid contamination (e.g., covering or shielding crop if necessary). It is also important to ensure that plots are adequately buffered or separated. There is no minimum distance between plots which ensures adequate buffering, however prevailing wind, slope and distance between plots should all be considered prior to designing the field trial.
Control samples are needed:

(i) to ascertain that no artefact in the crop derived from local conditions could give rise to interference in the analysis;
(ii) to establish the recovery level of the pesticide from the crop or soil by the analytical method;
(iii) in the case of a new crop or pesticide, to investigate the storage stability of any residue.
The control plot should be large enough to satisfy these requirements and should be located close enough to secure identical growing and climatic conditions.

Specific trial protocols (procedures) shall be prepared for specific pesticide / crop combinations based on the type of trials to be conducted.

6.1.5 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 factor or combination of 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.

6.1.6 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 analyzed 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.

6.1.7 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 mainly produced commercially in one geographic locality/ climatic area, then trial sites should be situated at least thirty five (35) kilometres apart. If this is not possible, trials should be separated by time e.g. done over a minimum of two seasons.

6.1.8 Application rates

Supervised residue field trials should be carried out according to the typical commercial practice(s) in regard to spray volume ensuring that the range of volumes utilized is captured. For all applications, the application rate should be expressed in terms of amount of product and/or active ingredient per unit area (e.g., kg a.i. per hectare or per acre) and where appropriate, the concentration (e.g., kg a.i. /100 liters or) at which it is applied. Due consideration should be made for foliar application of “tall” crops, (e.g., orchard and vine crops, greenhouse tomatoes), where flat boom spraying is not common practice and (air assisted) mist blowing equipment is often used. Spray concentration and spray volume should be considered and reported when conducting SRFT. Application rates for seed and seedling treatments are expressed as concentration per unit of seed weight or seedling rate.

For dip or drench of fruit, concentration of the active ingredient in solution should be recorded ((e.g., kg a.i. /100 liters) as well as the amount of fruit treated per volume and contact time in seconds. Where dips are replenished to maintain the active ingredient concentration during treatment (i.e., where residue stripping occurs), the additional ‘top-up’ treatments should also be recorded. The application rate for gases and aerosols used in fumigation should be expressed as amount per unit volume of treated bulk good.

The maximum label rate or maximum proposed label rate of the active ingredient (according to the *c*GAP) should be used when applying the test substance for crop field trials. The maximum number of applications and minimum re-treatment interval for use of the test substance under evaluation should reflect the *c*GAP. It is important to indicate the types of crop varieties included in a trial in order to evaluate an appropriate range of pre- (PHIs) (e.g., shorter and longer intervals from planting to maturity in the case of pre-emergence application to an annual crop). Basically in all trials both the growth stage at application (preferably as BBCH code) and PHI should be recorded.

6.1.9 Equipment and Mode of application:

Applications should preferably be made with equipment similar to that used in normal commercial practice for application to that crop. Other forms of applicators may be used, provided the deposition and coverage achieved are similar to what would occur in normal practice. Consideration should also be given to selection of appropriate nozzles in crop field trials. Ensure that the application is appropriate to the anticipated use of the pesticide, as indicated in the product label. Care should be taken to avoid contamination of neighbouring plots

6.1.10 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. To ensure correct usage rates and uniformity of application the operation should be carried out under the supervision of qualified personnel.

6.2 Other general considerations:

Other considerations to take into account include:

i) Adequate separation between plots should be provided to avoid contamination especially during sampling.
ii) Adequate buffering should be provided between plots, however, 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.
iii) Selection of crop variety should be taken into account to ensure that varieties of commercial importance, size variation and time of maturity of the varieties. The tests should be carried out in plots with the same edaphic homogeneity.
iv) Crop protection measures in the trial plot should be chosen in such a way that they do not affect or interfere with the residue analysis of the pesticide and metabolites under trial
v) Soil types should be reported in all field sites.
vi) Trials can be conducted under complete protected conditions; the type of protection should be stated in the planning of the trial.
vii) Appropriate care should be made to minimize drift especially into water bodies such as lakes and rivers.

6.3 Decline studies:

Residue decline data are 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. Residue decline data are used in residue evaluation for purposes such as:

i) Determining if residues are higher at longer PHIs than requested;
ii) Estimating the half-life of the residues;
iii) Determining whether alteration of the PHI to levels represented in the decline trials around the GAP PHI affects the residue levels;
iv) Allowing for a degree of interpolation to support use patterns, including PHIs, not directly equivalent to those used in the trials on a case-by-case basis;
v) Determining the profile of the residue over time to add to the understanding of metabolism of the pesticide under conditions more applicable to GAP and to assist in appropriate selection of residue definitions; and
vi) Determining the time interval to reach maximum residues for a systemic compound applied to crops such as potatoes or peanuts.

When residue decline data are necessary, up to 50% of the residue trials should be decline studies to demonstrate the behavior of the active ingredient and relevant metabolites close to harvest.

When decline data is generated, sampling of more than one commodity or matrix per crop may be needed. This will be the case whenever different commodities are used as food or feed at different growth stages of the crop (e.g., cereal forage, cereal fodder, cereal grain and straw). This will result in two or more sets of sampling dates within one residue decline trial.

The design of *residue decline studies* should include 3 to 5 sampling intervals in addition to the target PHI (if practical, include 0-day sampling). These sampling intervals should be spaced somewhat equally and, where possible, sampling should occur at shorter and longer time points relative to the target PHI, when such is permitted by the window of commercial maturity. When

multiple applications are involved, a sampling point immediately prior to the final application is desirable to determine the contribution of earlier applications and the effect on residual half-life

6.4 Number of Crop Field Trials

In the East African Community, trials should be conducted to represent the typical growing areas of crops. The number of crop field trials conducted at the critical GAP 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 - beneath crop canopy vs. overhead sprinkler; planting densities of fruit trees) 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 area (acres or hectares) or production quantity(tons).
iii) The importance of the crop in the national diet.

A minor use crop may be defined as a crop that is grown on a small area and therefore uses amounts of pesticides that are too small to justify standard pesticide registration. A crop may be considered a minor crop based on the description provided in the Guidance to facilitate the establishment of MRLs for pesticides for minor crops [10].

For major crops in the EAC, the minimum total number of trials in a complete (comprehensive) submission is eight but ideally at least fifteen (15).

A complete (comprehensive) data set in the context of the Crop Field Trials Test Guideline is the number of supervised field trials matching the critical GAP (cGAP) which are required for setting an appropriate MRL and/or obtaining a new registration or new use (i.e. plant protection product in/on a crop). A reduced data set on the other hand refers to a reduced number of supervised field trials matching the cGAP which may be adequate to obtain a new or amended registration and/or MRL for a plant protection product in/on a specific crop. A reduced data set may be sufficient when conducting trials in cases where no residues are anticipated at or above the limit of quantitation.

To qualify for this comprehensive submission approach, all crop field trials should meet the following criteria[1]:

i) Field trials are conducted according to the (*c*GAP) (within ± 25% of the application rate, number of applications or PHI). At least 50% of the trials should be conducted at or above, but within 25% of the cGAP. Trials whose intended application rates match the cGAP but actual rates fall up to 10% below the cGAP (e.g., due to the normal variability in preparing spray solutions) are considered acceptable. In addition, at least 50% of the trials need to be decline studies.
ii) The trials span a range of representative crop production practices for each crop including those likely to lead to the highest residues (e.g., irrigated vs. non-irrigated, trellis vs. non-trellis production, fall-planted vs. spring-planted, etc.).

For minor crops the EAC shall adopt the decision from the 47thSession of the CCPR which decided that the a minimum number of four and five independent supervised field trials would be conducted, reflecting the respective good agricultural practice for Category 2 and 3 respectively [11]. For minor crops in Category 1, fewer trials (four) may be acceptable on a case by case basis. Crops would be assigned to the Categories defined using the methodology described in the guidance document.

6.4.1 Requirements for independent supervised residue trials

The following trial conditions are usually recorded and are taken into consideration in defining an independent supervised residue trial:

i) Geographical location and site – trials at different geographic locations are considered

independent;

ii) Dates of planting (annual crops) and treatments - trials involving different planting dates or treatment dates (> 30 days apart) are considered independent;
iii) Formulations – comparability or independence of trials with different formulations should to be assessed;
iv) Types of treatment, e.g., foliar, seed treatment, directed application – different types of treatment on different plots at the same site are considered as separate trials;
v) Addition of surfactants – a trial with the addition of surfactant may constitute sufficient difference to be treated as independent, provided the relevant label does not prescribe the use of adjuvant;
vi) Application rates and spray concentrations – trials conducted at the same location with significantly different application rates and spray concentrations are not independent; the principle of proportionality may be applied to select the trial which leads to the highest residues;
vii) Crop varieties – different varieties at a single site may not be 'independent'; some varieties may be sufficiently different (different morphology etc.) to influence the residue;
viii) Treatment operations – trials at the same site treated in the same spray operation are not counted as separate trials;
ix) Application equipment – trials at the same site treated by different equipment, other things being equal, are not counted as separate trials.

7.0 TEST SUBSTANCE

The test substance(s) (pesticide) should be stored under appropriate conditions for the study duration and applied soon after preparation or mixing. If residue data is generated for a single active ingredient, there are no additional data requirements for tank mix, pre-mix or other types of combinations with other active ingredients as long as there is no evidence of synergism associated with the combination(s) and as long as the cGAP for the active ingredient is not exceeded with any of the combinations.

Active ingredients may be applied in combination (i.e., tank mix, pre-mix or sequential) in crop field trials to a single treated plot as long as there is clear analytical separation (i.e., no analytical interference) of active ingredients and any relevant metabolites. A single sample may then be collected from the treated plot and prepared for residue analysis for two or more active ingredients.

7.1 Formulations

The formulation tested in crop field trials should be as close as possible to the intended enduse product for the crop or commodity. The requirements in this guideline in regard to a complete data set (the number of crop field trials matching the cGAP which are required) are generally based upon only one formulation type being requested for use on a specific crop. The decision will be based upon how similar the formulations are in composition and physical form, the mode of application, and the timing of the application. Controlled release formulations (e.g., certain microencapsulated products) normally require a complete data set tailored to that particular use. Granules (GR) and dusts (DP) are the most common examples of the latter. Granular formulations applied intact will generally require a complete data set regardless of what data are already available for other formulation types.

The most common formulation types which are diluted in water prior to application include Emulsifiable Concentrates (EC), Wetable Powders (WP), Water dispersible Granules (WG), Suspension Concentrates (SC)(also called flowable concentrates), and Soluble Concentrates (SL). Experience from trials demonstrates that these formulations lead to similar residues. Residue data may be translated among these formulation types for applications that are made to seeds, prior to crop emergence, i.e., pre-plant, at-plant, and pre-emergence applications, just after crop emergence or directed to the soil, such as row middle or post-directed applications (as opposed to foliar treatments). Most of the remaining types of formulations can be divided into two groups—those that

are diluted with water prior to application and those which are applied intact.

In many situations different formulations would cause no more variation than other factors, and data derived with different formulations would be considered comparable.

8.0 BRIDGING STUDIES:

Bridging studies are an essential extrapolation tool to make the best use of existing data to support minor changes or variations to existing uses. A bridging study normally involves a comparison of different formulations or application methods for the purpose of data extrapolation, but may or may not involve side-by-side comparisons.

For late season foliar applications of formulations diluted in water, the decision on the need for additional data depends upon two factors:

i) the presence of organic solvents or oils in the product and
ii) the pre-harvest interval.

Wider extrapolation of data will generally be permitted for formulations that do not contain organic solvents or oils.

Some active ingredients, e.g., phenoxy herbicides, can be applied as one or more salts and/or esters. Different salts of an active ingredient may be considered equivalent for residue purposes in most cases regardless of the timing of the application. However, examples for which additional data may be needed for a new salt include the presence of counter ions that impart surfactant properties, significantly change the degree of dissociation, or chelate with the active ingredient ion. If the PHI is less than or equal to 7 days, the different esters are considered as new formulations of that active ingredient for the purposes of determining data needs, and bridging studies would be required as for different formulations.

If bridging trials are deemed necessary and a pesticide is used on a wide range of crops, data should be generated for at least three major crop groups (one crop per crop group), e.g., a leafy crop, a root crop, a tree fruit, a cereal grain, an oilseed with a minimum of four trials per crop. The trials should be carried out on crops that would be expected to show high levels of residue (often those with applications at or near harvest). If a bridging study is conducted and residues are significantly higher with a new formulation or different application method, or the combined residue data set obtained with different formulations would lead to a higher MRL, generation of a complete new data set may be necessary.

9.0 GENERAL GUIDANCE ON CROP GROUPS ANDEXTRAPOLATION

9.1 Extrapolation and principles of representative commodities

Residue extrapolation is the process by which the residue levels on representative commodities are utilized to estimate residue levels on related commodities in the same commodity group or subgroup for which trials have not been conducted.

The establishment of commodity group MRLs as opposed to MRLs for individual commodities has long been considered an acceptable procedure since economics may not justify residue trials on all of the individual crops in a group. In principle the approach recognizes that adequate data for the major crop commodities of a group may be sufficient to estimate maximum residue levels for the whole group. Since some pesticides may behave differently in different circumstances. Consequently, it is not possible to define precisely those commodities on which trials will always provide data that can lead to a group MRL. Extrapolation is possible if the GAP of the minor crop is similar to that of a relevant major crop (e.g. in the same crop grouping).

Preconditions for extrapolation of residues

Extrapolation of residue data for different crops presumes that the following are comparable:

i) conditions of use with regard to the amount of active substance applied,
ii) the time of application,
iii) the number of applications,
iv) the interval between applications,
v) application methods,
vi) formulation used, and
vii) climatic conditions.

The following are the principles of selection of representative commodity within groups as agreed by the Codex Committee on Pesticide Residues (CCPR) [12]. A representative commodity is:

- most likely to contain the highest residues.
- likely to be major in terms of production and/or consumption.
- is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

The application of the three principles is based on the assumption that all commodities of the respective group or subgroup are treated according to a similar use pattern or GAP. To facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

9.2 Wider extrapolations

The term 'wider extrapolations' (also referred to as 'cross group extrapolations') is used in this context for extrapolations that go beyond the bounds of a crop group or subgroup. Such extrapolations may be possible in special circumstances, on the basis of residue data. Consideration on a case-by-case basis may be given to commodities with very similar shapes, volumes, and weights. For example in Australia, apple, peach, and nectarine may be extrapolated to persimmon.

Wider extrapolations may also be considered, on a case-by-case basis, for:

i) Situations where residues are expected to be <LOQ (e. g. pre-emergence herbicide uses, pre-flower treatments);
ii) Situations where the active substance is used early in the growing season (last application before consumable parts of the crop have started to form). (This kind of extrapolation should be used with caution since for some crops the edible part of the crop is always present either as a food or a feed item.);
iii) Seed treatments, if data from treatment of several different 'representative' seed types all report no detectable residues in the commodities from crops grown from the treated seed;
iv) Post-harvest treatments for non-systemic pesticides to commodities of similar size and morphology on the basis of the same treatment regimes; and
v) Soil treatments with granules (depending on extent of residue uptake and distribution in the plant as evidenced by data from different crop types including a root crop).

A representative commodity should meet at least two (2) of the principles stated in 10.1 above. More details on the selection of representative commodities can be found in Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups (CAC/GL 84-2012).

It may not always fit well with the growth habits or pest problems of morphology within one group or subgroup. In such situations, extrapolations beyond the members of a commodity group may be appropriate. These can be considered on a case-by-case basis when commodities (with similar GAPs) have similar size, shape and surface area. Examples of these possible wider extrapolations include:

i) Translation of certain stone or pome fruit MRLs to a tropical fruit;
ii) Where residues are all <LOQ for pre-emergent herbicide uses and
iii) Seed treatments for non-systemic pesticides.

10.0 FIELD SAMPLING

For raw agricultural commodities (RAC), samples should be taken of the commodity as it is traded. . The detailed sampling procedures are outlined in the FAO Manual [13].
Below are general provisions for sampling:

10.1 Sample handling

Care should be taken not to remove surface residues during handling, packing or preparation.

i) Avoid any damage to or deterioration of the sample which might affect residue levels.
ii) To provide a representative sample of the raw commodity, adhering soil may have to be removed from some crops, such as root crops. This may be done by brushing and, if necessary, gentle rinsing with cold running water.
iii) Sample untreated control plots before treated plots

10.2 Contamination

It is essential to avoid any contamination with the pesticide under study or with other chemicals during sampling, transportation or subsequent operations. Special attention should, therefore, be paid to the following:

i) Ensure that sampling tools and bags are clean. To avoid contamination use new bags and containers of suitable size and adequate strength. The bags or containers should be made of materials which will not interfere with the analysis.
ii) Avoid contamination of the sample by hands and clothes which may have been in contact with pesticides.
iii) Do not allow the samples to come into contact with containers or equipment (including vehicles) that have been used for transporting or storing pesticides.
iv) Avoid sampling at the plot borders because the residue deposit may not be representative.
v) Take special care to avoid contamination when commercial mechanical harvesting practices are used
vi) Avoid cross-contamination of crop and soil samples.
vii) Sampling should proceed from the control to the lowest treatment and so on to the highest treatment.

10.3 Control samples

Control samples (samples taken from the untreated plot) are in every way as important as samples from test plots. The quality of control samples should be similar to that of the test samples, e.g., maturity of fruit, type of foliage, etc. Always take control samples. In decline studies of up to 14 days' duration, control samples from the start and from the end of the study may suffice.

10.4 Sampling in decline studies

The first sampling in a decline study may take place on the day of application. These samples

should be taken immediately after application, or in the case of spray application, immediately after the spray has dried (approximately 1-2 hours). Care should be taken to avoid contamination and samples should be taken to be representative of the average size or weight of crop on the plot.

10.5 Sampling at normal harvest time

i) Take samples so as to be representative of typical harvesting practice.
ii) Avoid taking diseased or undersized crop parts or commodities at a stage when they would not normally be harvested.

11.0 DETAILED SAMPLING PROCEDURES

The guidelines give a detail on the number of samples to take per site for both treated and untreated controls; and the number of composite samples to be taken and the minimum field sample size (by weight and number of samples).

Details of the sampling procedures are described in detail in the FAO Manual [13] Recommended sampling methods for supervised residue field trials; as follows.

i) Table V.1 Sampling of fruits
ii) Table V.2 Sampling of bulb, root and tuber vegetables
iii) Table V.3 Sampling of other vegetables
iv) Table V.4 Sampling of cereals
v) Table V.5 Sampling of forage crops and animal feed
vi) Table V.6. Sampling of herbs, spices; tea leaves; hops and beer

11.1 Sample transportation

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 sample deterioration and decomposition of the residue(s). It is not advisable to allow samples to thaw once frozen; therefore shipment of frozen samples should be either by freezer truck or packed in dry ice. It is acceptable to ship samples overnight, with coolant such as “blue ice”, to the sample preparation facility as long as they are “peeled” or “pitted”, or otherwise prepared for analyses and frozen immediately upon arrival.

11.2 Sample reception and handling

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

- Sampling record is included with the samples, and the sample details should match the sampling record
- Check and report 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 organizer should then be contacted immediately to determine how to proceed.

Once the samples are packed and labelled, they may be stored or preferably immediately sent to the residue laboratory according to the nature of the sample. The mode of shipping (e.g. deep-frozen or at ambient temperature shall be selected taking into account the stability of the residue and the kind of study undertaken. It is important that packing and shipment are carried out in such a way that the

samples arrive as soon as possible (normally within 24–36 hours) after being taken and without change of any kind, e.g., deterioration, physical damage, contamination, loss of residue, or change in moisture content. Storage and shipping should always be under deep-frozen conditions. Mixing of samples and sample size reduction at the field site is not recommended and should be avoided.

11.3 Sub-sampling and processing

The laboratory samples should be prepared for analysis following the instructions of the Codex Standard on Portion of commodity to which MRLs apply and which is analyzed [14].

It is acceptable to subsample 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. If analyses are planned on matrices such as pulp and peel (e.g., for dietary risk assessment refinement), the whole commodity should be shipped to the analysis lab to avoid cross contamination of peel and pulp.

Shelling, removing seeds or beans from pods, etc. should be undertaken in the pesticide residue laboratory to ensure minimum contamination e.g. through using clean tools and changing gloves between plot samples. In cases where commodities such as peel and pulp or stone and pulp are separated for analyses, weights should be determined for each commodity

Apart from superficial cleansing i.e., removal of any extraneous matter such as soil, no intrusive cleaning should be attempted. In the case of root crops recovered with soil, where light brushing is not sufficient to remove soil, gentle minimal rinsing under cold running water may be used.

11.4 Sample size reduction

The Codex guideline on the Portion of Commodities To Which Codex Maximum Residue Limits Apply and Which is Analyzed [14] provides a table to guide on the part of the raw agricultural commodity to which the maximum residue limit applies and which is to be prepared as the analytical sample for the determination of pesticide residues.

11.5 Storage

Samples should be analyzed 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 analyzed immediately on receipt at the laboratory.

12.0 RESIDUE ANALYSIS

Residue analysis consists of a chain of procedures, done in accordance with the principles of pesticide residue analysis and the requirements of Analytical Quality Assurance (AQA) systems such as ISO 17025 (2005) [15].

Pesticide residue laboratories should use the guidelines on good laboratory practice in pesticide residue analysis (CAC/GL 40-1993) [16]. Further, the Guidance Document on pesticide residue analytical methods", 2007 published by the OECD; should be used in providing guidance on the residue analytical methods used to generate the data for establishing Maximum Residue Limits (MRLs) and to determine processing factors [17]. Method validation should be undertaken in accordance with principles set out in the said guidelines.

13.0 DATA REPORTING

The data obtained from the supervised residue field trials shall be reported using internationally harmonized formats.

The reporting of supervised trials are assisted with the attached electronic versions of the Excel templates and spreadsheets to the Manual that can be downloaded from the FAO Homepage [18].

Detailed outline of how to organize 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 [19, Appendix VII: Standardized Format for Organizing The Data Directory (Index) of Information to be Submitted for Evaluation]. A summary of the data layout in table form is also described in the FAO Manual [20, Appendix XI: "Table and Spreadsheet Examples].

The following information shall be provided:

1. Summary

(A) Study ID, Title, Author(s), Publication date, Report No., Study dates
(B) Testing Laboratory
(C) Test Guideline, including deviations
(D) Purpose of studies
(E) Description and rationale for the total number of field trials and the locations chosen (countries/regions)
(F) Results (including explanations for apparently aberrant or atypical values, discussion of geographical representation (major growing areas), seasonal variation (summer/winter, wet/dry, etc.) and representative nature of types and varieties of the raw agricultural commodity).
(G) Field procedures
(H) Analytical procedures/instrumentation
(I) Method recovery and validation data
(J) Storage stability / Storage period for samples should be compared to those utilized in storage stability study.
(K) Discussion (including Quality Control measures taken; GLP compliance; statistical treatments of data; and information on the levels of the components of the residue definition in or on the RAC (specific plant parts) arising from the use of the pesticide formulated product on the test crop under specific use conditions and storage stability).
(L) Conclusions

2. The following information shall be provided on the data tables and other graphical representations:

(A) Summary map of crop field study sites (by crop)
(B) Summary tables of residue results of individual field trials
(C) Graphic representations (e.g., residue decline, figures, flowcharts,etc.)
(D) Summary tables of recovery data via the analytical methodology
(E) Summary tables of storage stability validation data
(F) Chromatograms (as applicable)

3. Raw data on individual field trials (specifically, each individual field trial report should include the following information):

(A) Reporting of Test substance(pesticide).

(i) Identification of the test pesticide active ingredient (a.i.), including CAS and IUPAC chemical name, common name (e.g., BSI, ISO), and company developmental or experimental name.

(ii) Identification of the pesticide formulated products used in the field trial, including trade name, type (EC, WP, G, etc.), and amount of active ingredient per gallon, pound, liter, kg, etc., and manufacturer.
(iii) Information on other relevant parameters, as pertinent, (e.g., tank mates, spray additives, carrier (encapsulating polymer, etc.)).
(iv) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the test substance.

(B) Test commodity(RAC).
(i) Identification of the RAC, including type/variety.
(ii) Identification of specific crop parts harvested; used in residue analytical methodology validations; and subjected to residue analysis for a determination of the components of the residue definition.
(iii) The developmental stages, general condition (immature/mature, green/ripe, fresh/dry, etc.) and sizes of the RAC at time of pesticide application(s) and at harvestings.
(iv) Any other information that may be considered appropriate and relevant to provide a complete and thorough description of the RAC.

4. Reporting test procedures.

(A) A detailed description of the experimental design and procedures followed in the growing of the RAC, applications of the pesticide formulated products, and harvestings of samples. The information provided, which should be presented on standardized field sheets, should include (in addition to a description of the test substance and test commodity):
(i) Trial identification number.
(ii) Cooperator (name, address), test location (e.g., state, country) and year.
(iii) Field trial lay-out (e.g., size and number of control and experimental plots; number of plants per plot/unit area, number of rows per plot, length of rows and row spacing).
(iv) Cultural treatments - farming practice (cultivation, irrigation, etc.) and cropping system.
(v) Soil characteristics (name/designation of the soil type). If application rate of the pesticide is dependent on any soil properties such as percent of organic matter, these should also be described.
(vi) Methods of application (air or ground) of the pesticide formulated products, description of the application equipment, type of application (band/broadcast, soil/foliar/ directed, ULV/concentrate/dilute, other), and calibration of pesticide application equipment, including methods and dates.
(vii) Application rates (amount of active ingredient and formulated product per acre, row, volume, etc.) and spray volumes per acre or hectare.
(viii) Number and timing of applications (total number, during dormancy, pre-plant, pre-emergence, pre-bloom, etc., between-application-intervals, and treatment-to-sampling intervals (pre-harvest intervals =PHI)).
(ix) Other pesticides applied (identity (name and type of formulated products, active ingredients), rates, dates, purpose of use, indicate whether applied separately or mixed with active ingredient of interest in trials).
(x) Climatological data (record of temperature and rainfall during the growing season from the nearest weather station, and wind speed during application).
(xi) Dates (planting/sowing/transplanting, as applicable, other significant dates in the growing of the crop (e.g., husk split for tree crops), pesticide applications, harvests).
(xii) Harvest procedures (method of harvesting (mechanical/hand, from the plant/ground/flotation, etc.), type equipment used, number/weight of samples collected per replication and number of replications per treatment level, statistical nature of sampling (e.g., fruit taken from upper, middle, and lower portions of tree exterior and interior), sample coding (cross-referenced to sample history), etc.).
(xiii) Quality control (control measures/precautions followed to ensure the fidelity of the crop field test).
(xiv) Other. Any and all additional information the applicant considers appropriate and relevant to

provide a complete and thorough description of the growing of the RAC, applications of the pesticide formulated products, and harvesting of samples.

(B) A detailed description of the handling, pre-shipping storage, and shipping procedures for harvested RAC samples. The information provided, which shall be presented on a standardized form, should include (in addition to a description of the test substance and the test commodity):
(i) Sample identification (means of labeling/coding).
(ii) Conditions (temperatures, container types/sizes, sample sizes, form (e.g., whole commodity; chopped), etc.) and duration of storage before shipping.
(iii) Methods of packaging for shipment (container types/sizes, sample sizes, ambient/iced, labeling/coding, etc.).
(iv) Means of transport from the field to the laboratory.
(v) Dates (harvest, pre-shipping storage, shipping, and receipt in the laboratory).
(vi) Quality control (control measures/precautions followed to ensure the integrity of harvested samples during handling, pre-shipping storage, and shipping operations).
(vii) Other: All additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the handling, pre-shipping storage, and shipping procedures for harvested samples.
(C) A detailed description of the conditions and length of storage of harvested RAC samples following their receipt in the laboratory.
(D) A detailed description of the residue analyses used in determining the components of the residue definition in field trial RAC and storage stability samples. If the specified information is provided elsewhere within the overall data submission package, it need not be reiterated here. In that case, a reference to the relevant analytical methodology would be sufficient.
(E) Method recovery validation studies should be run concurrently with the residue analyses of crop field trial samples from each individual field trial in order to provide information on the recovery levels of the test compounds from the test substrates at various fortification levels using the residue analytical methods, and to establish a validated limit of quantification. The following information specific to the method validations, which may be presented on a standardized form, should include:
(i) Experimental design: Identity of test substrates (specific plant parts) and test compounds (parent/specific metabolites). Number and magnitude of fortification levels, number of replicate samples per test compound per fortification level, sample coding, control samples, etc.
(ii) Fortification procedure: Detail the preparation of the test compounds and test substrates and the manner in which the test compounds were introduced to the test substrates.
(iii) Dates: Test sample preparation (maceration/extraction/etc.), test compounds preparation (standard solutions of known concentration), residue analyses.
(iv) Residue results: Raw data, ppm or mg/kg found uncorrected (corrected values may also be reported but the basis of correction should be explained), procedures for calculating percent recoveries, recovery levels (range), and limits of quantitation and detection.
(v) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of analytical methodology validation procedures.

5. Organization of data tables and forms.

(A) Tables of residue assay data for specific plant parts analyzed. Residue levels should be reported uncorrected. Corrected values may also be presented but the procedure needs to be explained with sample calculations.
(B) Tables on residue recovery values.
(C) Graphs, as pertinent (e.g., residue decline).
(D) Forms containing field trial history information.
(E) Forms containing harvesting, shipping, storage information.
(F) Tables of weather data if unusual conditions claimed to result in aberrant residues.
(6) Trial Information
(A) Geographic Location (Trial Specific information – should be provided for all trial locations)

(i) Trial ID No (Trial Specific, unequivocal identification code (e.g., Company Internal Code)
(a) Trial Deviation (List any deviations which may impact the trial results or study conclusions)
(ii) Year (the year in which the first GLP data are collected in trial)
(iii) Country
(iv) Geographic Region (e.g., lowland, coastal, high altitude and mid altitude or stating agroecological zone)
(v) Province/Country (e.g.,Kwale/Kenya)
(vi) County
(vii) GPS Coordinates (if possible)
(viii) Describe the agricultural practice of producing this crop in this region
(ix) Crop Grouping
(x) Crop
(a) Crop Variety (e.g., Apple mango)
(xii) Crop Code
Codes can be obtained from FAO/WHO. 1993. Codex Classification of Foods and Animal Feeds in Codex Alimentarius, 2nd ed., Volume 2. Pesticide Residues, Section 2.Joint FAO/WHO Food Standard Programme. FAO, Rome. Note: the CCPR currently is working on the revision of classification of commodities. The implementer is advised to check which groups have been finalised and enforced By the Committee/Codex Alimentarius Commission
(xiii) Soil Characterization (e.g., sandy loam, sandy clay loam, etc.)
(B) Plot (Information should be provided for all plots)
(i) Plot ID (Unequivocal Plot Identification; e.g., consecutive number). Numerical field or combination
(ii) Control Plot (yes or no)
(iii) Plot Description - Describe plot specific information: e.g., plot size or area, row spacing, plant spacing, plants/area, crop height, seeding rates, number of seeds/area, exaggerated application rate, type of protection in case of a protected crop scenario, in case of a storage protection use give type, size and volume of store, also type and size of package of stored products (e.g., bulk, paper, plastic bag)etc.

(iv) Environmental Conditions
Describe abnormal weather conditions, if applicable, soil properties, any other environmental effect that might have had an impact on the results observed in this study; for storage protection or glasshouse application give room/glasshouse temperatures/humidities
(v) Describe crop maintenance on the plot, e.g., all procedures used in planting, maintenance, and harvest, including irrigation, application of fertilizers and other maintenance chemicals
(vi) Date of planting/sowing (for permanent crops year of planting is sufficient); in case of seed treatment give date of seed treatment and date of sowing, beginning and end of flowering, beginning and end of commercial harvest
(vii) Application
(a) Application No (e.g. 1, 2, ...)
Consecutive numbers of the applications. i.e., 1st application = 1, 2nd application = 2. In the case of seed treatment, the sowing of the seeds is the first application.
(b) Growth stage at application, height of plants at application in case of “tall crops” (e.g., vines) and both height and crown height of plants in case of tree crops
(c) Date of Application (indicate format e.g.:dd/mm/yyyy)
In case of seed treatment, state the date of sowing, in case of post-harvest dip, state the date of dip. In case of storage treatment give beginning and end of treatment together with beginning and end of ventilation
(d) Method of Application
(e) Seeding Rate (Used in conjunction with seed treatment. Using this, combined with no. seeds/ Unit, one can determine TGW (Thousand Grain Weight), etc.)
- Number of seeds/unit (no. seeds/kg)
(f) Test Item (Pesticide(s) tested in this study)
- Description of Test Item; information regarding tested Pesticide Product, End-Use Product,

formulation, treated/dressed seed, etc. used in the test item applied to the trial plot, crop, and/or the harvested commodity
- Test Item Formulation Type
- Test Item Trade Name
- Test Item Active Ingredient Code/unique identifier (e.g., Company Internal Code)
- Test Item Active ingredient name(s)
- Test Item Nominal active ingredient content (e.g., grams a.i./liter)
- Test Item actual amount active ingredient applied (e.g., grams a.i./ha); for storage protection uses: application rate (e.g., kg a.i./m^3), duration of treatment (h),duration of ventilation
(h) - Test Item actual amount active ingredient/seed if seed treatment (e.g., g a.i./100 kg seed)
- Test Item cumulative amount applied
- Adjuvant Added, Adjuvant Type, Adjuvant Name, Adjuvant amount in Spray Volume(%)
- Amount of water used in spray application(actual)
(viii) Sampling
(a) Sampling No.
Consecutive numbering of sampling events
(b) Sample ID – Unique sample identification code
(c) Sampling Timing: Provide any information regarding the timing of the sampling, e.g., relation to application events, days after last application, etc.
PHI – pre-harvest interval
DALA - Days after last application
Days Before Harvest
(d) Growth Stage at sampling
(e) Date of Sampling(dd/mm/yyyy)
(f) Sampling Information:
Description of sampling method, special remarks (e.g., cabbage was harvested according to agricultural practice, 1st set of outer leaves were removed), sample handling (e.g., samples were frozen within 24 hours)
(g) Sampled Material/Commodity (Field RAC Sample)
- Analysis Sample (Description of Analysis sample)
Field Sample should be separated into several analysis samples, e.g., whole mango may be separated into a peel sample and a flesh sample for analysis (in that case also give weights of peel and pulp).
- Analysis Sample ID
- Analysis Sample Description
- Analyte measured
- Analyte ID.
- Extraction Date(dd/mm/yyyy)
- Actual date of extraction
- Analysis Date(dd/mm/yyyy)
- Actual date of analysis
- Method ID
- Recovery
- Residue Level (e.g., mg/kg). The value should not be corrected for recovery and rely on the measured level of the analyte. Additionally give calculated residue if appropriate (e.g., residue xy calculated/expressed as yz or acid calculated/expressed as carboxylic ester, sum of a.i. and metabolites x and y, expressed as a.i.…)
- Number of analytical replicates

(7) Analytical Methodology: Describe basic principle of analytical method(s) and their LOQ(s), Method ID or cross-reference to relevant method template
(A) Analytical Method Information
(B) Fortification Level
(C) Recovery(%)

(8) References

List of references used should also be included in the Report.

14.0 DATA SHARING AND USE OFDATA

Data sharing is a useful tool in providing transparency in the registration of pesticides across the EAC Partner States. Data sharing is also a critical step in the harmonization of registration regimes across the EAC Partner States. Harmonization would enable countries to work together more closely, share resources, lower the costs of pesticide registration, and coordinate implementation of international conventions. The ultimate goal of pesticide regulatory harmonization is reducing duplication of efforts and streamlining review processes and reduce the burden of member economies in carrying out independent field trials and data generation in support of the establishment of pesticide MRLs.

To ensure sustainability, the EAC Partner States shall establish a central data repository that is accessible to all Partner States responsible authorities. This 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. EAC Partner States from the responsible authorities of pesticides shall meet to periodically to share information on new needs for data sharing.

15.0 ACCEPTANCE OF DATA AND RECOGNITION OF INSTITUTIONS:

Entities undertaking supervised residue data generation should be accredited by the responsible authority using the following criterion:

i) For pesticide residue laboratories: They should be accredited by a 3rd party accreditation body such as provided by the ISO/IEC17025:2005.
ii) For the crop field study: The field part should be close to Good Laboratory Practice.

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