



agriculture, forestry & fisheries

Department:
Agriculture, forestry & fisheries
REPUBLIC OF SOUTH AFRICA

GUIDELINES ON RESIDUE STUDY REQUIREMENTS FOR REGISTRATION OF AGRICULTURAL REMEDIES AND SETTING OF MAXIMUM RESIDUE LIMITS (MRLs) IN SOUTH AFRICA

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Republic of South Africa

Tel. (27 12) 319 7000 / Fax (**27 12) 319 7179**

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DEFINITION OF TERMS

For the purpose of this document the following terms should be considered to mean -

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| Active ingredient(s) | - The component(s) of a formulation responsible for the direct or indirect biological activity against pests or diseases, or in regulating metabolism/growth etc. A single active ingredient may be comprised of one or more chemicals or biological entities which may differ in relative activity. A formulation may contain one or more active ingredients (FAO specifications). |
| Adjuvant(s) | - Any substance which, when it is added to an agricultural remedy which is prepared for application in accordance with the approved instructions for use of that agricultural remedy, will enhance the efficacy of such agricultural remedy. Examples of adjuvants are wetting agents, spreaders, stickers, compatibility agents, buffering agents, de-foamers, surfactants, oils |
| Critical GAP (cGAP) | - The GAP selected to represent the worst case scenario that will produce the highest possible field residues on crop commodities. It usually includes the maximum use rate, maximum number of applications and the shortest re-treatment and post-harvest intervals. |
| Crop Group | - A group of crops in which the expected residues on the commodities are likely to be similar (from treatment under similar GAP) and where Group or Subgroup MRLs can be considered. Crop grouping is based on similarities in appearance, harvestable commodity, edible portions and or growth habit etc. |
| Edible commodity | - Any commodity that is or may be consumed by man and/or domestic animals. |
| Generic product | - Is a copy of a product already registered in terms of active ingredient content, formulation type and claims made on label. |
| Good Agricultural Practice (GAP) | - The registered (authorized) safe use of an agricultural remedy under actual conditions necessary for the effective and reliable pest/disease/weed/growth control. |
| Good Laboratory Practice (GLP) | - The formalized process and conditions under which laboratory studies on pesticides are planned, performed, monitored, recorded, reported and audited and are designed to assure reliability and integrity of the data generated. |
| Limit of quantification (LOQ) | - The lowest concentration of a pesticide residue in a defined matrix where positive identification and quantification can be achieved using a specified method. |
| Maximum Residue Limit (MRL) | - The maximum permitted concentration of a pesticide resulting from its use according to good agricultural practice directly or indirectly for the production and/or protection of the commodity for |

	which the limit is recommended.
Method of application	- The means by which an agricultural remedy is applied e.g. ground application by means of low volume, high volume or ultra-low volume, aerial application by means of low volume or ultra-low volume, soil drench, etc.
Non-detectable (ND)	- The level, below which it will not be possible for reliable detection and quantification of a specific pesticide, in a specific matrix, applying a specific analytical procedure.
OECD	- Organization for Economic Co-operation and Development
Official withholding period	- The minimum permissible time allowed between the last application of a pesticide and harvesting of an edible commodity for human consumption or grazing by livestock
Pre-harvest Interval (PHI)	- The interval between the last application of a pesticide and harvest.
Post-Harvest Treatment	- A pesticide application to the harvested crop/commodity which may occur before or during storage.
Product	- An Agricultural Remedy consisting of <i>inter alia</i> active ingredient(s) and formulants / inert ingredients which may or may not be registered under Act No. 36 of 1947.
Reference Product	- A registered product whose label is referred to when the registration of an equivalent generic product or a new formulation containing the same active ingredient is proposed.
Source	- The manufacturer of the active ingredient and/or formulation (not agent).
Terminal residue study	- The determination of residues in a commodity sampled at the commencement of harvesting.
Type of formulation (formulation type)	- Wettable powder, emulsifiable concentrate, suspension concentrate, water soluble liquid or powder, granule, dusting powder, etc.

1. INTRODUCTION

The purpose of this document is to outline requirements for agricultural remedy residue trials. As part of risk/benefit assessment in the registration process of agricultural remedies, residue studies/data are required to ensure that food safety is not compromised. This is achieved mainly through quantifying the expected range of residues in crops after their treatment with registered pesticides as well as through setting of Maximum Residue Limits (MRLs) on commodities. Furthermore, to ensure compliance with international trade requirements regarding the acceptable levels of residues on food commodities, the FAO and OECD residue requirements were used in compiling the residue requirements contained in this guidelines document.

This document supersedes the Agricultural Remedies Residue Trial Data Requirements Document of 1998. This document must be read in conjunction with all other relevant guidelines related to pesticide registration requirements under Act No. 36 of 1947. This document is effective as from 1st April 2016.

2. RESIDUE TRIAL REQUIREMENTS FOR REGISTRATION OF AGRICULTURAL REMEDIES

2.1 TRIAL DESIGN

Trials done for residue studies should be designed to yield reliable residue data. These can either be stand-alone residue trials, or combined with efficacy/ phytotoxicity trials. If efficacy/ phytotoxicity trials are used for residue sampling, the appropriate treatment programme must be included in these trials and the plot size must be sufficient to allow for this. The trials must reflect the proposed use with respect to the rate and mode of application, number and timing of applications, and formulations proposed. It is a known fact that in practical field conditions various factors influence the dissipation of residues. To cater for all these factors individually in trials is impractical. The alternative is to design trials such that all these factors are catered for collectively. This can best be done by increasing the number of trial sites, varying the location of the trial sites and or conducting trials over two seasons if a particular crop is mainly grown commercially in a particular geographic location e.g. apples grown in the Western Cape. The presence of the target organism at the residue trial site is immaterial.

2.1.1 Selection of trial sites

Trial sites should be selected carefully to be located in major areas of cultivation or production of the crop and should be sited to cover a range of representative conditions in which the agricultural remedies will be used. The trial localities chosen should represent a range of conditions including different bioclimatic regions, climate, cultivars, agricultural practices and soil characteristics.

2.1.2 Number of sites and trials

The number of trials and number of studies in the residue programme depends on the range of conditions to be covered, the uniformity of the crop and the variation in agricultural practices. It is impossible, to indicate precisely the number of trials that need to be conducted to establish an MRL and withholding period. However, as a general rule, a minimum of five trials (for major crops) or a minimum of three trials (for minor crops) are required from three different bio-climatic areas per crop at the highest recommended rate. In cases where production of a particular crop occurs only in a single bio-climatic area, trial sites should be situated at least 100 km apart. If this is not possible, trials should be done over a minimum of two seasons.

2.1.3 Plot size, layout and replication

Plot size may vary from crop to crop. However, plots should be large enough to allow application of the test substance in a manner which reflects or simulates routine use and such that sufficient representative sample(s) can be obtained without bias, generally at least 10 m² for row crops and typically 4 trees or 8 vines for orchard and vineyard crops. Plots should also be large enough to avoid contamination during mechanical sampling or harvesting if applicable. An untreated plot similar in growth and condition and in the immediate vicinity of the treated plots should be included at each site in order to provide the analyst with a suitable control sample of the particular crop. 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.

Replication within the site is not required as this is better covered by replication between sites. Post-harvest treatments on stored products such as potatoes, grains, fruits and seeds (etc) are often carried out in a number of storage locations with variable conditions in regard to temperature, humidity, aeration, etc. Information should be available on the use practice and all the conditions under which the treated commodities are kept.

2.1.4 Number of seasons

Residue data from only one season are considered sufficient provided that crop field trials are located in a wide range of 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 100 km apart. If this is not possible, trials should be done over a minimum of two seasons.

2.1.5 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 crop is commonly grown, then more than one variety should be used in the trials.

2.1.6 Crop Maintenance and Agricultural Practices

Trials should reflect the main types of crop maintenance and agricultural practice, especially those which can significantly impact residues (e.g., bagged and unbagged bananas, furrow and overhead irrigation, pruning of grape leaves).

2.1.7 Soil Type

Soil type (e.g., sand, loam, sandy loam) should be identified and reported for all crop field trial sites. In trials where the product is applied directly to the soil, these should be conducted at field sites with different soil types and a physical soil analysis report from an ISO17025 or OECD GLP accredited or AgriLasa¹ affiliated laboratory should be submitted from each site. Such reports should not be from more than five years before or after the commencement dates of the trials.

2.1.8 Timing of applications

Timing of spray application is governed by requirements to control pest and plant growth stage, e.g., pre-bloom or 50% head emergence, and/or as number of days prior to harvest. Any time that a specific PHI is indicated on the label, e.g., “Do not apply this product less than 7 days prior to harvest.”, that specific PHI must be used in the crop field trials as a component of the cGAP, whereas the growth stage at application is of minor importance. Conversely, there are cases where the growth stage is a critical component of the GAP, e.g., pre-emergence, at planting, pre-bloom, flag leaf, while the PHI is of secondary importance. In these cases it is important to include fast maturing varieties of the crop in order to determine appropriate PHI's that would allow safe harvesting of an early variety. Basically in all trials both the growth stage at application (preferably as BBCH code) and PHI should be recorded.

2.1.9 Method of application

The method of application used in trials should reflect the recommendations and directions on the product label. 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. Application equipment must be properly calibrated. To ensure correct usage rates and uniformity of application the operation should be carried out under the supervision of qualified personnel. Care should be taken to avoid contamination of neighbouring plots.

Because of differences observed in residue levels resulting from ultra-low volume (ULV) and aerial applications, these too may need to be represented unless the proposed label specifically prohibits such application methods. If these methods are to be recommended (on the label), then at least one successful trial with results consistent with the ground application must be done with ultra-low volume applicators/aerial application.

2.1.10 Dosage Rates and Number of applications

Trials must include the highest recommended rate (refer to Par. 2.1.2). The number of applications and the intervals between applications should reflect the closest use to harvest and the maximum use of the product. Generally, it is the final application that has the greatest influence on the magnitude of residues at harvest. The growth stages at each application spray should be specified. If multiple applications of a product are recommended, the maximum number and the minimum interval between treatments should be studied.

In cases where the same active ingredient may be applied at different stages to the crop within the same growing season (e.g. seed treatment followed by foliar application), trials reflecting the total treatment regimen are required.

2.1.11 Additional crop maintenance measures

Ideally, 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 pesticides that will not interfere with the analysis of the residue of the compound tested may be used. All the pesticides used should be noted and the advice of a qualified analyst should be obtained. It is important that the control and experimental plot receive the same treatments, other than the product under investigation.

2.2 TEST SUBSTANCE

2.2.1 Formulation

The actual formulation of the pesticide to be marketed must be used in the trials. Applicants seeking to register more than one formulation type of the same active constituent may need to generate residue data for the additional formulation types. The number of trials required to register additional formulations of a chemical will depend on the use pattern and the relative risks involved. The factors to consider include mode of application, timing of application and crop growth stage, and formulation type. In cases of a different formulation type where the agricultural practice and loading of a.i. are the same and the PHI is >7 days, residue studies will not be required (refer to Par. 2.5).

2.2.2 Tank Mixes

When residue data have already been generated for a particular active ingredient, there are no additional data requirements for tank mixes provided the cGAP of all the active ingredients has not changed (the active loading has not increased, the PHI has not been shortened and the number of applications has not increased). However if the PHI is 7 days or less for any active ingredient(s) in the tank mixture, then residue data will be required for that/those active ingredient(s).

2.2.3 Adjuvants

Adjuvants such as wetting agents, spreaders, stickers, surfactants and crop oil concentrates may result in better deposition, penetration, or persistence of pesticide residues in or on the plant. Therefore, when testing products with a label allowance for the use of an adjuvant, crop field trials must include the recommended adjuvant applied according to the label recommended rate. This information must be recorded in the laboratory residue test report. In such cases it will not be necessary to determine residues both with and without the addition of the adjuvant.

If an adjuvant is to be registered for use with already registered pesticide(s), trials will be needed to demonstrate compliance with Maximum Residue Limits of the pesticide(s) concerned. These trials should be done with the maximum recommended rates of both the adjuvant and the pesticide(s).

For a new adjuvant being registered for the first time for use with already registered pesticide(s), the following trials will be needed:

For each chemical group with which the use of the adjuvant is proposed (e.g., triazoles, pyrethroids, sulfonylureas, etc.) trials should be done with one representative pesticide in one crop from each crop group (Table 3) in which its use is proposed. This requirement does not apply to pesticide/crop combinations where the withholding period is >7 days.

If a generic adjuvant is to be registered for use with already registered pesticide(s), the following trials will be needed:

For each chemical group with which the use of the adjuvant is proposed (e.g., triazoles, pyrethroids, sulfonylureas, etc.) trials should be done with one representative pesticide in one crop from each of one third of the crop groups (Table 3) in which its use is proposed. This requirement does not apply to pesticide/crop combinations where the withholding period is >7 days.

2.3 COLLECTION AND HANDLING OF RESIDUE SAMPLES

2.3.1 Field sampling

Reliable results can only be obtained from samples taken according to the objectives of the study. Utmost attention should be given to the selection of sampling methods, handling (packing, labelling, shipping and storage) of samples. The study should be designed to assure the integrity of the whole chain of activities. The sampling method and the selection of the objects of sampling depend on the purpose of the study.

The best information about the residue behaviour of the pesticide under study would be obtained by the analysis of the entire yield of a plot. Since this is not practicable, representative samples have to be taken. Careful attention to the details of sampling is essential if worthwhile samples are to be obtained. Valid analytical results can only be obtained if the samples have been properly taken, despatched and stored before analysis. In selecting sampling points and the sampling methods, all factors that control the residue distribution over the entire experimental plot must be considered. The best approach for any given plot can only be determined by a sufficiently trained person who is capable of recognising the importance and usefulness of the residue data sought, and who can interpret the results. The samples must be representative to enable the analytical result to be applied to the entire experimental unit. The greater the number of plants sampled in a field plot, the more representative the sample will be. However, economics and the practical problems involved in handling large samples affect the magnitude of the sampling programme. The sample size suggested is the minimum that experience has shown is needed to give a representative, valid sample. The sizes are not usually dictated by the analytical method, which can often determine minute amounts of pesticides in small sample amounts.

The detailed sampling method for trials is described in appendix A

2.3.2 Storage and shipping conditions

Samples should be frozen as soon as possible following collection to avoid sample deterioration and decomposition of the residue(s). If prolonged storage is unavoidable, it is usually preferable to store the samples at a low temperature, preferably at or below -20°C . 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 however acceptable to ship samples overnight with coolant such as "blue ice" immediately after collection provided the samples are frozen upon arrival at the laboratory or processing facility as appropriate for each matrix.

Proper labelling of samples is of utmost importance. Sample labels must indicate company name, crop, variety, trial site, active ingredient, pesticide formulation, dosage rate, date of sampling, time of sampling and name of sampler.

2.4 RESIDUE DECLINE STUDIES

Residue decline studies are needed to demonstrate how the residue levels change with time. A full set of decline studies is required under the following conditions:

- New end use(s)/claim(s)/ agricultural practices (GAP) of an agricultural remedy; or active ingredient which is registered for the first time on a crop.
- New nanotechnology based formulations, regardless of data already available for other formulations of the same active ingredient

- Controlled release formulations e.g. microencapsulated and slow release granular or other slow release formulations regardless of data already available for other formulations of the same active ingredient.
- Proposal to shorten the Official withholding period of a product.

2.5 TERMINAL RESIDUE STUDIES

2.5.1 Terminal residue studies are sufficient to obtain registration approval under the following conditions:

- Addition of a diluents(s) or carrier other than water; change in content of adjuvants/fertilizers/botanical extracts i.e. wetting agents and surfactants etc. that may lead to better penetration of the active substance;
- Changes in parameters such as (cGAP) e.g. increase in concentration of the active ingredient/s, application rates, application methods, timing of applications and frequency, area of application (indoor versus outdoor); The data requirements guidelines provide such explanations.
- Postharvest treatment applications – (This must be done at zero (0) days only).

2.5.2 In the following cases when the Official withholding period is 7 days or less and when the application rate of the active ingredient is the same as for an already registered formulation, terminal residue data will be required.

- A new formulation type is introduced for an already registered active ingredient, on a particular crop, where the dosage rate of the active ingredient remains the same.
- A formulation type similar to that already registered (Act No. 36 of 1947) on the particular commodity whether originating from a source other than those already acknowledged or not, but which is to be applied using a different method of application which has not yet been registered for use on that particular commodity.
- A formulation type similar to that already registered (Act No. 36 of 1947) on a particular commodity but originating from a source other than that of the original formulator or other formulators holding registration (commonly referred to as Generic Registration).
- Changes are made to content of formulation components i.e. wetting agents and surfactants etc. that may lead to better penetration of the active ingredient(s).

For each of the situations in Section 2.5.2 above, the number of studies required is determined as follows: Referring to the crops on the label of the registered reference product, residue data should be generated on one third of those crops intended for inclusion on the label of the formulation being registered.

2.6 ANALYSIS OF RESIDUES

Residue analysis is the process of extracting and detecting the residue content present in food and environmental commodities.

The chemical analysis of all residue samples must be done by an OECD GLP accredited or ISO17025 compliant laboratory.

2.6.1 Analytical methods

Validated analytical methods capable of determining many or specific residues in a single analysis should be used. The method(s) used for residue determination should be described in the residue test report. Recoveries should be at the spiking levels appropriate to the proposed Limit of Quantification (LOQ) per the analyte. Recovery determinations should lie between 70% and 120% of the known quantity of the pesticide and its metabolites spiked into the matrix blanks and should not exceed $\pm 20\%$ standard deviation from sample to sample. If 70% recovery determination is not achieved, a different validated analytical method must be used, or a convincing explanation given specifying at which step the pesticide active ingredient loss occurred. Where less than 70% recovery determinations have been achieved, particularly for new molecules, such an active ingredient and its metabolites must not be acutely toxic.

Test Methods must be reported in accordance with the requirements of the specific OECD test guidelines. The main purpose of the OECD Pesticide Residue Analytical Methods Guidance Documents – EHS publication, series on Testing and Assessment, No 72; series on pesticide, No. 39, 2007 is to provide guidance on the residue analytical methods; it addresses the quality criteria and method validation criteria including independent laboratory validation requirements.

2.6.2 Storage stability tests for analytical samples

In cases where the storage of residue samples is longer than 12 months between sampling and analysis of residues, storage stability tests must be done following the guidelines in OECD 506: Stability of Pesticide Residues in Stored Commodities. Alternatively, information on the storage stability of pesticide residues in representative commodities which is available in the public domain (such as JMPR reports) is also acceptable.

2.7 RESIDUE METABOLISM STUDIES

Metabolism studies are required for new active ingredients to be registered for the first time in South Africa. The purpose of conducting metabolism studies is to determine the metabolic fate of the active ingredient. Many agricultural compounds undergo change during and after application to plants, soil, water and livestock. The composition of the terminal residue must therefore be determined before the analytical methodology can be developed and residues can be quantified. These studies need not have been conducted in South Africa.

2.7.1 Plant metabolism

Plant metabolism studies should:

- Provide information on the approximate level of total residues.
- Identify the major components of the total terminal residue.
- Discuss the presence of metabolites in the different plant parts (surface, leaves, stems etc).
- Indicate the route of distribution of any residue and its mobility (uptake from soil, absorption by plants or surface residue).
- Transgenic and non-transgenic crops may metabolise residues differently. Full and detailed information will be required for a transgenic crop with metabolism differences from the non-transgenic crop.

- Study conduct must be in accordance with OECD guideline 501 http://www.oecd-ilibrary.org/environment/test-no-501-metabolism-in-crops_9789264061835-en.

2.7.2 Animal metabolism (For new molecules)

- Animal metabolism studies are required where there is any potential for livestock to be exposed to residues.
- The information must include documentation on the identity of the metabolites and the quantities present in different animal tissues (fat, muscle, kidneys etc) and excreta.
- For milk, the fat fraction should be separated from the aqueous portion by physical means and the total recovered residue in each fraction quantified.
- Study conduct must be in accordance with OECD guideline 503. http://www.oecd-ilibrary.org/environment/test-no-503-metabolism-in-livestock_9789264061873-en

2.7.3 Soil metabolism and mobility

- Document the identity of the metabolites and the quantities present in different soil types (for example, sandy loam, clay).
- Soil mobility and half lives (DT50) of metabolites must be quantified.

2.7.4 Metabolism Study Residues Definition

Outcomes of metabolism studies are utilised to generate appropriate residue definitions for enforcement and risk assessment as they provide information of sufficient quality to allow generation of a concise residue definition for:

- Enforcement purposes in plant commodities (and, if necessary, animal tissues);
- Assessing the dietary burden of residues (this will require data on the toxicological properties of any significant metabolites, degradation products or impurities).

2.8 CROP GROUPS AND EXTRAPOLATION OF MRLs (REFER TO TABLE 3)

South Africa uses the Codex classifications for foods and feeds in establishing MRLs and approving use patterns.

Some crops can be grouped together based on their biological qualities e.g. citrus. When the use patterns are similar it is possible to extrapolate MRLs to other crops within the group (Table 3). Codex Crop Grouping has been used to group the commonly grown crops in South Africa and their possible extrapolation to other crops within the group. In order to extrapolate MRLs from one crop to another within the same group the following must be met:-

- The representative commodity must be major in terms of production and consumption and must be most likely to contain the highest residues
- All crops within the crop group must have similar pesticide requirements and use pattern must be similar.
- All the crops in a group/subgroup should be grown in South Africa
- A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to related commodities within a group or subgroup.

- The applicant has the right to choose which crops should be listed on the label based on the crop grouping concept.

The application of the above-mentioned principles in the selection of representative commodities is based on the assumption that all of the commodities in the same group are produced following a similar use pattern or good agricultural practice.

3 RESIDUE TRIAL REQUIREMENTS FOR SETTING OF MRLs

This section outlines the minimum data required to support a proposal for a maximum residue limit (MRL) for registration. The report on the study must include sufficient data and information detailing how the study was conducted and how the results were derived. This will aid in decision making on whether the study was scientifically valid.

The report should state the purpose of the study and describe the methods and materials used and the results, in a suitable format. Discussion of the results should be given to permit the evaluator (s) to make a recommendation on the MRL and proposed withholding period relative to the label use pattern.

The components of the report should include, but not necessarily be limited to, the following:

3.1 Introduction

Objectives of the trial

3.2. Materials and Methods

3.2.1. Site Details

- Location of trial site(s) — for example Province, City, GPS Coordinates
- Description of the climatic geographic location
- Test system details—for example, crop/variety, animal/breed, planting date, summer/winter, growth stage, age, lactation period, plot dimensions, covered or open pens, number of replicates, treatment, number of controls, cultivation, feed regime, other treatments applied.
- Plot description - 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
- Describe the agricultural practice of producing this crop in this region
- Soil type if the test material was applied directly to the soil, includes data on soil classification (for example, soil type, pH and organic matter).

3.2.2. Application details

- Test substance(s)—including batch number, content of active ingredient in formulation, formulation type, assay and/or stability data as applicable.
- Adjuvant (s) applied if any
- Other agricultural remedies applied for crop maintenance
- Dosage rates

- Volume applied—for example, L/ha, litres of spray.
- Number and Interval of applications - Timing between treatments—for example, days, weeks, months.
- Date(s) of application(s).
- Method of Application
- Equipment used—for example, mist blower, knapsack or boom sprayer; animals—shower, jetting, dipping

3.2.3. Sampling

- Part of crop/animal sampled.
- Soil depth of sampling if applicable.
- Sample weight and number of units per replicate if applicable.
- Date(s) of sampling—the sampling regime is dependent on the persistency of the pesticide residues and must include the time of any proposed withholding period. sampling date(s) may be expressed as follows: T - 1 day
 - T + hours, after application.
 - T + 24 hours
 - T + days, etc
- Method of sampling—samples should be taken first from the control group then from the lowest to the highest application. A specific description should be given of how the sample was taken and what was done to ensure the sample was representative.
- Growth stage/animal weight at sampling (including normal harvest date if applicable).
- Method of storage and shipment of samples from field site to laboratory.
- Storage conditions from time of collection/shipment/analysis.

3.2.4. Preparation of sample

- Details should be provided on how the samples were prepared for analysis, such as subsampling, chopping, mixing and grinding.
- Details should be provided on any pre-treatment carried out such as removal of fat, washing, peeling, soil removal.
- A homogenised sample is essential if a meaningful result is to be obtained.

3.2.5. Analysis Details

A summary of the method (uniquely numbered) should be given in the report. The entire method must be provided either as an appendix to the report or with the submission.

Analytical Methodology: Describe basic principle of analytical method(s) and their LOQ(s), Method ID or cross-reference to relevant method template

- Address of the facility carrying out the analysis
- Accreditation status of the laboratory
- Analytical Method Information
- Fortification Level
- Recovery (%)
- The period in which the analysis was carried out

3.2.6 Storage Stability

Describe longest storage interval between sampling in the field and analysis in the laboratory, and cross-reference to storage stability study, as applicable.

3.2.7 Other information

Weather details should be provided at or as close to the site(s) as possible. Include rainfall/irrigation and air temperature on day of application and daily for one week afterwards. Thereafter, data can be averaged on a weekly or monthly basis depending on the length of the trial.

Report on weather conditions during the post-application / pre-sampling period. Specify total amount of rain and general weather pattern. Mention dates in case of unusual conditions, e.g. heat/cold, wind, hail, etc. or where more than 15 mm of rain has fallen within 24 hours of an application. Indicate which application was thus affected.

3.2.8 Discussion and Conclusions

The discussion should include any aspects of the report that require explanation, including any unexpected results. Conclusions should be made to permit a recommendation to be made on the MRL and proposed withholding period relative to the label use pattern. Where applicable, climatic effects should be discussed.

4. REFERENCES

1. Australian Residue guideline No. 24, December 2000, *Residue trials to obtain Permanent MRLs for crops*.
2. Australian Pesticides and Veterinary Medicines Authority: *Guidelines for the registration of agricultural adjuvant products (March 2009)*.
3. Department of Agriculture, South Africa, August 1998. *Agricultural remedies Residue trial data requirements document*
4. European Commission, SANCO 7525/VI/95 – 9 March 2011. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs.
www.ec.europa.eu/food/plant/protection/resources/app-d.pdf.
5. Food and Agricultural Organization (FAO) Evaluation of pesticide residues for estimation of maximum residue levels and calculation of dietary intake, Training Manual, 2011.
6. Food and Agricultural Organization (FAO) Plant Production And Protection Paper 197, Second Edition, 2009. *Submission and Evaluation of Pesticide Residue Data for The Estimation of Maximum Residue Levels in Food and Feed*
7. Food and Agricultural Organization (FAO), 1990, *Guidelines on Producing Pesticide Residues Data from Supervised Trials*
www.fao.org/AG/aGP/AGPP/Pesticide/code/download/pesticide/pdf
8. OECD, Guidelines for the testing of chemicals, July 2013.

9.OECD, Pesticide Residue Analytical Methods Guidance Documents – EHS publication, series on Testing and Assessment, No 72; series on pesticide, No. 39, 2007

10. OECD 506: *Stability of Pesticide Residues in Stored Commodities*

http://www.oecd-ilibrary.org/environment/test-no-506-stability-of-pesticide-residues-in-stored-commodities_9789264061927-en

11.Organisation for Economic Co-operation and Development, OECD 509 guideline for testing of chemicals (Crop Field Trials), September 2009.

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)17&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)17&doclanguage=en)

12.United States Environmental Protection Agency (US EPA), November 2008. *Crop Field trial Test Guideline, Version 5.0.6, November 2008*;

[Http://febbs.access.gpo.gov/library/epa_860/860-1500pdf](http://febbs.access.gpo.gov/library/epa_860/860-1500pdf)

APPENDIX A: METHOD OF SAMPLING

1. General considerations

Generally, the selection of the portions that make up the field sample should be made depending on the circumstances:

- randomly, e.g., by the use of random numbers
- systematically, .e.g., in the case of field crops on a diagonal (“X” or an “S” course)
- stratified random sampling from predetermined sampling-positions, e.g., in the case of tree fruits inner part and outer part of the canopy, i.e., fruits , directly exposed to spray and those covered by foliage, proportionally to the abundance of fruits in each stratum; within one stratum each fruit has an equal chance of being taken.

Points to be considered are:

- Avoid taking samples at the beginning or at the extreme ends of plots (start and finish of spraying).
- Take and bag the required weight or number of samples in the field and do not subsample until the samples are in a clean field laboratory or in the analytical laboratory.
- Sample all parts of the crop that can be consumed by humans or livestock.
- Where appropriate, consider commercial harvesting practice which reflects normal Good Agricultural Practice.
- Sampling should preferably be undertaken in the early hours of the morning when dew or rain has dried away and before the crop has been warmed by the sun.

Replication

Under normal circumstances one sample per plot is sufficient. Additional samples may be taken and held for security reasons, i.e., to guard against the possibility that a sample is lost or destroyed during transport, to ensure the investment in the trial is not wasted.

Sample handling

- Sample integrity should be maintained throughout the procedure.
- Take care not to remove surface residues during handling, packing or preparation.
- Avoid any damage to or deterioration of the sample which might affect residue levels.
- 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.
- Sample control plots before treated plots (see also this appendix sections “Contamination” and “Control samples”).

2. Contamination

It is vital 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:

- 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.
- Avoid contamination of the sample by hands and clothes which may have been in contact with pesticides.

- Do not allow the samples to come into contact with containers or equipment (including vehicles) that have been used for transporting or storing pesticides.
- Avoid sampling at the plot borders because the residue deposit may not be representative.
- Take special care to avoid contamination when commercial mechanical harvesting practices are used
- Avoid cross-contamination of crop and soil samples.
- Sampling should proceed from the control to the lowest treatment and so on to the highest treatment.

3. Sampling in residue decline studies

Samples to establish the residue decline should be taken as soon as the spray has dried (approximately two hours) and at regular intervals thereafter. The choice of sampling intervals will depend on the persistence of the chemical and the anticipated period between treatment and harvest or grazing. As guideline, samples should be collected at T + 0 days, T + 3 days, T + 7 days; T + 0 days, T + 7 days, T + 14 days, T + 28 days, T + 56 days etc. as may be necessary. In situations where it is expected that no residue will be present at harvest, samples should be taken at intervals up to the time the residue is expected to reach the non-detectable level. If multiple applications are recommended, a sample taken before the final application may be of value in determining the rate of degradation or decline between sprays. Sampling on at least four occasions, up to and including harvest, is recommended and it is important that the plot size is large enough to allow sampling at each interval. The proposed withholding period should be one of the sampling points.

DETAILED SAMPLING PROCEDURE

Table 2 shows the commodity to be analysed and sampling procedure outlining the quantity of sample to be taken, the edible portion of the commodity for particular crop groups and the portion of the commodity to which the MRL applies.

Fruits and tree nuts

- Circle each tree or bush and select fruit from all segments of the tree or plant, high and low, exposed and protected by foliage. For small fruits grown in a row, select fruit from both sides, but not within 1 metre of the end of the row.
- Select the quantity of the fruit according to its density on the tree or plant, i.e., take more from the heavily-laden parts.
- Take both large and small fruits where appropriate, but not so small or damaged that they could not be sold (except when taking immature samples for a residue decline study).

Vegetables

Bulb vegetables, root vegetables, tuber vegetables:

- Take samples from all over the plot, excluding 1 metre at the edges of the plot and the ends of the rows.
- To provide a representative sample of the raw commodity, adhering soil may have to be removed. This may be done by brushing and, if necessary, gentle rinsing with cold running water.

- Trim off tops according to local agricultural practice. Details of any trimming should be recorded. Where the tops are not used as animal feed (carrots, potatoes) they should be discarded; otherwise, e.g., turnips, beets, they should be bagged separately.

Brassica vegetables, leafy vegetables, stalk and stem vegetables, legume vegetables and fruiting vegetables:

- Take the sample from all parts of the plot, leaving 1 metre at the edges and ends of rows. The number of sampling points depends on the sample size of the crop (see below).
- Sample items of crops such as peas or beans protected from the spray by foliage and also from parts exposed to the spray.
- To provide a representative sample of the raw commodity, adhering soil may have to be removed. This may be done by brushing and, if necessary, gentle rinsing with cold running water.
- Do not trim except for the removal of obviously decomposed or withered leaves.
- Details of any trimming should be recorded.

Cereals:

- If the plot is small, cut the whole yield.
- If the plot is large but mechanical harvesting is not carried out, cut not less than twelve short lengths of row chosen from all over the plot. Cut stalks 15 cm above the ground and remove the grain from the straw.
- Care should be taken to avoid contamination when mechanical methods are used to separate the parts of the crop. The operation is best carried out in the laboratory.
- If the plots are harvested mechanically, take not less than twelve grab samples of grain and straw from the harvester at uniform intervals over the plot.
- Do not sample within 1 metre of the edges of the plot.

Grasses, forage and animal feed:

- Cut with shears at normal harvest height (usually 5 cm above the ground) the vegetation from not less than twelve areas uniformly spaced over the entire plot, leaving 1 metre at the edges of the plot.
- Record height of cutting and avoid soil contamination.
- Crops which are harvested mechanically can be sampled from the harvester as it proceeds through the crop.

Sugar cane

Select whole canes from 12 areas of the plot and take short, e.g., 20 cm, sections from all parts of the length of the canes. Care is necessary owing to the rapid changes which normally occur in cane juices. If required, 1 litre samples of juice should be taken and frozen immediately and then shipped in cans.

Seeds

Use essentially the same technique as for cereals, taking samples of mature seed from at least twelve parts of the plot. Where the sample is harvested by hand, seed should normally be sent to

the laboratory in the pod. Where mechanical harvesting is used, only the seed should be supplied.

Cotton seed

Pick the cotton at the normal stage of harvesting.

Peanuts

Collect at the normal stage of harvesting.

Sunflower seed:

- Where the sampling is done by hand select ripe heads.
- Where it is done mechanically submit the seed to the laboratory.

Herbs, Spices and Tea:

- Take samples in a manner reflecting common practice.
- The freshly harvested produce is not normally required for tea although herbs, such as parsley and chives, should be sampled fresh. In the case of hops, both fresh and dried cones should be supplied.

SAMPLING STORED COMMODITIES

Trials of post-harvest treatments of stored products should be carried out over a wide range of storage facilities, and the sampling technique must be carefully chosen if valid samples are to be obtained. The sampling procedures are usually designed for three kinds of storage conditions.

Sampling from bulk

Obtaining a representative sample from a (large) bulk container, e.g., of cereal grains, is difficult. If possible, samples should be taken at frequent intervals from the stream during transfer into another container. A probe sample is not representative but may be acceptable if:

- it is possible to reach every part of the storage container
- a larger number of individual samples are taken before mixing and reducing to produce a final sample.

Agricultural residues are normally higher in the dust fraction and this should be recognised in the sampling procedure.

Sampling bagged commodities

Sampling of the commodity within a bag must be random. A representative sample from a large stack of bags can be obtained only if every bag is accessible. This is not always possible in practice and the alternative is to obtain a sample from a number of randomly chosen bags by probing. Since pesticide treatments are often directed to the surface of the bag, selective sampling to show the effect of the position of the bag in the stack and the penetration of the pesticide into the bag may be necessary.

Sampling fruit and vegetables in packing houses

Where post-harvest treatments are applied to fruit and vegetables in packing houses, an adequate number of samples must be taken to determine the range of residue levels resulting from variations in the treatment process. The effects on residue levels of concentration, temperature, duration of treatment, drying (after dip treatments) and subsequent handling may need to be considered. Post-harvest treated fruit and vegetables should be kept in, or packed in, commercial containers or punnets and stored at ambient or cool-room temperature according to normal commercial practice. Samples should then be drawn for analysis from the commercial containers at suitable intervals representing the time expected between treatment and subsequent marketing. The rate of disappearance or degradation of some residues depends on whether the commodity is held in a sealed or partly sealed container or is open to the air.

TABLE 1: REQUIRED RESIDUE TRIALS

The following residue trial work is required on edible commodities and tobacco:

	SITE OF APPLICATIONS	CLASS OF ACTIVE INGREDIENT	Number of sites (Three different bioclimatic zones)	Minimum number of trials at the HIGHEST RECOMMENDED DOSAGE	INFORMATION TO BE PRESENTED
*A	Made directly to edible portion or via roots (systemic)	Systemic or non-systemic	3	5	Full degradation pattern in three trials and at harvest in the other two trials
	Made to soil (pre-plant or at planting), seed or seedling prior to development of edible portion via roots (systemic) or to plant prior to the development of edible portion	Systemic	3	5	As above
		Non-systemic	3	5	Residue at earliest possible stage for harvest

Section A above is applicable in the following situations:

- A formulation type to be used on a particular commodity of which the active ingredient has never been registered on that particular commodity (Act No. 36 of 1947) -
- A micro-encapsulated or controlled release formulation that would have the potential to extend the presence of residues, -
- A granular formulation applied intact and without further dilution.
- A formulation applied in conjunction with an adjuvant, diluent or carrier other than water (e.g. vegetable oil, mineral oil).
 - If the label specifies the use of a particular adjuvant the trials must include that adjuvant applied according to the label recommendation of the adjuvant.
 - If the label use is for an unspecified adjuvant, the residue data must include the adjuvant most commonly used in that agricultural sector.

	SITE OF APPLICATIONS	CLASS OF ACTIVE INGREDIENT	Number of sites (Three different bioclimatic zones)	Minimum number of trials at the HIGHEST RECOMMENDED DOSAGE	INFORMATION TO BE PRESENTED
**B	Made directly to edible portion or via roots (systemic)	Systemic or non-systemic	3	5	Residue at end of official withholding period
	Made to soil, seed or seedling prior to development of edible portion via roots (systemic) or to plant prior to the development of edible portion	Systemic	3	5	Residue at earliest possible stage for harvest
		Non-systemic	0 / 3	0 / 5	None if conditions set below on section B are met . If conditions set below are not met in full, then a minimum of 5 trials must be done in 3 bioclimatic zones.

** Section B above is applicable in the following situations:

- A formulation type similar to that already registered (Act No. 36 of 1947) on the particular commodity whether originating from a source other than those already acknowledged or not, but which is to be applied using a different method of application which has not yet been registered for use on that particular commodity –
- A formulation type containing an active ingredient already registered (Act No. 36 of 1947) on a particular commodity but being of a different type of formulation not registered for application on that particular commodity -,
 - If the different formulation type is a wettable powder, suspension concentrate, dustable powder, soluble powder, soluble liquid, water dispersible granule, emulsifiable concentrate or a tablet and the already registered formulation type any of the mentioned formulation types, no residue trials are required on condition that:
 - (a) the official withholding period is longer than 7 days, and
 - (b) the application rate of the active ingredient is the same as that of the already registered formulation, and
 - (c) the method and timing of application are the same as for the already registered formulation.

	SITE OF APPLICATIONS	CLASS OF ACTIVE INGREDIENT	Number of sites (Three different bioclimatic zones)	Minimum number of trials at the HIGHEST RECOMMENDED DOSAGE	INFORMATION TO BE PRESENTED
***C	Made directly to edible portion or via roots (systemic)	Systemic or non-systemic	3	5	Residue at end of official withholding period
	Made to soil, seed or seedling prior to development of edible portion via roots (systemic) or to plant prior to the development of edible portion	Systemic	3	5	Residue at end of official withholding period
		Non-systemic	0 / 3	0 / 5	None if all condition set below on Section C are met. If conditions on Section C are not met in full, then a minimum of 5 trials must be done in 3 bioclimatic zones.

*** Section C above is applicable in the following situations:

- A formulation type similar to that already registered on a particular commodity (Registered Reference Product) but originating from **a source other than that of the original formulator** or other formulators holding registration-

Referring to the crops on the label of the Registered Reference Product, residue trials must be undertaken on one third of those crops intended for inclusion on the label of the product to which the application pertains. However, where the formulation type from a new source is a wettable powder, suspension concentrate, dustable powder, soluble powder, soluble liquid, water dispersible granule, emulsifiable concentrate or a tablet and the already registered formulation type any of the mentioned formulation types, no residue trials are required on condition that:

- (a) the official withholding period is longer than 7 days, and
- (b) the application rate of the active ingredient is the same as that of the already registered formulation, and
- (c) the method and timing of application are the same as for the already registered formulation

TABLE 2: COMMODITY TO BE ANALYSED AND SAMPLING PROCEDURE

Classification of Commodities	Field Sample Size	Portion of Commodity to Which the Codex MRL Applies (and Which Is Analysed)
Group 1 - ROOT AND TUBER VEGETABLES (Codex Classification ⁶⁹ Group 016: Root and tuber vegetables)		
Root and tuber vegetables are starchy foods derived from the enlarged solid roots, tubers, corms or rhizomes, mostly subterranean, of various species of plants. The entire vegetable may be consumed.		
<u>Root and tuber vegetables:</u> Beets, carrots, celeriac, parsnips, potatoes, radishes, rutabagas, sugar beet, sweet potatoes, turnips, yams	Tubers or roots sampled from 12 plants (the sample should weigh at least 2 kg)	Whole commodity after removing tops. Wash the roots or tubers in cold running water, brushing gently with a soft brush to remove loose soil and debris, if necessary, and then dab lightly with clean tissue paper to dry. For carrots, after drying the tops are carefully cut off with a knife by cutting through the bottom of the stem at the lowest point of attachment of the outer petioles. If an annulus of root tissue is thereby severed from hollow-crown roots, the material should be re-combined with the roots.
Group 2 - BULB VEGETABLES (Codex Classification Group: 009 Bulb vegetables)		
Bulb vegetables are pungent, flavourful foods derived from the fleshy scale bulbs or growth buds of alliums of the lily family (<i>Liliaceae</i>). The entire bulb may be consumed following removal of the parchment-like skin.		Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity).
<u>Bulb vegetables:</u> Garlic, leeks, onions, spring onions	Leeks, bulb onions: 12 plants Spring onions: 24 plants (the sample should weigh at least 2 kg) Garlic, shallots: 12 bulbs from at least 12 plants (the sample should weigh at least 2 kg)	Bulb, dry onions and garlic: Whole commodity after removal of roots and whatever parchment skin is easily detached. Leeks and spring onions: Whole vegetable after removal of roots and adhering soil.
Group 3 - LEAFY VEGETABLES (EXCEPT BRASSICA VEGETABLES) (Does not correspond to Codex Classification Group 013: Leafy vegetables (including Brassica leafy vegetables))		
Leafy vegetables (except Group 4 vegetables) are foods derived from the leaves of a wide variety of edible plants including leafy parts of Group 1 vegetables. The		

entire leaf may be consumed. Leafy vegetables of the brassica family are grouped separately.		
<u>Leafy vegetables:</u> Beet leaves, corn salad, endive, lettuce, radish leaves, spinach, sugar beet leaves, Swiss chard	Endive, lettuce: 12 plants Spinach, chicory: 1 kg from >12 plants Small leafed salad crops: 0.5 kg from 12 plants or sites in plot	Whole commodity after removal of obviously decomposed or withered leaves.
Group 4 - BRASSICA (COLE) LEAFY VEGETABLES (Does not correspond to Codex Classification Group 010: Brassica vegetables)		
Brassica (cole) leafy vegetables are foods derived from the leafy parts, stems and immature inflorescences of plants commonly known and botanically classified as brassicas and also known as cole vegetables. The entire vegetable may be consumed.		
<u>Brassica leafy vegetables:</u> Broccoli, Brussels sprouts, cabbage, Chinese cabbage, red cabbage, Savoy, cauliflower, collards, kales, kohlrabi, mustard greens	Large brassica crops: 12 plants Broccoli: 2kg from 12 plants Brussels sprouts: 2kg from 12 plants. Buttons to be taken from at least 2 levels on each plant. Kale: 2 kg from 12 plants sampled from 2 levels per plant The total should be 2 kg sample for each sampled crop.	Whole commodity after removal of obviously decomposed or withered leaves. For cauliflower and headed broccoli analyse flower head and stems, discarding leaves; for Brussels sprouts analyse "buttons" only.
Group 5 - STEM VEGETABLES (Codex Classification Group 017: Stalk and stem vegetables)		
Stem vegetables are foods derived from the edible stems or shoots of a variety of plants.		
<u>Stem vegetables:</u> Artichoke, celery, chicory (witloof), rhubarb	At least 12 stalks (the sample should weigh at least 2 kg.	Whole commodity after removal of obviously decomposed or withered leaves. Rhubarb and asparagus: stems only. Celery and asparagus: remove adhering soil (e.g., by rinsing in running water or by gentle brushing of the dry commodity).

Group 6 - LEGUME VEGETABLES (Codex Classification Group 014: Legume vegetables Group 015: Pulses)		
Legume vegetables are derived from the dried or succulent seeds and immature pods or leguminous plants commonly known as beans and peas. Succulent forms may be consumed as whole pods or as the shelled product. Legume fodder is in Group 18.		
<u>Legume vegetables:</u> beans, broad beans, cow peas, dwarf beans, French beans, green beans, kidney beans, Lima beans, navy beans, runner beans, snap beans, soybeans, peas, sugar peas	1 kg	Whole commodity.
Group 7 - FRUITING VEGETABLES - EDIBLE PEEL (Combination of Codex Classification Groups 011: Fruiting vegetables, Cucurbits; 012 Fruiting vegetables other than Cucurbits)		
Fruiting vegetables - edible peel are derived from the immature or mature fruits of various plants, usually annual vines or bushes. The entire fruiting vegetables may be consumed.		
<u>Fruiting vegetables - edible peel:</u> cucumber, eggplant, gherkin, okra, pepper, summer squash, tomato, mushroom.	At least 12 fruits from 12 separate plants (the sample should weigh at least 2 kg)	Whole commodity after removal of stems
Group 8 - FRUITING VEGETABLES - INEDIBLE PEEL (Codex Classification Group 011 Fruiting vegetables, Cucurbits)		
Fruiting vegetables inedible peel are derived from the immature or mature fruits of various plants, usually annual vines or bushes. Edible portion is protected by skin, peel or husk which is removed or discarded before consumption.		
<u>Fruiting vegetables - inedible peel:</u> cantaloupe, melon, pumpkin, squash, watermelon, winter squash	At least 12 fruits from 12 separate plants (the sample should weigh at least 2 kg)	Whole commodity after removal of stems.

Group 9 – CITRUS FRUITS (Codex Classification Group 001 Citrus Fruits)		
<p>Citrus fruits are produced by trees of the Rutaceae family and are characterized by aromatic oily peel, globular form and interior segments of juice-filled vesicles. The fruit is fully exposed to pesticides during the growing season. The fruit pulp may be consumed in succulent form and as a beverage. The entire fruit may be used for preserving.</p>		
<p><u>Citrus fruits:</u> Orange, lemon, mandarin, grapefruit</p>	<p>12 fruits from several places on 4 individual trees. If this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample.</p>	<p>Whole commodity after removal of stems.</p>
Group 10 - POME FRUITS (Codex Classification Group 002 Pome fruits)		
<p>Pome fruits are produced by trees related to the genus <i>Pyrus</i> of the rose family Rosaceae. They are characterised by fleshy tissue surrounding a core consisting of parchment-like carpels enclosing the seed. The entire fruit, except the core, may be consumed in the succulent form or after processing.</p>		
<p><u>Pome fruits:</u> apple, pear, quince</p>	<p>12 fruits from several places on 4 individual trees. If this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample.</p>	<p>Whole commodity after removal of stems.</p>
Group 11 - STONE FRUITS (Codex Classification Group 003 Stone fruits)		
<p>Stone fruits are produced by trees related to the genus <i>Prunus</i> of the rose family Rosaceae characterized by fleshy tissue surrounding a single hard-shelled seed. The entire fruit, except seed, may be consumed in a succulent or processed form.</p>		

<p><u>Stone fruits:</u> Apricots, cherries, sour cherries, sweet cherries, nectarines, peaches, plums</p>	<p>12 fruits from several places on 4 individual trees. If this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample.</p>	<p>Whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stem.</p>
<p>Group 12 - SMALL FRUITS AND BERRIES (Codex Classification Group 004: Berries and other small fruits)</p>		
<p>Small fruits and berries are derived from a variety of plants whose fruit is characterized by a high surface-weight ratio. The entire fruit, often including seed, may be consumed in a succulent or processed form.</p>		
<p><u>Small fruits and berries:</u> blackberries, blueberries, boysenberries, cranberries, currants, dewberries, gooseberries, grapes, loganberries, raspberries, strawberries</p>	<p>12 bunches, or parts of 12 bunches from separate vines to give at least 1 kg</p>	<p>Whole commodity after removal of caps and stems. Currants: fruit with stems</p>
<p>Group 13 - ASSORTED FRUITS - EDIBLE PEEL (Codex Classification Group 005: Assorted tropical and sub-tropical fruit - edible peel)</p>		
<p>Assorted fruits - edible peel are derived from the immature or mature fruits of a variety of plants, usually shrubs or trees from tropical or subtropical regions. The whole fruit may be consumed in a succulent or processed form.</p>		
<p><u>Assorted fruits - edible peel:</u> dates, figs, olives, guavas, kumquats</p>	<p>1 kg from several places on 4 trees. Record weight ratio of stone and flesh.</p>	<p>Dates and olives: whole commodity after removal of stems and stones but residue calculated and expressed on the whole fruit. Figs: Whole commodity.</p>
<p>Group 14 - ASSORTED FRUITS - INEDIBLE PEEL (Codex Classification Group 006: Assorted tropical and sub-tropical fruit - inedible peel)</p>		
<p>Assorted fruits - inedible peel are derived from the immature or mature fruits of different kinds of plants, usually shrubs or trees from tropical or subtropical regions. Edible portion is protected by skin, peel or husk. Fruit may be consumed in a fresh or processed form.</p>		

<u>Assorted fruits - inedible peel:</u> avocados, bananas, kiwi fruit, mangoes, papayas, passion fruits, pineapples	12 fruits from several places on 4 individual trees. If this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample.	Whole commodity unless qualified. Pineapples: after removal of crown. Avocado and mangoes: whole commodity after removal of stone but calculated on whole fruit. Bananas: after removal of crown tissue and stalks.
Group 15 - CEREAL GRAINS (Codex Classification Group 020: Cereal grains)		
Cereal grains are derived from the clusters of starchy seeds produced by a variety of plants primarily of the grass family (Poaceae). Husks are removed before consumption.		
<u>Cereal grains:</u> Barley, maize, oats, rice, rye, sorghum, sweetcorn, wheat	1 kg	Whole commodity. Fresh maize and sweetcorn: kernels plus cob without husk.
Group 16 - STALK AND STEM CROPS (Codex Classification Group 051: Straw, fodder and forage of cereal grains and grasses)		
Stalk and stem crops are various kinds of plants, mostly of the grass family Poaceae cultivated extensively as animal feed and for the production of sugar. Stems and stalks used for animal feeds are consumed as succulent forage, silage, or as dried fodder or hay. Sugar crops are processed.		
<u>Stalk and stem crops:</u> barley fodder and straw, grass fodders, maize fodder, sorghum fodder	1 kg	Whole commodity.
Group 17 - LEGUME OILSEEDS (Part of Codex Classification Group 023: Nuts and seeds)		
Legume oilseeds are mature seeds from legumes cultivated for processing into edible vegetable oil or for direct use as human food.		
<u>Legume oilseeds:</u> Peanuts (also known as Groundnuts)	1 kg	Whole kernel after removal of shell
Group 18 - LEGUME ANIMAL FEEDS (Codex Classification Group 050: Legume animal feeds)		
Legume animal feeds are various species of legumes used for animal forage, grazing, fodder, hay or silage with or without seed. Legume animal feeds are consumed as succulent forage or as dried fodder or hay.		

<u>Legume animal feeds:</u> lucerne fodder, bean fodder, clover fodder, peanut / groundnut fodder, pea fodder, soybean fodder	1 kg	Whole commodity.
Group 19 - TREE NUTS (Codex Classification Group 022: Tree nuts)		
Tree nuts are the seeds of a variety of trees and shrubs which are characterized by a hard, inedible shell enclosing an oil seed. The edible portion of the nut is consumed in succulent, dried or processed form.		
<u>Tree nuts:</u> almonds, chestnuts, filberts, macadamia nuts, pecan nuts, walnuts	1 kg from all parts of the tree or bush, top and bottom, exposed and covered by foliage	Whole commodity after removal of shell. Chestnuts: whole in skin.
Group 20 – OILSEEDS (Codex Classification Group 23: Nuts and seeds)		
Oilseed consists of the seed from a variety of plants used in the production of edible vegetable oils. Some important vegetable oilseeds are by-products of fibre or fruit crops.		
<u>Oilseed:</u> cotton seed, linseed, rapeseed, safflower seed, sunflower seed	0.5 kg from at least 12 separate areas of each plot	Whole commodity.
Group 21 - TROPICAL SEEDS (Codex Classification Group 024: Seed for beverages and sweets)		
Tropical seeds consist of the seeds from several tropical and semitropical trees and shrubs mostly used in the production of beverages and confections. Tropical seeds are consumed after processing.		
<u>Tropical seeds:</u> Cacao beans, coffee beans	1 kg	Whole commodity.
Group 22 - HERBS (Codex Classification Group 027: Herbs)		
Herbs consist of leaves, stems and roots from a variety of herbaceous plants used in relatively small amounts to flavour other foods. They are consumed in succulent or dried form as components of other foods.		

<u>Herbs:</u>	0.5 kg fresh 0.2 kg dry	Whole commodity.
Group 23 – SPICES (Codex Classification Group 028: Spices)		
Spices consist of aromatic seeds, roots, fruits and berries from a variety of plants used in relatively small amounts to flavour other foods. They are consumed primarily in the dried form as components of other foods.	0.5 kg fresh 0.2 kg dry	
<u>Spices:</u>		Whole commodity.
Group 24 – TEAS (Codex Classification Group 066: Teas)		
Teas are derived from the leaves of several plants, but principally <i>Camellia sinensis</i> . They are used in the preparation of infusions for consumption as stimulating beverages. They are consumed as extracts of the dried or processed product.		
<u>Teas:</u>	0.2 kg dry leaves	Whole commodity.

Table 3. Commodity Crop Groupings and Possible Crop Extrapolations for Residues (Adapted from CODEX and APVMA Guidelines). NB: Refer to the latest CODEX or minor crops guidelines for latest changes in Crop Groups. For crops not indicated on this table, full developmental residue data are required

Crops		Possible Extrapolation	
		From	To
Citrus fruit	Subgroup 1 Lemons Limes Mandarins	Oranges + Lemons or Oranges + Limes or Oranges + Mandarins	Whole group
	Subgroup 2 Grapefruit Oranges Tangelos		
Pome fruit	Apples Crab apples Pears Quinces	Apples + Pears	Whole group
Stone fruit	Subgroup 1 Apricots Nectarines Peaches	Peaches + Nectarines + Cherries or Peaches + Plums + Cherries	Whole group
	Subgroup 2 Cherries Plums Prunes	Peaches	Nectarines, plums
Berries and other small fruit	Subgroup 1 Blackberries Boysenberries Cranberries Raspberries	Grapes + Strawberries and one other from Subgroups 1 or 2 Raspberries	Whole group Subgroup 1
	Subgroup 2 Blueberries Currants	Currants	Subgroup 2
	Other Grapes Strawberries		
Assorted tropical and sub-tropical fruits with edible peel	Dates Figs Guavas Olives Persimmons	No extrapolation from one crop to another is possible although if data from these crops are consistent, a group MRL may be possible	
Assorted tropical and sub-tropical	Avocados Bananas Custard apples	No extrapolation from one crop to another is possible although if data from these crops are consistent, a group MRL may	

Crops		Possible Extrapolation	
		From	To
	Subgroup 3 Gherkins		
Fruiting vegetables other than cucurbits	Subgroup 1 Eggplants Tomato	Tomato + capsicum (note it may be more appropriate to generate data as growing patterns and size vary widely)	Whole group
	Subgroup 2 Fungi Mushrooms Other Peppers Cape gooseberry Sweet corn Okra Roselle	Maize	Sweet corn
Legume vegetables (succulent seeds and immature pods)	Beans (green) Peas (green)	Beans (green) + Peas (green)	Whole group
Pulses dry	Peas Beans Chickpeas Lentils Lupins Soybeans	Field peas (dry) + Faba beans (dry) + Lupins or Beans (dry) + Chickpeas + Lupins or Beans (dry) + Peas (dry) + Lupins	Whole group
Root and tuber vegetables	Subgroup 1 Carrots Parsnips Subgroup 2 Beetroots Swedes Turnips Subgroup 3 Sweet potatoes Potatoes Yams Subgroup 4 Radishes Horseradishes	Potatoes + Carrots + Beetroots or Potatoes + Carrots + Swedes or Potatoes + Carrots + Radishes	Whole group

Crops		Possible Extrapolation	
		From	To
	Subgroup 5 Chicory		
Stalk and stem vegetables	Artichokes Asparagus Celery Witloof Rhubarb	Celery + Asparagus + Artichokes Celery	Whole group Rhubarb
Cereal grains	Subgroup 1 Wheat Triticale Cereal rye Subgroup 2 Barley Oats Subgroup 3 Maize Sorghum Millet Subgroup 4 Rice	Wheat + Barley + Oats Maize + Sorghum Rice Wheat or Barley Wheat	Subgroups 1 and 2 Subgroup 3 Subgroup 4 Oats, rye, triticale, durum wheat (treatments applied before GS32 only) Whole group except rice for post harvest treatment only
Grasses for sugar or syrup production	Sugarcane	Sugarcane	Sugarcane
Leguminous Pastures	Lupins, Lucerne, Medics (<i>Medicago</i> spp), Serradella, Clover	Lupins + Clover	Whole group
Tree nuts	Almonds Cashew nuts Chestnuts Hazelnuts Macadamia nuts Pecan nuts Pistachio nuts Walnuts	Pecan nuts + Macadamia nuts	Whole group
Herbs	Many	Parsley, mint (extrapolations to a group on a case by case basis)	Whole group