OECD/OCDE 509

OECD GUIDELINE FOR THE TESTING OF CHEMICALS

Crop Field Trial

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PURPOSE AND SCOPE

1 Crop field trials (also referred to as supervised field trials) are conducted to determine the magnitude of the pesticide residue in or on raw agricultural commodities, including feed items, and should be designed to reflect pesticide use patterns that lead to the highest possible residues. Objectives of crop field trials are

1) to quantify the expected range of residue(s) in crop commodities following treatment according to the proposed or established good agricultural practice (GAP);

2) to determine, when appropriate, the rate of decline of the residue(s) of plant protection product(s) on commodities of interest;

3) to determine residue values such as the Supervised Trial Median Residue (STMR) and Highest Residue (HR) for conducting dietary risk assessment and calculation of the dietary burden of livestock; and

4) to derive maximum residue limits (MRLs).

Crop field trials may also be useful for selecting residue definitions by providing information on the relative and absolute amounts of parent pesticide and metabolites.

2 For the purposes of this document the terms “crop field trial” and “supervised field trials” are synonymous. The term “crop field trial” will be used in the remainder of the document. In addition to addressing studies for residues in crops grown in fields (i.e., outdoors), this guideline also includes studies to assess residues in protected crops grown in greenhouses (glass or plastic covering) and in crops treated after harvest (e.g., stored grains, wax or dip treatment of fruits).

3 This Crop Field Trial test guideline provides a harmonised approach to conducting and reporting crop field trials in OECD member countries. This guideline, along with the Guidance Document on Crop Field Trials [ENV/JM/MONO(2011)50/REV1], provides for generation of complete field trial data sets for pesticide uses on crops in comprehensive submissions to all OECD countries.

GENERAL CONSIDERATIONS

4 A complete data set in the context of this guideline is the number of crop field trials matching the critical GAP (cGAP) which are required for setting an appropriate MRL and obtaining a new use of a pesticide on a crop. A reduced data set on the other hand refers to a reduced number of crop field trials matching the cGAP, which may be adequate to obtain a new or amended registration or MRL for a plant protection product on a specific crop. A reduced data set may be sufficient where no residues are anticipated at or above the limit of quantitation (LOQ). This may be the result of a very long pre-harvest interval (PHI), or with seed treatment, pre-emergence or pre-plant uses of a plant protection product for example. This crop field trial guideline provides guidance for determining when complete data sets are necessary for determining MRLs and when it may be feasible to set an MRL using a reduced data set.

5 Bridging studies provide an essential tool in a harmonised approach to compare different situations like formulation changes, new formulations, or different application methods. The results help to decide whether different use scenarios either generate a similar residue level or a higher residue level. For a higher residue level a full data set is required. For situations generating comparable residues, a reduced data set or side-by-side bridging data set is sufficient.

6 A special situation where a reduced data set is sufficient is a comprehensive submission for a crop/pesticide combination to all OECD member countries for which all crop field trials are performed at the same cGAP. In such a case a 40% reduction in total number of trials (i.e., the sum of all trials required per country or geographical region) can be achieved provided all crop field trials are submitted for evaluation and that residue levels are consistent within the whole data set.

7 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 meteorological conditions are taken into account.

8 In the case of up to 25 % increases or decreases of the active ingredient application rate, the number of applications, or the PHI, under otherwise identical conditions, the residue results can be assumed to be comparable. When combining field trials for a complete data set for a crop use, this “25 % rule” may be applied to any one of the cGAP components; however, it is not acceptable to apply the rule to more than one cGAP component listed here at a time.

Note: When residues primarily depend on the crop growth stage at application (e.g. flowering stages) it may not be appropriate to apply the +/-25% rule to the delay between (last) application and harvest (and select all trials for which this delay within the PHI +/-25% (see paragraph 47).

9 This crop field trial guideline requires one sample from treated plots at each sampling interval for crops that have 8 or more crop field trials. Some OECD countries require analysis of two independently collected samples.

PLOT AND CROP CHARACTERISTICS

Plot Size

10 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 m^2 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. Control (untreated) plots should be located in the immediate vicinity of the treated plot(s) so that cultivation and cropping take place under similar/identical conditions. 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.

11 Post-harvest treatments on stored products such as potatoes, grains and seeds 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. How commodities are stored during application can vary from commodities stacked in sacks, box stores and heaps to automated systems in large-scale silos or automated systems for fruit treatment.

Crop Variety

12 Crop variety may influence the uptake of the active ingredient and the metabolism capability. Residue trials should identify which crop varieties were utilised. In a set of residue trials, a selection of commercially important varieties of a crop (e.g., table and wine grapes), seasonal variations (e.g., winter wheat vs. spring wheat), vegetation period of different varieties, different maturation periods (e.g., early and late maturing fruit varieties) and morphologic variability (e.g., cherry tomatoes) should be considered. This will provide a range of conditions of use that are representative of actual agricultural situations.

Crop Maintenance and Horticultural Practices

13 Trials should be conducted in regions where the crops are predominantly grown commercially and should reflect the main types of crop maintenance and agricultural practices, especially those which can significantly impact residues (e.g., bagged and unbagged bananas, furrow and overhead irrigation, pruning of grape leaves).

Crop and Plot Maintenance Products

14 Additional plant protection measures, which are not the subject of crop field trials, are often required for crop management during the course of a study to control weeds, disease or other pests (also may include fertilizers, plant growth regulators, etc.). These crop and plot maintenance products should be chosen from among those products which do not affect (i.e., interfere with) residue analyses for the components of the relevant

residue definition. Additionally, these maintenance products should be applied to both the control and treated plots in the same manner (i.e., rate and timing).

Soil Type

15 Soil type (e.g., sand, loam, sandy loam) should be identified and reported for all crop field trial sites. If the product is directly applied to soil, the field trials should include field sites with different soil types.

Greenhouse Uses

16 There are a number of protected crop scenarios such as greenhouse (glass or plastic covering), plastic tunnel, shade house, etc. which offer varying degrees of protection from environmental conditions. In matters related to residue trial conduct, greenhouse production is defined as a crop grown in its entirety (i.e., planting to harvest) in a completely enclosed structure.

TEST SUBSTANCE

Test Substance Handling

17 The 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.

Storage

18 The test substance(s) should be stored under appropriate conditions for the study duration and applied soon after preparation or mixing.

Environmental conditions

19 Test substance applications should not be made in strong wind, during rain or when rainfall is expected shortly after application.

Active ingredients in tank-mixes, pre-mixes, sequentials

20 If residue data are 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.

21 In many cases, 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. Exceptions from this rule are combinations with active ingredients known to be synergistic like morpholine derivatives

or combinations with synergists or certain additives. Caution should be given to other substances that may have an impact on the level of residues of other active ingredients like plant growth regulators that hasten maturity.

Formulations

22 The formulation tested in crop field trials should be as close as possible to the intended end-use 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. Data needed to register additional formulation types or classes is dependent on how similar the formulations are in composition and physical form, the mode of application, and the timing of the application. General information on types of formulations and data requirements for additional formulation types are given in the following paragraphs.

23 Most types of formulations can be divided into two groups – those which are diluted with water prior to application and those which are applied intact. Emulsifiable concentrates (EC) and wettable powders (WP) are examples of the first type whereas granules (GR) and dusts (DP) are the most common examples of the latter. Some special types of formulations are described in paragraphs 29-30. A description of the various types of formulations including coding is given in the Manual of the Joint Meeting on Pesticide Specifications (JMPS) (FAO, 2010) [see also Table 2 in the Crop Field Trial Guidance Document].

Formulations diluted in water

24 The most common formulation types which are diluted in water prior to application include EC, WP, water dispersible granules (WG), suspension concentrates (SC)(also called flowable concentrates), and soluble concentrates (SL). 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) or just after crop emergence. Data may also be translated among these formulation types for applications directed to the soil, such as row middle or post-directed applications as opposed to foliar treatments.

25 In a publication by Maclachlan and Hamilton (2010) it was shown by evaluation of side by side trials with the same application rate and similar spray volumes that WP, EC, CS (capsule suspension) and SC formulations do not show a significant difference in day-zero residues after foliar treatment (JMPR data from 2000 to 2004). The evaluation includes trials with PHIs of less than seven days. If the PHI is exceeding 7 days, for mid-season and late-season foliar applications of formulations diluted in water, those formulations not containing oils or organic solvents (e.g., WG, SC) are considered equivalent and those containing oils or organic solvents (e.g., EC, OD) are also considered equivalent. Some authorities may require bridging data between the two formulation types (to demonstrate similarity of residue levels) where a complete data set exists for one type.

Water Soluble Bags

26 Placing a formulation (typically WP) in a ‘water soluble’ bag does not require additional residue data provided adequate data are available for the unbagged product and

the formulation chemistry data provided show acceptable dissolution of the water soluble bag will be expected under practical conditions of use.

Formulations Applied Intact

27 Granular formulations applied intact will generally require a complete data set regardless of what data are already available for other formulation types. This is based on several observed cases of residue uptake being quite different for granules versus other types of formulations of the same active ingredient.

Formulations Designed for Seed Treatments

28 Some formulations are often designed specifically for seed treatment use such as DS powder for dry seed treatment use and ES emulsion for seed treatment. Residue data for seed treatment uses may be extrapolated between such formulation types. Nevertheless, it may be necessary to consider the chemical loading data to ensure the amount of active ingredient per seed is comparable as to confirm the applicability of extrapolation between residue data generated with any of these formulation types.

Controlled Release Formulations

29 Controlled release formulations (e.g., certain microencapsulated products) normally require a complete data set tailored to that particular use. Since these formulations are designed to control the release rate of the active ingredient, increased residues are possible compared to other formulation types.

Formulations that Contain Active Ingredients as Nanomaterials

30 In general, it is expected that formulations that contain nanoparticles would have different properties compared to normal sized material (active ingredient and/or co-formulants). At present no definitive statement can be made as to whether or not current data requirements are sufficient to carry out risk assessments for nanopesticides. For the time being a complete data set is needed for plant protection products containing nanomaterials in order to compare residue behaviour with conventional products.

Variants of active ingredients

31 In formulations of plant protection products, variants of the active ingredients can be applied (e.g. salts or esters). Different salts of an active ingredient (e.g. for phenoxy herbicides) 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.

32 Some authorities consider that different ester formulations of an active ingredient result in comparable residues when applied at PHIs longer than 7 days. If the PHI is less than or equal to 7 days, these authorities treat different esters as new formulations of that active ingredient for the purposes of determining data needs. Thus, a new ester could be subject to a reduced data set (50% fewer trials than initial formulation with absolute minimum of four trials per crop) or compared to the original ester of the active ingredient in a study with at least three trials having side-by-side plots. Other authorities require the reduced data set or side-by-side trials on a new ester for all uses other than those described in paragraph 24 (i.e., early season or soil applications).

Changing the content of the active ingredient in the formulation

33 Generally it is not considered necessary to provide residue data for a change in active ingredient concentration within a specific formulation type, provided the cGAP is not changed significantly as a result (e.g., no more than 25% increase in amount of active ingredient per unit area).

Changes of co-formulants

34 Changes in formulations on the basis of a change in the content of formulants (e.g., solvents) need to be evaluated on a case-by-case basis. Solvents and other inert components may have an influence on the uptake or movement of the active ingredient into the plant. Special consideration should be given to changes in the content of formulants like wetting agents, which may lead to better penetration of the active ingredient into the plant, particularly when the PHI is equal to or less than 7 days. In such a situation, at least a bridging study may be needed to show that residues of the active ingredient and relevant metabolites are not significantly increased by the addition of a new formulant.

Diluents and Carriers

35 Additional residue data may be required when using a diluent or carrier other than water (e.g., vegetable oil, mineral oil). The need for these data will be determined on a case-by-case basis.

Adjuvants

36 Adjuvants are products added to the spray tank for the purpose of improving the performance of the test substance or active ingredient. Adjuvants such as wetting agents, spreader-stickers, non-ionic surfactants, and crop oil concentrates may result in better deposition, penetration, or persistence of pesticide residues in or on the plant. Therefore, for a test substance which has a label allowance for the use of an unspecified adjuvant, crop field trials should include an adjuvant (any locally-available adjuvant), applied according to the label recommendation of the adjuvant. For a test substance which has a label recommendation for the use of a specific adjuvant, crop field trials should include the adjuvant, or where applicable another adjuvant with similar properties, applied according to the label recommendation of the adjuvant. Applicants should consult regulatory authorities for advice on whether the submission of trials with a similar adjuvant will be accepted.

APPLICATION PARAMETERS

Spray Volume

37 Spray volumes may differ depending on the target crop or target pest (e.g., tree crops versus row crops). Crop field trials should be carried out according to the typical commercial practice(s) in regard to spray volume ensuring that the range of volumes

utilised is captured. The spray volume (per unit surface area) should be recorded in all cases. The spray volume is normally included in the GAP as a range to ensure proper plant protection under all circumstances. A range may also be used to adjust for a higher leaf surface area, which is normally covered by the spray concentration (see next paragraph). Quite high amounts of water, e.g. more than 400 L/ha in field crops, may have the disadvantage that higher amounts of active ingredient will reach the soil due to run-off from the leaf surface. A very small amount of water, e.g. less than 100 L/ha in field crops, may enhance spray drift. For more information on aerial applications and comparison to ground sprays, refer to paragraph 57 ("Equipment and Mode of Application").

Expression of Application Rate

Application rate

38 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 lb a.i. per acre) and where appropriate, the concentration (e.g., kg a.i./100 liters or lb a.i./100 gal) at which it is applied. In some cases only spray volume and spray concentrations are given. Both values allow a calculation of the amount of product and/or active ingredient per unit area applied. In case a range of spray volume is given the actual application rate cannot be estimated and therefore the trial cannot be used for estimating the expected residue resulting from a certain application rate.

Plant height and volume

39 Row crops (potatoes, wheat, soybeans, etc.) are typically treated with broadcast sprays for which plot area (length X width) is a key consideration. In contrast, for some crops such as tree nuts, tree fruits, trellised vegetables and vines, the crop height, crown height or tree height (i.e., treated foliage height) should be recorded in order to allow crop row volume or tree row volume estimations or rate per unit area calculation as needed.

Leaf wall area (LWA)

40 For three dimensional crops the dose expression given as area treated per hectare of ground area is normally not sufficient for an efficient treatment against insects, fungi and other pests. The spray solution has to reach the leaves above the ground, which means that the overall leaf area is a better description of the area to be treated. In some regions, this approach based on the treated "leaf wall area" unit (LWA) is becoming the standard dose expression method for three-dimensional crops. The method is described in detail in EPPO General Standard PP1/239(2). The Standard also provides a method to convert between the country dose expression methods. This approach both encourages a common dose expression method to be used in trials for generating data and when conducing assessments, whilst allowing the retention of country specific dose expression terms on National labels like concentration (%) or kg (L) per hectare and m crown height. It should be emphasised that this approach can only be used if all relevant parameters of crop structure are recorded, to allow the appropriate dose expression conversions to be made. Nevertheless, as additional information, the dose of active ingredient per hectare of ground area should always be calculated and reported.

Solution concentration

41 Special consideration may be needed for foliar applications to 'tall' crops (e.g., orchard and vine crops, hops, greenhouse tomatoes), where flat boom spraying is not common practice and (air assisted) mist blowing equipment is often used. It is important to

consider and report both the spray concentration (e.g., kg a.i./100 liters) and spray volumes (e.g., liters spray mixture/ha) at the various crop growth stages when planning and conducting crop field trials in these crops.

Seed treatment uses

42 Application rates for seed treatments are normally expressed as amount of active ingredient per unit of seed weight (e.g., g a.i./100 kg seed) and seeding rate (e.g., kg seed/hectare).

Post-harvest uses

43 For dip or drench of fruit, concentration of the active ingredient in solution should be recorded (e.g., kg a.i./100 liters (or hL)) 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. For powdering, fogging or spraying of stored goods (e.g., potatoes or grains), the application rate should be recorded (e.g., kg a.i./ton or 1000 kg).

Fumigation uses

44 The application rate for gases and aerosols used in fumigation should be expressed as amount per unit volume of treated bulk good (e.g., g a.i./m^3) or as amount•time per unit volume of treated bulk good (e.g., g a.i. hours/m^3), when specified as such on the label.

Application Rate, Timing and Frequency

Maximum label rate

45 The maximum label rate or maximum proposed label rate of the active ingredient (according to the cGAP) should be used when applying the test substance for crop field trials.

Number of applications and re-treatment interval

46 The maximum number of applications and minimum re-treatment interval for use of the test substance under evaluation should reflect the cGAP.

In cases where the maximum seasonal application rate is less than the product of the maximum single application rate and the maximum number of applications, trials should normally be conducted with the maximum single rates applied closest to harvest. For example, if the cGAP is 3 applications with a maximum per-application rate of 1 kg a.i./ha and a **maximum seasonal** rate of 2.5 kg a.i./ha, then the trials should be done with the first application at 0.5 kg a.i./ha and the second and third applications at 1 kg a.i./ha each. However, in justified cases, a different approach may be more appropriate (e.g. for systemic compounds for which the maximum residues are not necessarily observed on day 0).

Pre-harvest interval (PHI) in days versus final application at a specific growth stage

47 Application timing is governed by plant growth stage (e.g., pre-bloom, 50% head emergence, etc.) 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 14 days prior to harvest."), that specific PHI should be used in the crop field trials as a component of the cGAP,

whereas the growth stage at application is of minor importance. Inversely, there are cases where the growth stage is a critical component of the GAP, (e.g., pre-emergence, at planting, pre-bloom, flag leaf or head emergence, etc.) while the PHI is of secondary importance. In these cases, it is important to include as many varieties of the crop as possible in order to evaluate an appropriate range of 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.

Residue Decline Trials

48 Residue decline data are necessary for uses where the pesticide is applied when the edible portion (human food or animal feed) 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:

1) determining if residues are higher at longer PHIs than requested;

2) estimating the half-life of the residues;

3) determining whether alteration of the PHI to levels represented in the decline trials around the GAP PHI affects the residue levels;

4) 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;

5) 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

6) determining the time interval to reach maximum residues for a systemic compound.

49 When residue decline data are necessary, some regulatory authorities require that up to 50% of the residue trials be decline studies to demonstrate the behavior of the active ingredient and relevant metabolites close to harvest.

50 When residue decline data are necessary, 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 or dill leaves and dill seeds). This will result in two or more sets of sampling dates within one residue decline trial. Nevertheless, in case different GAPs are applied for the different matrices used, trials with both GAPs are necessary. In case of where these trials are conducted as residue decline trials the aforementioned provisions for sampling will not change.

51 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). The preferred minimum number of samples is 5 from a PHI of $\geqslant$10 days. Sampling should occur at shorter and longer time points relative to the target PHI, when such is permitted by the window of commercial maturity. In the case of decline studies which include the 0 day sampling and especially if the residues are expected to decline quickly it is recommended to take samples more frequently shortly after the last application than later on (e.g. on days 0, 1, 3, 7 and 14). Otherwise, the sampling intervals may be spaced somewhat equally. For cGAPs including multiple applications, 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.

Reverse Decline Trials

52 Another acceptable residue decline study design option, referred to as "reverse decline," involves applications being made to separate plots at different time intervals from the targeted commercial harvest date. All plots are then harvested on the same day, the commercial harvest date, resulting in different intervals from last application to harvest. Such a design may be appropriate for situations where the commodity is likely to be harvested within a narrow time window. For example, such a study could examine the use of a pre-harvest desiccant close to maturity where harvest should occur within a short time frame after application.

Bridging studies

53 Bridging studies are a possibility to compare the residue behaviour of different situations where residues are not assumed to be equivalent. This might be the case in formulation changes, new formulations, or different application methods. The best results might be obtained by conducting trials at the same site which will minimise environmental effects on the level of residues. Such side-by-side comparisons are favoured but not always necessary. As to the number of side-by-side trials needed, a minimum of 4 trials is generally needed. The reduced number of trials is considered adequate due to the fewer number of environmental variables inherent in side-by-side trials.

54 Comparing the results from the original situation with the new situation using the Kruskal-Wallis H-test (or Mann-Whitney U-test in case of more than 2 datasets) can give an indication, whether both situations are comparable or not. However, due to the limited power of the test, expert judgement may be required to decide if the data sets are comparable (for using statistical tests see OECD Guidance Document on Crop Field Trials).

55 If residues from the new situation are comparable to or less than those from the original situation, no additional data are required. However, if residues are higher from the new situation, a complete data set will be required for the new situation.

56 Two different situations as described before can be considered comparable under all circumstances if the data sets for at least three major crops are comparable. Data should be generated for at least 3 major crop groups (one crop per crop group), e.g., a leafy crop, a root crop, a tree fruit, a cereal grain, an oilseed. 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 situation, generation of a complete data set may be necessary. Also in such situations a Kruskal-Wallis H-test (two datasets) or a Mann-Whitney U-test (multiple datasets) can be used to decide whether results are comparable. Regulatory authorities should be consulted in cases where such wider extrapolations (see also point "Beyond the Crop Group or Wider Extrapolation" below, paragraphs 123 - 126) are being considered.

Equipment and Mode of Application

Ground versus aerial application

57 Provided the proposed use does not involve ultra-low volume spraying or diluents other than water (e.g., vegetable oils), crop field trials using actual aerial application equipment can generally be waived where adequate data are available from use of ground equipment reflecting the cGAP as long as the product label specifies that aerial applications are to be made in spray volumes of 19 liters or more per ha (2 gallons or more per acre) for row crops, or 94 liters or more per ha (10 gallons or more per acre) for tree and orchard crops.

Hand-held versus commercial equipment

58 Application of the test substance may be made with hand-held or commercial equipment as long as the equipment is conducive to calibration procedures. Hand-held equipment used to make test substance applications in crop field trials should do so in a manner that simulates commercial practice. If single unit (e.g., one tomato) residue data need to be generated, the use of small plot precision sprayers is not representative of the variability expected under commercial spraying applications and should be avoided. Consideration should also be given to selection of appropriate nozzles in these trials.

Alternative application modes to the same crop

59 There are a number of soil application methods such as pre-emergence, pre-plant incorporated, in-furrow at planting, drip/drench and seed treatment. Many product labels give options for applications made prior to crop emergence, such as allowing the use to be pre-plant, at-plant, or pre-emergence. These soil-applied applications may be grouped for the purposes of determining the residue(s) resulting from the test substance application, i.e. pre-emergence applications, which occur within one week after planting are considered equivalent to at-plant uses. If the label gives a choice of soil incorporation or subsequent surface application, residue data reflecting both modes of application will be required.

60 There are also a number of foliar application methods including broadcast and airblast. Field trials should reflect these multiple methods if permitted by pesticide product labels.

61 Typically, unless data from metabolism studies indicate differently, foliar application is considered the worst case compared to soil application or seed treatment and therefore would be considered to be the cGAP. This is especially the case if the foliar application is made when the food or feed commodity has formed and is directly exposed.

Multiple application modes to the same crop

62 It is also not uncommon to have more than one application mode of a product to the same crop within one growing season (e.g., seed treatment or pre-plant soil incorporation followed by foliar broadcast). Data from metabolism or radio-tracer studies will be helpful in determining the best approach for designing crop field trials leading to the highest residue scenario. In the absence of data indicating relative contributions to the final residue, trials reflecting the total treatment regimen may be needed, e.g., at-plant plus foliar applications.

FIELD SAMPLING

Raw Agricultural Commodity (RAC) Characteristics

63 Samples taken from field trials should be of the whole RAC as it moves in commerce. For some crops, there may be more than one RAC. For example, the RACs for field corn include the grain (seed), fodder (stover), and forage. Annex 1 contains a list of the RACs derived from each crop. Some crops may be shipped without having been stripped, trimmed or washed; therefore these procedures should only be used on residue samples to the extent that these are commercial practices prior to shipment. Of course, data on trimmed or washed samples may be generated at the applicant's option for use in risk assessment.

Number of Samples per Site (Treated and Controls)

64 A minimum of one sample per treated plot per sample matrix is required to be collected and analysed at each crop field trial site. In addition to the treated sample(s), one sample of each matrix should be collected from the control plot and analysed for each field trial site. It is recommended, however, especially in trials where multiple samples are not taken for residue decline purposes, that a second treated sample be independently collected for each matrix at each site in case problems arise during shipping or residue analysis. Specific cases where certain regulatory authorities require two samples per treated plot are detailed in paragraph 65. Analysis of a second sample would also be useful in cases where the results at a particular site are suspicious or are inconsistent with results from other trial sites. Another factor that could promote the analysis of a second sample is the presence of high residues due to late-season foliar use (as opposed to early season use with residues <LOQ where analysis of a second sample adds very little data value).

65 Some regulatory authorities require that more than one treated sample be analysed per site for a specific crop, including bridging studies which are used for purposes such as comparison of formulations or application methods. The specific requirements for CANADA/MEXICO/USA regulatory authorities are detailed in the following table 1 for submissions limited to only CANADA/MEXICO/USA countries and those made to multiple OECD regions.

Table 1. Number of treated samples in CANADA/MEXICO/USA countries

Study Type	CANADA/MEXICO/USA Only Submission	Multiple OECD Regions
Standard crop field trials	2 treated samples per site[1]	1 treated sample per site (assuming minimum 8 trials per crop)
Residue decline trial	1 treated sample per time point	1 treated sample per time point
Bridging studies	2 treated samples per plot[1]	2 treated samples per plot[1] (unless >8 trials per crop)

[1] Although the two treated samples are to be collected independently, the residue values from these samples are not statistically independent.

Composite versus Single Unit Samples

66 Composite samples are adequate for crop field trials. Applicants may also wish to generate replicate single unit samples from a field to aid defining unit-to-unit variation, which is needed for the purposes of acute dietary intake assessment. To derive a variability factor from a residue trial, at least 119 single units should be sampled and analysed separately (Hamilton 2004).

Minimum Field Sample Size (Number and Weight)

67 Codex guidelines on minimum field sample sizes should be followed and are included in Annex 1. A control crop sample should also be collected from each crop field trial site and for each crop commodity (e.g., cereal forage, cereal fodder, cereal grain, and straw) for analysis. Control samples of each matrix are often larger than treated samples, in order to provide the needed amount for spiking with known amounts of active ingredient (and other components of the residue definition) and to determine the calibration curves for the concurrent method validation during the analytical phase of the study.

68 For commodities not included in Annex 1, applicants are advised to use the guidance on minimum field sample size for a crop part having a similar form (e.g., another seed, leafy material, root or tuber).

General Sampling Procedures

69 The sample should be representative of all portions of the crop from the field and samples should be collected without bias. Standardised procedures such as the use of the Latin squares for a forage crop, selection of tree fruits from the upper, middle, and lower levels of opposing quadrants of the tree, the use of grain triers for taking core samples of commodities in bulk quantities, and sample reduction by quartering of samples from a field are desirable. It is noted that JMPR recommends not to cut or break units of fresh plant products or whole eggs unless the tested pesticides can be considered stable in the halved or quartered portions or if there is potential for cross-contamination of residues from inedible to edible parts of the commodity (e.g., melons) (FAO 2016). See text starting in paragraph 79 and Annex 1 for crop specific sampling procedures.

70 Although samples should be collected in an unbiased fashion, whenever possible, avoid edges and ends of plots, which may be influenced by turning the boom or other sprayer type on and off (ends) or where spray nozzle may be designed for spray overlap (edge effect). In cases where more than one pass is made, it may also be advisable to avoid the center of the plot to avoid the possibility of high residues from improper spray overlap.

Subsampling

71 It is acceptable to subsample large commodities (e.g., head cabbage, melons, etc.) with procedures in the field such as quartering and collecting opposing quarters. However, 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 sample preparation facility to avoid cross contamination of peel and pulp. It is acceptable to ship these 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.

Shelling and seed removal

72 Shelling, removing seeds or beans from pods, etc. is acceptable in the field provided that procedures are used which eliminate the possibility of contamination. For example, using clean implements and changing gloves between plots. In cases where commodities such as peel and pulp or stone and pulp are separated for analyses, weights should be determined for each part.

Hand versus mechanical harvesting

73 Unless specifically directed otherwise (e.g., cotton gin byproducts), plant samples for residue analyses may be collected by hand. There is no general requirement for mechanical harvesting in crop field trials. However, in order to define a realistic residue at harvest, some mechanically harvested samples may be useful.

Washing, brushing

74 Apart from superficial cleansing, i.e., removal of any extraneous matter, 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. (See "Detailed Sampling Procedures" for additional information.)

Contamination

75 To avoid contamination, it is strongly recommended to take samples from the control plot before taking samples from the treated plot. Care should be taken to ensure that such samples are truly representative and that possible contamination or spoilage through decay is avoided.

Storage, shipping conditions and duration

76 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 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.

77 Normal frozen storage may not be appropriate for some pesticides (e.g., fumigants) and arrangements may be necessary for immediate residue analysis.

Form to be stored (homogenate, whole RAC)

78 Samples should be stored prior to analyses according to how the storage stability study was conducted and the analytical method for the active ingredient and relevant metabolites. For example, some methods indicate that sample homogenisation should be performed on the same day as extraction. As noted in the OECD Guideline "Stability of Pesticide Residues in Stored Commodities, TG 506" storage of homogenates is likely to represent a worse case (i.e., more degradation) compared to the storage of a whole commodity.

Detailed Sampling Procedures

79 Additional details regarding recommendations for the sampling of mature crops at normal harvest time, specifics on commodity sample size and the portions to be analysed are provided in Annex 1.

Fruits and tree nuts

80 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, avoiding the ends 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, as long as all samples are marketable (except when taking immature samples for a residue decline study).

Bulb vegetables, root vegetables, tuber vegetables:

81 Take samples from all over the plot, excluding the edges of the plot and the ends of the rows to avoid edge effect. The number of sampling points depends on the sample size of the crop.

82 To provide a representative sample of the raw commodity, adhering soil should be removed. This may be done by brushing and, if necessary, gentle rinsing with cold running water.

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

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

84 Take the sample from all parts of the plot, avoiding the edges and ends of rows. The number of sampling points depends on the sample size of the crop.

85 Sample items of crops such as peas or beans protected from the spray by foliage and also from parts exposed to the spray.

86 To provide a representative sample of the raw commodity, adhering soil should be removed. This may be done by brushing and, if necessary, gentle rinsing with cold running water.

87 For Brassica and leafy vegetables, do not trim except for the removal of obviously decomposed or withered leaves. Details of any trimming should be recorded. The fate of wrapper or outer leaves should be clearly described (i.e., included with sample or discarded in the field).

Cereals

88 If the plot is small, collect the entire yield as needed. 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.

89 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.

90 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 to make one bulk sample each for grain and straw.

Cereals/Legumes/Grasses/Oilseeds/Pulses - forage, hay, stover, vines, straw and other animal feed

91 Cut and/or collect these commodities according to the commercial practice. If the plots are harvested mechanically, take not less than 12 grab samples from the harvester at uniform intervals over the plot. However, care should be taken to avoid contamination (e.g., harvest control prior to treated plots). For crops that are windrowed, the samples should be taken from the windrow at the time corresponding to the point when used for animal feed. In the case of cutting green plant material for the production of hay, this timing would normally be when the moisture content has decreased to the typical level for hay in commercial practice. In the case of plant material which has dried before the plant is cut (e.g., stover, straw), collect the sample after cutting and not after windrowing in the field.

Sugar cane and cane tops

92 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. Collect samples of green cane tops, approximately 2 kg from each plot.

Pulses, Oilseeds, Coffee, Cocoa

93 Collect 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 (except for coffee and cacao beans). When mechanical harvesting is used, only the seed should normally be supplied. Take samples from the entire plot, avoiding the edges of the plot. For coffee and cacao, circle each tree or bush and select pods or fruit from all segments of the tree or plant, high and low, exposed and protected by foliage. Select the quantity of the pods or fruit according to its density on the tree or plant, i.e., take more from the heavily laden parts.

- Cotton seed, peanuts, sesame seed, rape seed: Collect at the normal stage of harvesting.
- Sunflower seed, safflower seed: When the sampling is done by hand, collect the entire ripe heads. When sampling is done mechanically, submit only the seed to the laboratory.
- Coffee and cacao beans: The freshly harvested produce is not normally required. Take samples in a manner reflecting common practice. For cacao sample the beans after drying or fermentation without the pod and after removal of the shell. For coffee sample the whole green bean after removal of the pulp and parchment surrounding the bean. The removal process (dry or wet) should be recorded

Herbs and spices; tea leaves; hops

94 Take samples in a manner reflecting common practice. Use only those plant parts which are representative of consumption.

95 For hops select cones from all parts of the plant and from both sides of the rows, high and low, exposed and protected by foliage.

96 Take samples from the entire plot, avoiding the edges of the plot. Herbs, such as parsley and chives, and hops should be sampled fresh. As fresh hop cones are not marketed, dried cones should be produced immediately, using drying procedure reflecting the usual practices.

Special cases

97 Tree nuts and olives for oil production are often harvested by shaking the tree and collecting the product in a net on the ground. In such cases the sampling procedure should ensure the harvest procedure in order to take account of the transfer of residues to the product when the cGAP is for application to the orchard floor.

Stored commodities

98 Trials reflecting post-harvest treatments of stored products should be carried out over a wide range of storage facilities, and the sampling technique should be carefully chosen if valid samples are to be obtained. Procedures for taking valid samples from most commodities in storage units should reflect or simulate commercial practices. Such procedures are acceptable in sampling for pesticide residue analysis and may be used if adequate references are given. The sampling procedures are usually designed for three kinds of storage conditions as described below.

Sampling from bulk

99 Obtaining a representative sample from a (large) bulk container (e.g., cereal grains or potatoes) 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; and a larger number of individual samples are taken before mixing and reducing to produce a final sample. However, it is also important for the sampling procedure to generate samples from only that portion of the store having the highest residues. For example, pesticide residues are normally higher in the surface layer of a pile of potatoes and this should be recognised in the sampling procedure. To account for the variability of residues in these situations, at least three samples should be collected and analysed for residues.

Sampling bagged commodities

100 Sampling of the commodity within a bag should 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. As with bulk containers, at least three samples should be collected and analysed.

Sampling fruit and vegetables in packing houses

101 Where post-harvest treatments are applied to fruit and vegetables in packing houses, an adequate number of samples should be taken to determine the range of residue levels resulting from variations in the treatment process. The effects on residue levels of dip or spray concentration, temperature, duration of treatment, drying (after dip treatments) and subsequent handling may need to be considered.

102 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. Day zero samples should be taken once the commodity is dried. 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.

RESIDUE ANALYSIS

103 The analytes relevant for risk assessment and enforcement should be quantified by an appropriate analytical method (Refer to OECD Guidance Document on Pesticide Residue Analytical Methods, ENV/JM/MONO(2007)17). 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 quantitation.

NUMBER OF CROP FIELD TRIALS

Combination of Data Sets for a Given Commodity

104 Individual OECD member countries or political regions typically require a geographic distribution of a specified finite number of crop field trials conducted at the critical GAP to generate data for the estimation of the STMR, HR and MRL. The same practice would apply to estimation of the STMR, HR and MRL when trials conducted at the same GAP are considered from more than one country or region. Provided the GAP is comparable, the results of trials conducted in two or more countries or regions should be considered in deriving the STMR, HR and MRL for a given commodity. The general rules as described in paragraph 8 or by the proportionality principles (see chapter 3 of the OECD Guidance Document on Crop Field Trials) apply.

105 Current guidelines in OECD countries or regions specify numbers of crop field trials based on consideration of the following factors:

1) 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.

2) Significance of the crop in a production region or country, most often determined by the production area (acres or hectares) or production quantity (tons). A crop may be considered a major or minor crop based on these factors. The production area or quantity for minor crops is not defined by all regulatory authorities.

3) Significance in the diet.

106 Having taken these factors into account, regulatory authorities in different OECD countries have each determined the minimum number of crop field trials required for registration of a use on a crop and establishment of a suitable MRL. More details can be found in table 3 of OECD Guidance Document on Crop Field Trials [ENV/JM/MONO(2011)50/REV1].

107 Geographic distribution of field trials within a country or region serves to ensure that data will be available for trials in key crop production areas, and a sufficient variety of horticultural practices, environmental (like soil) and weather conditions may be represented in a crop field trial data set. Specific analyses of the influence of climate and ecology on residue levels have been performed (FAO/OECD and USA). For more information see paragraphs 61 and 62 in OECD Guidance Document on Crop Field Trials as well as added documents in section references by D. Miller (2018) and J. Nguyen et al from 2019. According to the publication from 2019 the investigations can be considered as completed. The authors concluded, that their "assessment supports the concept of exchangeability of pesticide residue values across geographic regions and opens the possibility of improving harmonization of pesticide regulatory standards by establishing more globally aligned MRLs". Regulatory authorities should be consulted to determine which residue data are required.

Comprehensive Submissions

108 In the case of a comprehensive submission to all OECD member countries where the desired GAP is uniform, a 40% reduction in the total number of trials is feasible, compared to the total number of trials determined by summation of individual country requirements. The assumption is that the number of trials specified in each crop production region reflects the economic (acreage) importance and/or dietary significance of the crop within that production region. Therefore, there is no need to further consider acreage or dietary intake for a crop/commodity or to determine whether a crop is major or minor in terms of acreage, diet, or trade on a global basis for the purpose of determining a minimum number of crop field trials for a comprehensive submission.

109 The reduction in the total number of trials within any OECD country or crop production region is compensated for by the total number of crop field trials making up the comprehensive submission data set and the wider geographic distribution of these data. With this 40% reduction, regulatory authorities may receive fewer crop field trials in their specific country or region; however they will actually receive a greater number of trials in total with a more comprehensive geographical distribution. There are precedents in OECD member countries and regions for this approach.

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

1) Field trials are conducted according to the uniform cGAP. At least 50% of the trials should be conducted at or above (within 25%) the cGAP. For this purpose, 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, for some authorities at least 50% of the trials need to be decline studies (see paragraphs 48 - 51).

2) 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.).

111 Any reduction in the number of crop field trials should be distributed proportionally among the crop production regions as shown in the example for a 40% reduction below. A table with trial numbers for crops grown throughout OECD member countries is available in the OECD Guidance Document on Crop Field Trials [ENV/JM/MONO(2011)50/REV1]. In the event that the number of required trials changes in any given region, the total number and reduced number should be adjusted accordingly.

Table 2 Example for calculation a 40% reduction compared in number of trials

Country or Region	CANADA/MEXICO/USA	EU	JP	AUS	NZ	Total
Number without reduction	21	16	3	8	4	52
Number with 40% reduction	12	10	2	5	2	31

In no case may the number of trials in a given crop production region be reduced below 2.

112 The minimum total number of trials for any crop in a comprehensive submission is eight. In addition, the total number of trials to be conducted must not be less than the requirement for any given individual region. For example, upon calculation of the 40% reduction, some crops such as dried lima beans have fewer total trials (14) than required in one region (16 in the EU). Therefore, at least 16 trials are needed for dried lima beans in a comprehensive submission. (For more details see OECD Guidance Document on Crop Field Trials, ENV/JM/MONO(2011)50/REV1).

113 It is important to keep in mind that this comprehensive strategy would only apply to an OECD-wide submission. If, for example, the MRL submission is originally submitted to the US and Canada, the crop field trial guidelines, with respect to the number of trials, for those countries should be followed. Subsequently, if MRLs in additional OECD countries are pursued, the regulatory authorities in the additional countries should be consulted to determine what residue data are required. For example, following establishment of an MRL in the US and Canada, if an MRL for the same use is pursued in the EU, the applicant may consult with EU regulatory authorities about the possibility of using residue data from the US/Canadian data submission and performing fewer crop field trials in the EU.

114 The table of trial numbers in the OECD Guidance Document on Crop Field Trials [ENV/JM/MONO(2011)50/REV1] addresses only outdoor crop field trials and not greenhouse (glasshouse) or post-harvest treatments. For a comprehensive submission to OECD countries, with similar critical GAPs, a minimum of eight greenhouse trials is needed. For such greenhouse trials, geographic distribution typically is not an issue; however for active ingredients which are susceptible to photodegradation, consideration should be given to locations at different latitudes and winter/summer periods.

115 The number of post-harvest trials on a commodity should be at least four, taking into consideration the application techniques, storage facilities, and packaging materials used. As stated in paragraphs 98 - 99, at least three samples should be collected and analysed in studies on bulk and bagged commodities.

GENERAL INFORMATION ON CROP GROUPS AND EXTRAPOLATION

Extrapolation and Principles of Representative Commodities

116 National authorities use targeted data sets and data extrapolation to provide sufficient data for exposure assessment or for setting MRLs for both individual major and minor crop commodities, and crop commodity groups. It provides the mechanism for extending field trial data from several (typically two or three) representative commodities to related commodities in the same crop group or subgroup. Crop grouping and the identification of representative commodities are also critical for maximising the applicability of a targeted data set determined for representative commodities for minor uses. The representative commodity (within the group) has the following properties:

1) major in terms of production and consumption and

2) most likely to contain highest residue.

117 A number of different crop and commodity grouping systems have been developed within OECD countries to identify which commodities are likely to contain similar residues, and where group or subgroup MRLs can be considered. Characteristics of crop and commodity grouping systems are as follows:

- All or most of the crops in a group have similar pesticide use requirements (GAP within the 25% rule). Generally, this means that the registered uses (label claims) also refer to the crop group or to a substantial number of the crops within the group.
- The expected residues in all commodities in a group are similar at harvest.

118 It may be recognised that a major crop within a crop group may not have the highest residue. From a dietary exposure standpoint, using a major crop commodity as representative of the group is acceptable to some regulatory authorities because of the small consumption of minor commodities. However, particularly with regard to regional acute intake figures, this may not be the case.

119 If necessary groups can be further divided into subgroups that better reflect grouping criteria. Codex uses the following characteristics for crop grouping:

1) commodity’s similar potential for pesticide residues,

2) similar morphology,

3) similar production practices, growth habits, etc.,

4) similar edible portion,

5) similar GAP for pesticides uses,

6) similar residue behaviour, and

7) to provide flexibility for setting (sub) group tolerances.

Normally, data for at least one commodity would be needed from each subgroup to set a group MRL. For example, under Codex, citrus crops are divided into four subgroups. One commodity from each subgroup would be needed for a group MRL. In this case these are:

- Subgroup 001A, Lemons and Limes with the representative crops lemon or lime
- Subgroup 001B, Mandarin with the representative crop mandarin
- Subgroup 001C, Oranges, Sweet, Sour with the representative crop orange
- Subgroup 001D, Pummelos with the representative crops pummelo or grapefruit

The results from the four different subgroups will be used to determine whether it is appropriate to set a group MRL or if it is preferable to set specific MRLs for the individual subgroups.

120 The commodity consumed may also be reflected in the sub grouping. For example, bulb vegetables are sub grouped into

- Subgroup 009A, Bulb Onions with the representative crop bulb onion covering inter alia garlic, onion and shallots
- Subgroup 009B, Green Onions with the representative crops spring onion or leek covering inter alia chives, leek and spring onions.

The distinction is that only the bulb on those in subgroup 1 is consumed, whereas the bulb and aerial portions of the subgroup 2 may be eaten. Different residue levels might be expected on the two sub groupings for most pesticide applications. Thus, it might be possible to extrapolate from bulb onion to garlic and shallot, but not from bulb onion to spring onion.

121 Under mutual support, trials from two related commodities showing similar residue concentrations may be considered together in order to establish MRLs for both commodities when there may be an inadequate number of trials for one or both commodities. For example, there may be 8 trials for apples and 4 trials for pears, where both are conducted under the same GAP and have similar residues. Four trials would be considered to be too few for pears, but an MRL for pears could be estimated by considering both the apple and pear trials.

122 Applicants are advised to contact individual regulatory authorities for details on their policies with regard to crop groups and extrapolation of data.

Beyond the Crop Group or Wider Extrapolation

123 Extrapolation beyond a crop group may also be possible under special circumstances. A pesticide because of its use pattern, e.g., foliar application early season before edible portions form, seed treatments, or application as a directed herbicide, or because of its properties, e.g., non-systemic and rapid degradation, will consistently yield no or low concentrations of residue (< LOQ to just above the LOQ) on a wide variety of commodities. Under such circumstances it is possible to extrapolate to establish MRLs for many commodities or crop commodity groups beyond those for which field trial data have been generated.

124 Extrapolations beyond the bounds of a crop group or subgroup may also be possible on a case-by-case basis for commodities with very similar shapes, volumes, and weights. For example, data for peach and nectarine may be translated to persimmon.

125 Considerations of expanded crop group MRLs should be undertaken on a case-by-case basis and should be based on the following factors:

- Use pattern
- Systemic vs. non-systemic
- Stability (degradation rate)
- Residue levels measured across several crop or commodity types
- Properties of the harvested commodity

126 Determination of the sameness of the GAP should take into account not only the label instructions (rate, application method, timing, PHI) but also local agronomic practices that might impact the residue level. For example, wheat is generally grown under similar practices around the world, but grapes may be grown under widely varying practices. For the latter, care should be taken to ascertain if the relevant GAPs are actually the same. If adequate data are available, a test of the lack of difference of the data populations would be useful.

DATA REPORTING

127 Regulatory authorities recognise there are sections in the guideline, which do not apply in all cases. Therefore, applicants should exercise scientific judgment in deciding which portions are germane to a specific data submission. In particular, uses such as seed treatments and post-harvest applications will have elements, which are not applicable to other types of treatments or need to be modified to address the unique characteristics of these uses. For example, soil characteristics are not applicable to post-harvest applications. It is proposed to use the specific OECD Harmonised Template 85-5 as standard data format for reporting information. This template can be downloaded from the OECD webpage.

128 OECD Harmonised Templates (OHTs) were developed to be used for the risk assessment of chemicals, mainly studies done on chemicals to determine their properties or effects on human health and the environment, but also for storing data on use and exposure. They are aimed at developers of database systems, as they prescribe the formats by which information can be entered into and maintained in a database. By using these templates, governments and industry are easily able to electronically exchange study summary information.

129 The templates can be used to report summary test results for any type of chemical (e.g., pesticides, biocides, industrial chemicals). The OECD Harmonised Templates cover endpoints and reporting elements which are grouped as follows:

Administrative Data/Data Source

130 This section contains the following elements.

1) Reference, Study ID, Title, Author(s), Publication date, Report No., Study dates
2) Testing Laboratory
3) Test Guideline, including deviations
4) Purpose of studies
5) GLP Compliance

Materials and Methods (see below for more details)

Results and Discussion (see below for more details)

1) Results (including raw data on individual field trials and 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).
2) Storage stability / Storage period for samples should be compared to those utilised in storage stability study.
3) 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).

Overall remarks/Attachments

131 Concerning data tables and other graphic representations it is referred to the section "Organisation of data tables and forms".

Applicant's Summary and Conclusion

132 In addition to a textual summary/conclusion, the following maps/tables are expected to be reported in this section.

1) Summary map of crop field study sites (by crop)
2) Summary tables of residue results of individual field trials
3) Graphic representations (e.g., residue decline, figures, flowcharts, etc.)
4) Summary tables of recovery data via the analytical methodology
5) Summary tables of storage stability validation data
6) Chromatograms (as applicable)

133 In the following more details are provided concerning the information expected in the key chapters "Materials and Methods" and "Results".

Information/raw data on individual field trials (specifically, each individual field trial report should include the following information):

Test substance (pesticide)

134 For the description of the test substance (pesticide) the following information should be provided.

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

2) 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.

3) Information on other relevant parameters, as pertinent, (e.g., tank mates, spray additives, carrier (encapsulating polymer, etc.)).

4) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the test substance.

Test commodity (RAC).

135 For the description of the test commodity (raw agricultural commodity (RAC)) the following information should be provided.

1) Identification of the RAC, including type/variety.

2) 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.

3) 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.

4) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the RAC.

Test procedures

136 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 is expected. The information provided, which may be presented on standardised field sheets, should include (in addition to a description of the test substance and test commodity):

1) Trial identification number.

2) Cooperator (name, address), test location (e.g., state, country) and year.

3) 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).

4) Cultural treatments - farming practice (cultivation, irrigation, etc.) and cropping system.

5) 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.

6) Application rates (amount of active ingredient and formulated product per acre, row, volume, etc.) and spray volumes per acre or hectare.

7) 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)).

8) 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).

9) Meteorological data (record of temperature and rainfall during the growing season from the nearest weather station, and wind speed during application).

10) 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).

11) 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.) and post-harvest procedures such as quartering or other subsampling in the field.

12) Quality control (control measures/precautions followed to ensure the fidelity of the crop field test).

13) 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.

137 A detailed description of the handling, pre-shipping storage, and shipping procedures for harvested RAC samples is expected. The information provided, which may be presented on a standardised form, should include (in addition to a description of the test substance and the test commodity):

1) Sample identification (means of labelling/coding).

2) Conditions (temperatures, container types/sizes, sample sizes, form (e.g., whole commodity; chopped), etc.) and duration of storage before shipping.

3) Methods of packaging for shipment (container types/sizes, sample sizes, ambient/iced, labelling/coding, etc.).

4) Means of transport from the field to the laboratory.

5) Dates (harvest, pre-shipping storage, shipping, and receipt in the laboratory).

6) Quality control (control measures/precautions followed to ensure the integrity of harvested samples during handling, pre-shipping storage, and shipping operations).

7) Other. Any and 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.

138 A detailed description of the conditions and length of storage of harvested RAC samples following their receipt in the laboratory is necessary (see section “Storage Stability”).

139 A detailed description of the residue analytical methods used for field trial and storage stability samples should be provided (this is detailed below in the section " Analytical Methodology"). 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.

140 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 standardised form, should include:

1) 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.

2) 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.

3) Dates: Test sample preparation (maceration/extraction/etc.), test compounds preparation (standard solutions of known concentration), residue analyses.

4) 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.

5) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of analytical methodology validation procedures.

Organisation of data tables and forms.

141 The following elements are expected in this section.

1) Tables of residue assay data for specific plant parts analysed. Residue levels should be reported uncorrected. Corrected values may also be presented but the procedure needs to be explained with sample calculations.

2) Tables on residue recovery values.

3) Graphs, as pertinent (e.g., residue decline).

4) Forms containing field trial history information.

5) Forms containing harvesting, shipping, storage information.

6) Tables of weather data if unusual conditions claimed to result in aberrant residues.

Trial Information

142 Geographic Location (Trial Specific information – should be provided for all trial locations):

1) Trial ID No (Trial Specific, unequivocal identification code (e.g., Company Internal Code)

1.1 Trial Deviation (List any deviations which may impact the trial results or study conclusions)

2) Year (the year in which the first GLP data are collected in trial)

3) Country

4) Geographic Region (e.g., EU – N, EU – S, CANADA/MEXICO/USA 1….CANADA/MEXICO/USA 14)

5) State/Province (e.g., Bavaria/Germany)

6) County

7) City

8) GPS Coordinates (Optional)

9) Crop

Derived from EPPO plant thesaurus, can be updated by EPPO code members. In the case of post- harvest treatment of a harvested commodity, list the crop from which the harvested commodity was derived. The same applies for seed treatment. e.g., Sweet orange is written in EPPO code as CIDSI.

9.1 Crop Variety (e.g., Blood orange)

Crop Code

Codes can be obtained from www.eppo.org, utilise lowest (most detailed) level

143 Plot (Information should be provided for all plots):

1) Plot ID (Unequivocal Plot Identification; e.g., consecutive number). Numerical field or combination

2) Control Plot (yes or no)

3) 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.

4) Soil Characterization (name/designation of the soil type, e.g., sandy loam, sandy clay loam, etc.). If application rate of the pesticide is dependent on any soil properties such as percent of organic matter, these should also be described.

5) Environmental Conditions

Describe abnormal weather conditions, if applicable, 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

6) 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

7) 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

8) Application

(a) Application No (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 (BBCH) 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 (dd/mm/yyyy)

(d) 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

(e) Method of Application

(f) Seeding Rate (Used in conjunction with seed treatment. Using this, combined with no. seeds/ Unit, one can determine TGW (Thousand Grain Weight), etc.)

(g) Number of seeds/unit (no. seeds/kg, no. seeds/lb)

(h) Test Item/Test Material (Pesticide(s) tested in this study)

The term 'test item' is identical to the term 'test material', which is used in OHT 85-5.

- Description of tested Pesticide Product, End-Use Product, formulation, treated/dressed seed, etc. used in the test
- 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 including Adjuvant Type, Adjuvant Name, Adjuvant amount in Spray Volume (%)
- Amount of water used in spray application (actual)

9) 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 (BBCH) at sampling

(e) Date of Sampling (dd/mm/yyyy)

(f) Sampling Information (Optional)

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 may be separated into several analysis samples, e.g., whole orange may be separated into a peel sample and a pulp sample for analysis (in that case also give weights of peel and pulp), aspirated grain fractions are separated from grain. In OHT 85-5 this is called 'reference portion'.

- Analysis Sample ID
- Analysis Sample Description (Optional)
- 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). Some regulatory authorities do not allow this value to 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

Analytical Methodology

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

1) Analytical Method Information
2) Fortification Level
3) Recovery (%)

Storage Stability

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

REFERENCES – CITATIONS – LINKS

US and Canada

EPA – OPPTS 860.1000 Residue Chemistry Test Guidelines and 860.1500 Crop Field Trials, https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-860-residue-chemistry-test-guidelines

PMRA – Residue Chemistry Guidelines Section 9, Crop Field Trials, Regulatory Directive 98-02 at https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines.html

Joint Canada/United States Field Trial Requirements, Science Policy Note SPN2017-02, Pest Management Regulatory Agency, Health Canada, 11 July 2017. Actual version at https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/science-policy-notes/2017/guidance-joint-canada-united-states-field-trial-requirements-spn2017-02.html

Reduced Residue Chemistry Data Requirements for Seed-Treatment Uses, Memo, US EPA, 26 January 2018. Actual Version at https://www.epa.gov/sites/production/files/2018-01/documents/final-chemsac-seed-treatment-signed-012518.pdf

EU

European Commission, 1997. General Recommendations for the Design, Preparation and Realization of Residue Trials. SANCO 7029/VI/95 rev.5. Actual version at https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

European Commission, 2017. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95 Rev. 10.3. Actual version at https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

New Zealand

Data Requirements for A Food of Feed Use Clearance Plant Compounds, 41 ACVM 06/03 http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/pc-food-clearance.pdf

Australia

Australian Pesticide Veterinary Medicine data guideline: Residue trials to obtain permanent maximum residue limits for crops 1 July 2014

https://apvma.gov.au/node/1028

Brazil (non-OECD country included for reference only)

Sindicato Nacional da Industria de Produtos Para Defesa Agricola, Sao Paulo, December 18, 2006

Other documents:

Minimum Data Requirements for Establishing Maximum Residue Limits (MRLs) including Import Tolerances; Recommendations from the Scientific Workshop held at the Pesticides Safety Directorate, York, UK on 6-8 September 1999; Doc. 2734/SANCO/99 (prepared for the European Commission by Caroline Harris and Jeff Pim, Pesticides Safety Directorate, Mallard House, Kings Pool, 3 Peasholme Green, York, YO1 7PX, UK,on 29 September 1999)

A Survey Report to Follow-up the Development of the Concept of Minimum Data Requirements for Establishing Maximum Residue Limits (MRLs) Including Import Tolerances for Pesticides (2004)

Report of the OECD/FAO Zoning Project (2004)

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OECD Guidance Document on Crop Field Trials, Second Edition, Series on Pesticides - No. 66 and Series on Testing & Assessment - No. 164, ENV/JM/MONO(2011)50/REV1, 7th September 2016

OECD Guidelines for the Testing of Chemicals, TG 506: Stability of Pesticide Residues in Stored Commodities. Organisation for Economic Co-operation and Development, 16 October 2007.

OECD Guidance Document on Pesticide Residue Analytical Methods [ENV/JM/MONO(2007)17]. Environment, Health and Safety Publication, series on Testing and Assessment No. 72; 2007.

OECD Guidance Document on the Definition of Residue [ENV/JM/MONO(2006)31]. Environment, Health and Safety Publication, series on Testing and Assessment, No. 63; series on Pesticides, No. 31, 2006. (under revision).

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James Nguyen, Carmen Tiu, Jane Stewart, and David Miller, Global Zoning and Exchangeability of Field Trial Residues Between Zones: Are There Systematic Differences in Pesticide Residues Across Geographies? Statistics and Public Policy 2019, Vol. 6, No 1, 14–23, https://doi.org/10.1080/2330443X.2018.1555068

Denis Hamilton, Árpád Ambrus, Roland Dieterle, Allan Felsot, Caroline Harris, Barbara Petersen, Ken Racke, Sue-Sun Wong, Roberto Gonzalez, Keiji Tanaka, Mike Earl, Graham Roberts and Raj Bhula. Pesticide residues in food—acute dietary exposure, Pest Manag Sci. 60: 311-339, 2004

Annex 1 Raw Agricultural Commodities and Feedstuffs Derived from Crops (compiled from Codex Classification and the FAO Manual)

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
001 Citrus fruits			Fruit, whole	Whole commodity. Analyse peel and pulp separately; calculate and express the residue on the whole commodity	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
	001A, Lemons and Limes	Lemon			
		Lime			
	001B, Mandarins	Mandarin			
	001C, Oranges, Sweet, Sour	Orange			
	001D, Shaddock and Pomelos	Pummelo			
		Grapefruit			
002 Pome fruits			Fruit, whole	Whole commodity after removal of stems.	12 fruits from several places on 4 individual

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					trees. If this produces a sample weight of less than 2 kg, more fruit should be taken to yield a 2 kg sample
		Apple			
		Pear			
003 Stone fruits			Fruit	Whole commodity after removal of stems and stones but residue calculated and expressed on the whole fruit.	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
	003A Cherries	Cherry, sweet			Small stone fruit e.g., cherries: 1 kg from several places on 4 trees
		Cherry, sour			
	003B Plums	Plum			
		Prune Plum			
	003C Peaches	Apricot			
		Peach			
004 Berries and other small fruits				Whole commodity after removal of caps and stems. Currants, Black, Red, White: fruit with stem.	
	004A Cane berries	Blackberry	Berry		1 kg from 12 separate areas or 6 bushes
		Raspberry	Berry		
	004B Bush berries	Blueberry	Berry		1 kg from 12 separate areas or 6 bushes

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
		Currants, black, red or white	Berry		
	004C Large shrub/tree berries	Elderberry	Berry		1 kg from 12 separate areas or bushes
	004D Small fruit vine climbing	Grape (table grape; wine grape)	Fruit		12 bunches, or parts of 12 bunches, from separate vines to give at least 1 kg
	004E Low growing berries	Strawberry	Berry		1 kg from 12 different plants
005 Assorted tropical and sub-tropical fruits - edible peel				Whole commodity. Dates, olives and similar fruits with hard seeds: Whole commodity after removal of stems and stones but residue calculated and expressed on the whole fruit	1 kg from several places on 4 trees
	005A Assorted tropical and sub-tropical fruits - edible peel – small	Olive	Fruit		
	005B Assorted tropical and sub-tropical fruits - edible peel – medium to large	Fig	Fruit		
		Guava	Fruit		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

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
	005C Assorted tropical and sub-tropical fruits - edible peel – palms	Date	Fruit		
006 Assorted tropical and sub-tropical fruits – inedible peel		**Note: For all tropical or sub-tropical fruits with inedible peel, analyse peel and pulp separately; calculate and express the residue (MRL) on the whole commodity**		Whole fruit unless qualified: e.g., banana pulp. Pineapple after removal of crown. Avocado, mangos and similar fruit with hard seeds: Whole commodity after removal of stone but residue calculated and expressed on whole fruit.	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
	006A, Assorted tropical and sub-tropical fruits – inedible peel – small	Lychee (= litchi)	Fruit		
		Logans	Fruit		
		Spanish lime	Fruit		
	006B, Assorted tropical and sub-tropical fruits –inedible smooth peel - large	Avocado	Fruit		
		Mango	Fruit		
		Pomegranate	Fruit		
		Banana	Fruit	.	24 fruits. Take two fingers each from top, middle and lowest hand of four harvestable bunches
		Papaya	Fruit		

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
	006C, Assorted tropical and sub-tropical fruits – inedible rough or hairy peel – large	Pineapple	Fruit		12 fruits
		Atemoya	Fruit		
	006D, Assorted tropical and sub-tropical fruits – inedible peel – cactus	Pitaya			
		Prickly pear	Fruit		
	006E, Assorted tropical and sub-tropical fruits – inedible peel – vines	Kiwifruit	Fruit		
		Passion fruit	Fruit		
	006F, Assorted tropical and sub-tropical fruits – inedible peel – palms	Muriti	Fruit		
		Palmyra Palm	Fruit		
009 Bulb vegetables		Bulb vegetables may be rinsed lightly in cold running water, brushing gently with a soft brush to remove loose soil and debris, if necessary, and then dab lightly with a clean tissue paper to dry.		Bulb onions: Whole commodity after removal of roots and adhering soil and whatever parchment skin is easily detached. Green onions: Whole vegetable after removal of roots and adhering soil.	
	009A, Bulb onions	Onion, bulb	Bulb		12 bulbs from 12 plants.(the sample should weigh at least 2 kg - where necessary, take a

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					larger number to produce a 2 kg sample)
	009B, Green onions	Spring onion	Whole plant, without roots		24 plants (the sample should weigh at least 2 kg – where necessary, take a larger number to produce a 2 kg sample)
		Leek	Whole plant		12 plants, min 2 kg
010 Brassica vegetables (except Brassica leafy vegetables)				Head cabbages and Kohlrabi: Whole commodity as marketed, after removal of obviously decomposed or withered leaves. Cauliflower and broccoli: flower heads (immature inflorescence only). Brussels sprouts: "buttons" only. Kohlrabi: "tuber-like enlargement of the stem" only	
	010A Flowerhead Brassicas	Broccoli	Flower head and stem.		1 kg from 12 plants
		Cauliflower Flower	Flower head and stem		12 plants
	010B Head Brassicas	Brussels sprouts	Leaf sprouts		1 kg from 12 plants. Buttons to be taken

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					from at least two levels on each plant
		Head cabbage (white cabbage; red cabbage; Savoy cabbage) or Chinese cabbage (type Pe-tsai)	Fresh heads, with wrapper leaves		12 plants
	010C Stem Brassicas	Kohlrabi	Globe without leaves		12 plants
011 Fruiting vegetables, Cucurbits				Whole commodity after removal of stems	
	011A Fruiting vegetables, Cucurbits – Cucumbers and Summer squashes	Cucumber	Fruit		12 fruits from 12 separate plants
		Gherkin	Fruit		12 fruits from 12 separate plants (the sample should weigh at least 2 kg – where necessary, take a larger number to produce a 2 kg sample)
		Squash, summer	Fruit		12 fruits from 12 plants (the sample should weigh at least 2 kg - where necessary take a larger number of fruit to produce a 2 kg sample
	011B Fruiting vegetables, Cucurbits – Melons,	Melon (Cucumis melo)	Fruit		12 fruits from 12 separate plants

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
	Pumpkins and Winter Squashes				
012 Fruiting vegetables, other than Cucurbits				Whole commodity after removal of stems	
	012A Tomatoes	Tomato (large and small variety)	Fruit		24 fruits from small-fruiting varieties, 12 from large fruiting varieties. From 12 plants in all cases (the sample should weigh a minimum of 2 kg; where necessary take a larger number of items to produce a 2-kg sample.)
	012B Pepper and pepper-like commodities	Okra	Fruit (pods)		1 kg from 12 plants
		Sweet pepper	Fruit		24 fruits from small-fruiting varieties, 12 from large fruiting varieties. From 12 plants in all cases (the sample should weigh a minimum of 2 kg; where necessary take a larger number of items to produce a 2-kg sample.)
		Chili pepper	Fruit		24 fruits from small-fruiting varieties, 12 from large fruiting varieties. From 12

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					plants in all cases (the sample should weigh a minimum of 2 kg; where necessary take a larger number of items to produce a 2-kg sample.)
	012C Eggplant and eggplant-like commodities	Eggplant (= aubergine) (large and small variety)	Fruit	Whole commodity after removal of stems.	12 fruits from 12 separate plants
013 Leafy vegetables (including Brassica leafy vegetables)				Whole commodity as usually marketed, after removal of obviously decomposed or withered leaves.	
	013A Leafy greens	Lettuce, leaf	Leaves		12 plants
		Lettuce, head	Fresh head, with wrapper leaves		12 plants
		Lambs' lettuce	Leaves and stems		0.5 kg from 12 plants (or sites in plot)
		spinach	Greens (leaves)		1 kg from at least 12 plants
	013B Brassica leafy vegetables	Cress	Leaves and stems		0.5 kg from 12 plants (or sites in plot)
		Kale, collards	Leaves		2 kg from 12 plants sampled from two levels on the plan
		Radish, leaves	Leaves		0.5 kg from 12 plants (or sites in plot)
		Mustard, greens	Greens (leaves)		0.5 kg from 12 plants (or sites in plot)

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
	013C Leaves of root and tuber vegetables	Sweet potato leaves	Leaves		0.5 kg from 12 plants (or sites in plot)
		Arrowroot leaves	Leaves		0.5 kg from 12 plants (or sites in plot)
	013D Leaves of trees, shrubs and vines	Grape leaves	leaves		0.5 kg from 12 areas from separate vines
	013E Leafy aquatic vegetables	Kangkung	Leaves and stems		0.5 kg from 12 plants (or sites in plot)
		Water mimosa or watercress	Leaves and stems		0.5 kg from 12 plants (or sites in plot)
		Watercress	Leaves and stems		0.5 kg from 12 plants (or sites in plot)
	013F Witloof	Witloof chicory (sprouts)			1 kg from 12 plants
	013G Leaves of Cucurbitaceae	Chayote leaves	Leaves		0.5 kg from 12 plants (or sites in plot)
		Pimpkin leaves	Leaves		
	013H Baby leaves	Leaf lettuce or any crop intended to use as baby leaves (harvested up to 8 true leaf stage)	Leaves		0.5 kg from 12 plants (or sites in plot)
	013I Sprouts	Mung bean[3] sprouts	Bean sprouts	Whole commodity	0.5 kg
014 Legume vegetables				Whole commodity, unless otherwise specified.[11]	
	014A Beans with pods	Beans with pods (Phaseolus spp.)[1]	Beans (green) with pods		1 kg
	014B Peas with pods	Peas with pods (Garden pea or podded pea) and/or Beans with pods (Phaseolus spp.)	Peas (green) with pods		1 kg
	014C Succulent beans without pod	Succulent beans without pods (Phaseolus spp.)	Succulent (green) seeds		1 kg

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
	014D Succulent peas without pods	Garden pea	Succulent (green) seeds		1 kg
	014E Underground immature beans and peas	Bambara groundnut (immature seeds)			
015 Pulses			Dry seeds	Whole commodity	1 kg
	015A Dry beans	Bean, dry[2] (Phaseolus spp.)	Dry seeds		
		Soya bean, dry			
		Cowpea	Seed		
		Lupine	Seed		
		Mung bean[3]	Bean		
	015B Dry peas	Pea, dry (Pisum spp.)	Dry seeds		
		Lentil, dry	Seed		
		Pea, field[4]	Seed		
	015C Dry underground pulses	Bambara groundnut (dry)			
016 Root and tuber vegetables				Whole commodity after removing tops. Remove adhering soil (e.g. by rinsing in running water or by gentle brushing of the dry commodity).	12 tubers (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
	016A Root vegetables	Beet, sugar	Root	Leaves with heads are separated from the roots.	12 plants
		Beet, garden (= Beetroot)	Root		
		Carrot	Root		
		Celeriac	Root		
		Chicory, Salsify	Root		
		Horseradish	Root		
		Parsnip, Rutabaga (= swede),	Root		

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
		Radish	Root		
	016B Tuberous and corm vegetables	Cassava= tapioca	Roots		
		Jerusalem artichoke	Tuber		
		Potato, or sweet potato	Tuber		
		Taro	Corm		
	016C Aquatic root and tuber vegetables	Arrowhead			
017 Stalk and stem vegetables				Whole commodity as marketed after removal of obviously decomposed or withered leaves. Rhubarb, leaf stems only: globe artichoke, flowerhead only, celery and asparagus, remove adhering soil.	
	017A Stalk and stem vegetables - Stems and Petioles	Celery	Untrimmed leaf stalk (petiole)		12 plants
		Rhubarb	Spears (stems)	Stems only.	12 sticks from 12 separate plants. (The sample should weigh a minimum of 2 kg; where necessary take a larger number of sticks to produce a 2 kg sample)
	017B Stalk and stem vegetables - Young shoots	Asparagus	Spears (stems);	Stems only.	12 sticks from 12 separate plants. (The sample should weigh a minimum of 2 kg;

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					where necessary take a larger number of sticks to produce a 2 kg sample)
	017C Stalk and stem vegetables - Others	Artichoke, globe	Flower head	Whole commodity after removal of obviously decomposed or withered leaves.	12 flowerheads
018 Edible Fung		Mushroom	Cap and stem	Whole commodity after removal of soil and growing medium	12 items (the sample should weigh at least 0.5 kg – where necessary take a larger number of items to produce a 0.5 kg sample)
020 Cereal grains				Whole commodity in trade. Wheat, rye, triticale, maize, sorghum, pearl millet and other similar cereals with husks readily separable from kernels during threshing: kernels. Barley, oats, rice and other similar cereals with husks that remain attached to kernels even after threshing: kernels with husks (Note: For rice, only about 10% of traded	1 kg (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
				grains is with husk). Corn-on-the-cob (kernels plus cob with husk removed)	
	020A Wheat, similar grains, and pseudocereals without husks	Triticale	Grain		
		Rye	Grain		
		Wheat	Grain		
	020B Barley, similar grains, and pseudocereals with husks	Barley	Grain		
		Buckwheat	Grain		
		Oats	Grain		
	020C Rice Cereals	Rice	Grain		
	020D Sorghum Grain and Millet	Sorghum	Grain		
		Millet	Grain		
	020E Maize Cereals	Maize	Grain		
		Corn, pop	Grain	Whole commodity (grain without husk or cob)	1 kg
	020F Sweet Corns	Corn, sweet (Corn-on-the-cob) (kernels plus cob with husk removed)	Sweet corn (K + CWHR = kernels plus cob with husk removed)		
021 Grasses for sugar or syrup production		Sorghum, sweet	Stalk		
		Sugarcane	Cane	Whole commodity	Select whole canes from 12 areas of the plot and take short, e.g., 20 cm, sections

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					from all parts of the length of the canes.
		Sorgo			
		Sorghum, sweet			
022 Tree nuts				Whole commodity after removal of shell.	1 kg
		Almond	Nutmeat		
		walnut	Nutmeat		
		pecan	Nutmeat		
		chestnut	Nutmeat		
		pistachio	Nutmeat		
		Coconut	Coconut (meat and liquid combined)	Whole commodity after removal of shell. Analyse meat (= flesh) and liquid (=milk) separately; calculate and express the residue on the whole edible portion (meat and liquid).	12 nuts
023 Oilseeds and oilfruits				Oilseeds: Unless otherwise specified, seed or kernels, with shell or husk. Oilfruits: whole commodity	2 kg from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)
	023A Small seed oilseeds	Rape = rape seed = oilseed rape = canola	Seed		
		Flax = linseed	Seed		

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
		Sesame	Seed	Whole commodity	
	023B Sunflower seeds	Sunflower	Seed, dry	Whole commodity	
		Safflower	Seed	Whole commodity.	
	023C Cotton seed	Cotton	Undelinted seed	Whole commodity.	
	023D Other oilseeds	Peanut	Nutmeat	Whole commodity.	
	023E Oilfruits	Olives for oil production	Fruit, fresh	Whole commodity after removal of stems and stones but residue calculated and expressed on the whole fruit.	1 kg from several places on 4 trees Record weight ratio of stone and flesh.
024 Seeds for beverages and sweets		Cacao bean	Bean	Whole commodity.	1 kg
		Coffee	Bean	Whole commodity	1kg
025 Tree saps		Any commodity in this subgroup	Sap	Whole commodity	0.5 l
027 Herbs				Whole commodity as marketed, mainly in the fresh form.	0.5 kg fresh
	027A, Herbs (herbaceous plants)	Parsley	Leaves, fresh		
		Mint (Spearmint and, Peppermint) or Basil [or Leaf lettuce or Spinach]	Tops (leaves and stems)		
	027B Leaves of woody plants	Any commodity in this subgroup or Leaf Lettuce or Spinach	Leaves		
	027C Edible flowers	Any commodity in this subgroup or Leaf Lettuce or Spinach	Flowers		

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
028 Spices[9]				Unless specified, whole commodity as marketed, mainly in the dried form.	0.2 kg dry
	028A Spices, seeds	Any commodity in this subgroup			
	028B Spices, fruit or berry	Any commodity in this subgroup			
	028C Spices, bark	Any commodity in this subgroup			
	028D Spices, root or rhizome	Any commodity in this subgroup or commodity rom Root and Tuber Vegetables, applying an appropriate concentration factor			
	028E Spices, buds	Any commodity in this subgroup			
	028F Flower or stigma	Saffron			
	028G Spices, aril	Mace			
	028H Citrus peel	Any commodity in this subgroup			
	028I Dried Chili Peppers	Any commodity in this subgroup			
The following groups are under discussion in Codex					
050 Legume animal feeds			Fodder		2 kg from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it

Codex Commodity Group	Codex Subgroups	Crop	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					proceeds through the crop.)
			Hay		0.5 kg from 12 separate areas of plot
			Straw		0.5 - 1 kg from 12 separate areas of plot
			Forage		1kg from 12 separate areas of plot
		Soya bean	aspirated grain fractions[5]	North American requirement – Refer to OPPTS 860.1500 and Directive 98-02	
051 Straw, fodder and forage of cereal grains and grasses, except grasses for sugar production (including buckwheat fodder)			Fodder		2 kg from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)
			Hay		0.5 kg from 12 separate areas of plot
			Straw		0.5 - 1 kg from 12 separate areas of plot
			Forage		1kg from 12 separate areas of plot
		Wheat, sorghum, maize	Aspirated grain fractions[5]	North American requirement – Refer to OPPTS 860.1500 and Directive 98-02	
		Maize, pop corn, sweet corn	Stover[6]		

		Sorghum	Stover[7]		
		Grass (pasture & range-land)	Forage	Whole commodity	1 kg
		Grass (pasture & range-land)	Hay	Whole commodity	0.5 kg
052 Miscellaneous Fodder and Forage crops			Fodder		2 kg from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)
			Hay		0.5 kg from 12 separate areas of plot
			Straw		0.5 - 1 kg from 12 separate areas of plot
			Forage		1kg from 12 separate areas of plot
		Almond	Hulls	Whole commodity after removal of shell and nutmeat	1 kg
		Cotton seed	Cotton gin byproducts[8]		
057 Dried herbs		Hops	Hops cones, dried	Whole commodity.	Take green cone samples from at least 4 hop plants. Select cones from all parts of the plant, top and bottom, exposed and protected by foliage. Final product is at

					least 0.5 kg dried cones
066 Teas		Tea[10] (Camellia sinensis)	Plucked and dried leaves	Whole commodity as prepared for wholesale or retail distribution.	0.2 kg dry leaves

General Remarks

(A) Codex Commodity Groups and Subgroups for groups 001 to 028 as adopted; additional groups added are under discussion. They are added without prejudice to any later changes.

(B) Representative Crops according to agreed Codex Classification are underlined. It is not the aim of this table to exactly reproduce representative crops as agreed in Codex. Deviations from Codex Classification and/or from FAO Manual are intended. It is also not intended to repeat the codes from the Codex Classification here.

(C) The crops mentioned are examples. Crops belonging to the same group/subgroup should be handled in the same way. It is noted that for some Raw Agricultural Commodities edible portion(s) for some crops may vary between regions. Therefore, sampling should be used in an adequate manner.

Footnotes

1 Succulent seed without pod for beans consumed as succulent shelled beans (e.g., lima beans); succulent seed with pod for edible-podded beans (e.g., snap beans)

2 Beans consumed as dried shelled beans

3 Data on mung bean covers sprouts except when the product is used on the sprouts per se.

4 Does not include the canning field pea cultivars used for human food. Includes cultivars grown for livestock feeding only (such as Austrian winter pea). Field pea vines: Cut sample anytime after pods begin to form, at approximately 25 percent DM (dry matter). Field pea hay: Succulent plant cut from full bloom through pod formation. Hay should generally be field-dried to a moisture content of 10 to 20 percent.

5 Aspirated grain fractions (previously called grain dust). Dust collected at grain elevators for environmental and safety reasons. Residue data should be provided for any post-harvest use on corn, sorghum, soybeans, or wheat. For a pre-harvest use after the reproduction stage begins and seed heads are formed, data are useful unless residues in the grain are less than the limit of quantitation of the analytical method. For a pre-harvest use during the vegetative stage (before the reproduction stage begins), data will not normally be needed unless the plant metabolism or processing study shows a concentration of residues of regulatory concern in an outer seed coat (e.g., wheat bran, soybean hulls). Data needs vary among regulatory authorities.

6 Corn stover: Mature dried stalks from which the grain or whole ear (cob + grain) has been removed; containing 80 to 85 percent DM.

7 Sorghum stover: Mature dried stalks from which the grain has been removed; containing 80 to 85 percent DM.

8 Cotton gin byproducts (commonly called gin trash). Include the plant residues from ginning cotton, and consist of burrs, leaves, stems, lint, immature seeds, and sand or dirt. Cotton should be harvested by commercial equipment (stripper process) to provide an adequate representation of plant residue for the ginning process. Field trials for only the stripper type of harvesting are generally needed. Data reflecting picker cotton are not required.

9 Spices include aromatic seeds, buds, bark, berries, pods, and roots consumed and marketed primarily in their dried form.

10 Residue data are needed on plucked (or freshly picked) leaves and dried tea.

11 For Reference see Codex Classification