OECD/OCDE 509

OECD GUIDELINE FOR THE TESTING OF CHEMICALS

Crop Field Trial

Revised May 2020

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;

103) to determine residue values such as the Supervised Trial Median Residue (STMR)11and Highest Residue (HR) for conducting dietary risk assessment and calculation of the12dietary burden of livestock; and

4) to derive maximum residue limits (MRLs).

14 Crop field trials may also be useful for selecting residue definitions by providing 15 information on the relative and absolute amounts of parent pesticide and metabolites.

16 2 For the purposes of this document the terms "crop field trial" and "supervised field 17 trials" are synonymous. The term "crop field trial" will be used in the remainder of the 18 document. In addition to addressing studies for residues in crops grown in fields (i.e., 19 outdoors), this guideline also includes studies to assess residues in protected crops grown 20 in greenhouses (glass or plastic covering) and in crops treated after harvest (e.g., stored 21 grains, wax or dip treatment of fruits).

223This Crop Field Trial test guideline provides a harmonised approach to conducting23and reporting crop field trials in OECD member countries. This guideline, along with the24Guidance Document on Crop Field Trials [ENV/JM/MONO(2011)50/REV1], provides for25generation of complete field trial data sets for pesticide uses on crops in comprehensive26submissions to all OECD countries.

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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.
- 52 7 Residue data from only one season are considered sufficient provided that crop field 53 trials are located in a wide range of crop production areas such that a variety of 54 meteorological conditions are taken into account.
- 55 8 In the case of up to 25 % increases or decreases of the active ingredient application 56 rate, the number of applications, or the PHI, under otherwise identical conditions, the 57 residue results can be assumed to be comparable. When combining field trials for a 58 complete data set for a crop use, this "25 % rule" may be applied to any one of the cGAP 59 components; however, it is not acceptable to apply the rule to more than one cGAP 60 component listed here at a time.
- 61 <u>Note</u>: When residues primarily depend on the crop growth stage at application (e.g. 62 flowering stages) it may not be appropriate to apply the +/-25% rule to the delay between 63 (last) application and harvest (and select all trials for which this delay within the PHI +/-64 25% (see paragraph 47).
- 65 9 This crop field trial guideline requires one sample from treated plots at each 66 sampling interval for crops that have 8 or more crop field trials. Some OECD countries 67 require analysis of two independently collected samples.

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PLOT AND CROP CHARACTERISTICS

69 Plot Size

10 Plot size may vary from crop to crop. However, plots should be large enough to 70 allow application of the test substance in a manner which reflects or simulates routine use 71 and such that sufficient representative sample(s) can be obtained without bias, generally at 72least 10 m² for row crops and typically 4 trees or 8 vines for orchard and vineyard crops. 73 Plots should also be large enough to avoid contamination during mechanical sampling or 74 harvesting if applicable. Control (untreated) plots should be located in the immediate 75 vicinity of the treated plot(s) so that cultivation and cropping take place under 76 similar/identical conditions. Where treated and control plots are in close proximity, 77 measures should be taken to avoid contamination (e.g., covering or shielding crop if 78 necessary). It is also important to ensure that plots are adequately buffered or separated. 79 There is no minimum distance between plots which ensures adequate buffering, however 80 prevailing wind, slope and distance between plots should all be considered prior to 81 designing the field trial. 82

83 11 Post-harvest treatments on stored products such as potatoes, grains and seeds are 84 often carried out in a number of storage locations with variable conditions in regard to 85 temperature, humidity, aeration, etc. Information should be available on the use practice 86 and all the conditions under which the treated commodities are kept. How commodities 87 are stored during application can vary from commodities stacked in sacks, box stores and 88 heaps to automated systems in large-scale silos or automated systems for fruit treatment.

89 Crop Variety

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.

97 Crop Maintenance and Horticultural Practices

98 13 Trials should be conducted in regions where the crops are predominantly grown 99 commercially and should reflect the main types of crop maintenance and agricultural 100 practices, especially those which can significantly impact residues (e.g., bagged and 101 unbagged bananas, furrow and overhead irrigation, pruning of grape leaves).

102 Crop and Plot Maintenance Products

10314Additional plant protection measures, which are not the subject of crop field trials,104are often required for crop management during the course of a study to control weeds,105disease or other pests (also may include fertilizers, plant growth regulators, etc.). These106crop and plot maintenance products should be chosen from among those products which107do not affect (i.e., interfere with) residue analyses for the components of the relevant

110 Soil Type

111 15 Soil type (e.g., sand, loam, sandy loam) should be identified and reported for all 112 crop field trial sites. If the product is directly applied to soil, the field trials should include 113 field sites with different soil types.

114 Greenhouse Uses

115 16 There are a number of protected crop scenarios such as greenhouse (glass or plastic 116 covering), plastic tunnel, shade house, etc. which offer varying degrees of protection from 117 environmental conditions. In matters related to residue trial conduct, greenhouse 118 production is defined as a crop grown in its entirety (i.e., planting to harvest) in a 119 completely enclosed structure.

TEST SUBSTANCE

121 Test Substance Handling

- 122 17 The test substance is the product or formulation used in a crop field trial for the 123 purpose of generating residue data for a specific crop or commodity.
- 124 Storage

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12518The test substance(s) should be stored under appropriate conditions for the study126duration and applied soon after preparation or mixing.

127 Environmental conditions

128 19 Test substance applications should not be made in strong wind, during rain or when 129 rainfall is expected shortly after application.

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

- 131 20 If residue data are generated for a single active ingredient, there are no additional 132 data requirements for tank mix, pre-mix or other types of combinations with other active 133 ingredients as long as there is no evidence of synergism associated with the combination(s) 134 and as long as the cGAP for the active ingredient is not exceeded with any of the 135 combinations.
- 136 21 In many cases, active ingredients may be applied in combination (i.e., tank mix, 137 pre-mix or sequential) in crop field trials to a single treated plot as long as there is clear 138 analytical separation (i.e., no analytical interference) of active ingredients and any relevant 139 metabolites. A single sample may then be collected from the treated plot and prepared for 140 residue analysis for two or more active ingredients. Exceptions from this rule are 141 combinations with active ingredients known to be synergistic like morpholine derivatives

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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.

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146 **Formulations**

22 The formulation tested in crop field trials should be as close as possible to the 147 intended end-use product for the crop or commodity. The requirements in this guideline in 148 regard to a complete data set (the number of crop field trials matching the cGAP which are 149 required) are generally based upon only one formulation type being requested for use on a 150 specific crop. Data needed to register additional formulation types or classes is dependent 151 on how similar the formulations are in composition and physical form, the mode of 152 application, and the timing of the application. General information on types of formulations 153 and data requirements for additional formulation types are given in the following 154 paragraphs. 155

23 Most types of formulations can be divided into two groups - those which are diluted 156 with water prior to application and those which are applied intact. Emulsifiable 157 concentrates (EC) and wettable powders (WP) are examples of the first type whereas 158 granules (GR) and dusts (DP) are the most common examples of the latter. Some special 159 types of formulations are described in paragraphs 29-30. A description of the various types 160 of formulations including coding is given in the Manual of the Joint Meeting on Pesticide 161 Specifications (JMPS) (FAO, 2010) [see also Table 2 in the Crop Field Trial Guidance 162 Document]. 163

164 Formulations diluted in water

The most common formulation types which are diluted in water prior to application 24 165 include EC, WP, water dispersible granules (WG), suspension concentrates (SC)(also 166 called flowable concentrates), and soluble concentrates (SL). Residue data may be 167 translated among these formulation types for applications that are made to seeds, prior to 168 crop emergence (i.e., pre-plant, at-plant, and pre-emergence applications) or just after crop 169 emergence. Data may also be translated among these formulation types for applications 170 directed to the soil, such as row middle or post-directed applications as opposed to foliar 171 treatments. 172

25 In a publication by Maclachlan and Hamilton (2010) it was shown by evaluation of 173 side by side trials with the same application rate and similar spray volumes that WP, EC, 174 CS (capsule suspension) and SC formulations do not show a significant difference in day-175 zero residues after foliar treatment (JMPR data from 2000 to 2004). The evaluation includes 176 trials with PHIs of less than seven days. If the PHI is exceeding 7 days, for mid-season and 177 178 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 179 containing oils or organic solvents (e.g., EC, OD) are also considered equivalent. Some 180 authorities may require bridging data between the two formulation types (to demonstrate 181 similarity of residue levels) where a complete data set exists for one type. 182

183 Water Soluble Bags

184 26 Placing a formulation (typically WP) in a 'water soluble' bag does not require 185 additional residue data provided adequate data are available for the unbagged product and the formulation chemistry data provided show acceptable dissolution of the water solublebag will be expected under practical conditions of use.

188 Formulations Applied Intact

18927Granular formulations applied intact will generally require a complete data set190regardless of what data are already available for other formulation types. This is based on191several observed cases of residue uptake being quite different for granules versus other192types of formulations of the same active ingredient.

193 Formulations Designed for Seed Treatments

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.

200 Controlled Release Formulations

20129Controlled release formulations (e.g., certain microencapsulated products)202normally require a complete data set tailored to that particular use. Since these formulations203are designed to control the release rate of the active ingredient, increased residues are204possible compared to other formulation types.

205 Formulations that Contain Active Ingredients as Nanomaterials

20630In general, it is expected that formulations that contain nanoparticles would have207different properties compared to normal sized material (active ingredient and/or co-208formulants). At present no definitive statement can be made as to whether or not current209data requirements are sufficient to carry out risk assessments for nanopesticides. For the210time being a complete data set is needed for plant protection products containing211nanomaterials in order to compare residue behaviour with conventional products.

212 Variants of active ingredients

21331In formulations of plant protection products, variants of the active ingredients can214be applied (e.g. salts or esters). Different salts of an active ingredient (e.g. for phenoxy215herbicides) may be considered equivalent for residue purposes in most cases regardless of216the timing of the application. However, examples for which additional data may be needed217for a new salt include the presence of counter ions that impart surfactant properties,218significantly change the degree of dissociation, or chelate with the active ingredient ion.

32 Some authorities consider that different ester formulations of an active ingredient 219 result in comparable residues when applied at PHIs longer than 7 days. If the PHI is less 220 than or equal to 7 days, these authorities treat different esters as new formulations of that 221 active ingredient for the purposes of determining data needs. Thus, a new ester could be 222 subject to a reduced data set (50% fewer trials than initial formulation with absolute 223 minimum of four trials per crop) or compared to the original ester of the active ingredient 224 in a study with at least three trials having side-by-side plots. Other authorities require the 225 reduced data set or side-by-side trials on a new ester for all uses other than those described 226 in paragraph 24 (i.e., early season or soil applications). 227

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228 Changing the content of the active ingredient in the formulation

22933Generally it is not considered necessary to provide residue data for a change in230active ingredient concentration within a specific formulation type, provided the cGAP is231not changed significantly as a result (e.g., no more than 25% increase in amount of active232ingredient per unit area).

233 Changes of co-formulants

34 Changes in formulations on the basis of a change in the content of formulants (e.g., 234 solvents) need to be evaluated on a case-by-case basis. Solvents and other inert components 235 may have an influence on the uptake or movement of the active ingredient into the plant. 236 Special consideration should be given to changes in the content of formulants like wetting 237 agents, which may lead to better penetration of the active ingredient into the plant, 238 particularly when the PHI is equal to or less than 7 days. In such a situation, at least a 239 bridging study may be needed to show that residues of the active ingredient and relevant 240 metabolites are not significantly increased by the addition of a new formulant. 241

242 Diluents and Carriers

24335Additional residue data may be required when using a diluent or carrier other than244water (e.g., vegetable oil, mineral oil). The need for these data will be determined on a245case-by-case basis.

246 Adjuvants

36 Adjuvants are products added to the spray tank for the purpose of improving the 247 performance of the test substance or active ingredient. Adjuvants such as wetting agents, 248 spreader-stickers, non-ionic surfactants, and crop oil concentrates may result in better 249 deposition, penetration, or persistence of pesticide residues in or on the plant. Therefore, 250 for a test substance which has a label allowance for the use of an unspecified adjuvant, crop 251 field trials should include an adjuvant (any locally-available adjuvant), applied according 252 to the label recommendation of the adjuvant. For a test substance which has a label 253 recommendation for the use of a specific adjuvant, crop field trials should include the 254 adjuvant, or where applicable another adjuvant with similar properties, applied according 255 to the label recommendation of the adjuvant. Applicants should consult regulatory 256 authorities for advice on whether the submission of trials with a similar adjuvant will be 257 accepted. 258

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APPLICATION PARAMETERS

260 Spray Volume

261 37 Spray volumes may differ depending on the target crop or target pest (e.g., tree 262 crops versus row crops). Crop field trials should be carried out according to the typical 263 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 264 cases. The spray volume is normally included in the GAP as a range to ensure proper plant 265 protection under all circumstances. A range may also be used to adjust for a higher leaf 266 surface area, which is normally covered by the spray concentration (see next paragraph). 267 Quite high amounts of water, e.g. more than 400 L/ha in field crops, may have the 268 disadvantage that higher amounts of active ingredient will reach the soil due to run-off from 269 the leaf surface. A very small amount of water, e.g. less than 100 L/ha in field crops, may 270 enhance spray drift. For more information on aerial applications and comparison to ground 271 sprays, refer to paragraph 57 ("Equipment and Mode of Application"). 272

273 Expression of Application Rate

274 *Application rate*

For all applications, the application rate should be expressed in terms of amount of 38 275 276 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 277 it is applied. In some cases only spray volume and spray concentrations are given. Both 278 values allow a calculation of the amount of product and/or active ingredient per unit area 279 applied. In case a range of spray volume is given the actual application rate cannot be 280 estimated and therefore the trial cannot be used for estimating the expected residue 281 resulting from a certain application rate. 282

283 Plant height and volume

28439Row crops (potatoes, wheat, soybeans, etc.) are typically treated with broadcast285sprays for which plot area (length X width) is a key consideration. In contrast, for some286crops such as tree nuts, tree fruits, trellised vegetables and vines, the crop height, crown287height or tree height (i.e., treated foliage height) should be recorded in order to allow crop288row volume or tree row volume estimations or rate per unit area calculation as needed.

289 Leaf wall area (LWA)

290 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 291 and other pests. The spray solution has to reach the leaves above the ground, which means 292 that the overall leaf area is a better description of the area to be treated. In some regions, 293 this approach based on the treated "leaf wall area" unit (LWA) is becoming the standard 294 dose expression method for three-dimensional crops. The method is described in detail in 295 EPPO General Standard PP1/239(2). The Standard also provides a method to convert 296 between the country dose expression methods. This approach both encourages a common 297 dose expression method to be used in trials for generating data and when conducing 298 assessments, whilst allowing the retention of country specific dose expression terms on 299 National labels like concentration (%) or kg (L) per hectare and m crown height. It should 300 be emphasised that this approach can only be used if all relevant parameters of crop 301 structure are recorded, to allow the appropriate dose expression conversions to be made. 302 Nevertheless, as additional information, the dose of active ingredient per hectare of ground 303 area should always be calculated and reported. 304

305 Solution concentration

30641Special consideration may be needed for foliar applications to 'tall' crops (e.g.,307orchard and vine crops, hops, greenhouse tomatoes), where flat boom spraying is not308common practice and (air assisted) mist blowing equipment is often used. It is important to

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309consider and report both the spray concentration (e.g., kg a.i./100 liters) and spray volumes310(e.g., liters spray mixture/ha) at the various crop growth stages when planning and311conducting crop field trials in these crops.

312 Seed treatment uses

31342Application rates for seed treatments are normally expressed as amount of active314ingredient per unit of seed weight (e.g., g a.i./100 kg seed) and seeding rate (e.g., kg315seed/hectare).

316 **Post-harvest uses**

31743For dip or drench of fruit, concentration of the active ingredient in solution should318be recorded (e.g., kg a.i./100 liters (or hL)) as well as the amount of fruit treated per volume319and contact time in seconds. Where dips are replenished to maintain the active ingredient320concentration during treatment (i.e., where residue stripping occurs), the additional 'top-321up' treatments should also be recorded. For powdering, fogging or spraying of stored goods322(e.g., potatoes or grains), the application rate should be recorded (e.g., kg a.i./ton or 1000323kg).

324 Fumigation uses

32544The application rate for gases and aerosols used in fumigation should be expressed326as amount per unit volume of treated bulk good (e.g., g a.i./m³) or as amount•time per unit327volume of treated bulk good (e.g., g a.i. hours/m³), when specified as such on the label.

328 Application Rate, Timing and Frequency

329 *Maximum label rate*

33045The maximum label rate or maximum proposed label rate of the active ingredient331(according to the cGAP) should be used when applying the test substance for crop field332trials.

333 Number of applications and re-treatment interval

33446The maximum number of applications and minimum re-treatment interval for use335of the test substance under evaluation should reflect the cGAP.

In cases where the maximum seasonal application rate is less than the product of the 336 maximum single application rate and the maximum number of applications, trials should 337 normally be conducted with the maximum single rates applied closest to harvest. For 338 example, if the cGAP is 3 applications with a maximum per-application rate of 1 kg a.i./ha 339 and a maximum seasonal rate of 2.5 kg a.i./ha, then the trials should be done with the first 340 application at 0.5 kg a.i./ha and the second and third applications at 1 kg a.i./ha each. 341 However, in justified cases, a different approach may be more appropriate (e.g. for systemic 342 compounds for which the maximum residues are not necessarily observed on day 0). 343

344Pre-harvest interval (PHI) in days versus final application at a specific growth345stage

34647Application timing is governed by plant growth stage (e.g., pre-bloom, 50% head347emergence, etc.) and/or as number of days prior to harvest. Any time that a specific PHI is348indicated on the label (e.g., "Do not apply this product less than 14 days prior to harvest."),349that 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 350 where the growth stage is a critical component of the GAP, (e.g., pre-emergence, at 351 planting, pre-bloom, flag leaf or head emergence, etc.) while the PHI is of secondary 352 importance. In these cases, it is important to include as many varieties of the crop as 353 possible in order to evaluate an appropriate range of PHIs (e.g., shorter and longer intervals 354 from planting to maturity in the case of pre-emergence application to an annual crop). 355 Basically in all trials both the growth stage at application (preferably as BBCH code) and 356 PHI should be recorded. 357

358 Residue Decline Trials

- 35948Residue decline data are necessary for uses where the pesticide is applied when the360edible portion (human food or animal feed) of the crop has formed or it is expected that361residues may occur on the food or feed commodities at, or close to, the earliest harvest362time. Residue decline data are used in residue evaluation for purposes such as:
- 363 1) determining if residues are higher at longer PHIs than requested;
- 364 2) estimating the half-life of the residues;
- 365 3) determining whether alteration of the PHI to levels represented in the decline trials 366 around the GAP PHI affects the residue levels;
- 367 4) allowing for a degree of interpolation to support use patterns, including PHIs, not
 368 directly equivalent to those used in the trials on a case-by-case basis;
- 3695)determining the profile of the residue over time to add to the understanding of370metabolism of the pesticide under conditions more applicable to GAP and to assist in371appropriate selection of residue definitions; and
- determining the time interval to reach maximum residues for a systemiccompound.
- 37449When residue decline data are necessary, some regulatory authorities require that375up to 50% of the residue trials be decline studies to demonstrate the behavior of the active376ingredient and relevant metabolites close to harvest.
- When residue decline data are necessary, sampling of more than one commodity or 50 377 matrix per crop may be needed. This will be the case whenever different commodities are 378 used as food or feed at different growth stages of the crop (e.g., cereal forage, cereal fodder, 379 cereal grain and straw or dill leaves and dill seeds). This will result in two or more sets of 380 381 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 382 where these trials are conducted as residue decline trials the aforementioned provisions for 383 sampling will not change. 384
- 51 The design of residue decline studies should include 3 to 5 sampling intervals in 385 addition to the target PHI (if practical, include 0 day sampling). The preferred minimum 386 number of samples is 5 from a PHI of ≥ 10 days. Sampling should occur at shorter and 387 longer time points relative to the target PHI, when such is permitted by the window of 388 389 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 390 more frequently shortly after the last application than later on (e.g. on days 0, 1, 3, 7 and 391 14). Otherwise, the sampling intervals may be spaced somewhat equally. For cGAPs 392 including multiple applications, a sampling point immediately prior to the final application 393 is desirable to determine the contribution of earlier applications and the effect on residual 394 half-life. 395

396 Reverse Decline Trials

52 Another acceptable residue decline study design option, referred to as "reverse 397 decline," involves applications being made to separate plots at different time intervals from 398 the targeted commercial harvest date. All plots are then harvested on the same day, the 399 commercial harvest date, resulting in different intervals from last application to harvest. 400 Such a design may be appropriate for situations where the commodity is likely to be 401 harvested within a narrow time window. For example, such a study could examine the use 402 of a pre-harvest desiccant close to maturity where harvest should occur within a short time 403 frame after application. 404

Bridging studies

53 Bridging studies are a possibility to compare the residue behaviour of different 406 situations where residues are not assumed to be equivalent. This might be the case in 407 formulation changes, new formulations, or different application methods. The best results 408 might be obtained by conducting trials at the same site which will minimise environmental 409 effects on the level of residues. Such side-by-side comparisons are favoured but not always 410 necessary. As to the number of side-by-side trials needed, a minimum of 4 trials is generally 411 needed. The reduced number of trials is considered adequate due to the fewer number of 412 environmental variables inherent in side-by-side trials. 413

414 54 Comparing the results from the original situation with the new situation using the 415 Kruskal-Wallis H-test (or Mann-Whitney U-test in case of more than 2 datasets) can give 416 an indication, whether both situations are comparable or not. However, due to the limited 417 power of the test, expert judgement may be required to decide if the data sets are 418 comparable (for using statistical tests see OECD Guidance Document on Crop Field 419 Trials).

420 55 If residues from the new situation are comparable to or less than those from the 421 original situation, no additional data are required. However, if residues are higher from the 422 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 423 all circumstances if the data sets for at least three major crops are comparable. Data should 424 be generated for at least 3 major crop groups (one crop per crop group), e.g., a leafy crop, 425 a root crop, a tree fruit, a cereal grain, an oilseed. The trials should be carried out on crops 426 that would be expected to show high levels of residue (often those with applications at or 427 near harvest). If a bridging study is conducted and residues are significantly higher with a 428 new situation, generation of a complete data set may be necessary. Also in such situations 429 a Kruskal-Wallis H-test (two datasets) or a Mann-Whitney U-test (multiple datasets) can 430 be used to decide whether results are comparable. Regulatory authorities should be 431 consulted in cases where such wider extrapolations (see also point "Beyond the Crop Group 432 or Wider Extrapolation" below, paragraphs 123 - 126) are being considered. 433

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434 Equipment and Mode of Application

435 *Ground versus aerial application*

436 57 Provided the proposed use does not involve ultra-low volume spraying or diluents 437 other than water (e.g., vegetable oils), crop field trials using actual aerial application 438 equipment can generally be waived where adequate data are available from use of ground 439 equipment reflecting the cGAP as long as the product label specifies that aerial applications 440 are to be made in spray volumes of 19 liters or more per ha (2 gallons or more per acre) 441 for row crops, or 94 liters or more per ha (10 gallons or more per acre) for tree and orchard 442 crops.

443 Hand-held versus commercial equipment

444 58 Application of the test substance may be made with hand-held or commercial 445 equipment as long as the equipment is conducive to calibration procedures. Hand-held 446 equipment used to make test substance applications in crop field trials should do so in a 447 manner that simulates commercial practice. If single unit (e.g., one tomato) residue data 448 need to be generated, the use of small plot precision sprayers is not representative of the 449 variability expected under commercial spraying applications and should be avoided. 450 Consideration should also be given to selection of appropriate nozzles in these trials.

451 *Alternative application modes to the same crop*

- 59 There are a number of soil application methods such as pre-emergence, pre-plant 452 incorporated, in-furrow at planting, drip/drench and seed treatment. Many product labels 453 give options for applications made prior to crop emergence, such as allowing the use to be 454 pre-plant, at-plant, or pre-emergence. These soil-applied applications may be grouped for 455 the purposes of determining the residue(s) resulting from the test substance application, i.e. 456 pre-emergence applications, which occur within one week after planting are considered 457 equivalent to at-plant uses. If the label gives a choice of soil incorporation or subsequent 458 surface application, residue data reflecting both modes of application will be required. 459
- 46060There are also a number of foliar application methods including broadcast and461airblast. Field trials should reflect these multiple methods if permitted by pesticide product462labels.
- 46361Typically, unless data from metabolism studies indicate differently, foliar464application is considered the worst case compared to soil application or seed treatment and465therefore would be considered to be the cGAP. This is especially the case if the foliar466application is made when the food or feed commodity has formed and is directly exposed.

467 *Multiple application modes to the same crop*

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

FIELD SAMPLING

476 Raw Agricultural Commodity (RAC) Characteristics

Samples taken from field trials should be of the whole RAC as it moves in 63 477 commerce. For some crops, there may be more than one RAC. For example, the RACs for 478 field corn include the grain (seed), fodder (stover), and forage. Annex 1 contains a list of 479 the RACs derived from each crop. Some crops may be shipped without having been 480 stripped, trimmed or washed; therefore these procedures should only be used on residue 481 samples to the extent that these are commercial practices prior to shipment. Of course, data 482 on trimmed or washed samples may be generated at the applicant's option for use in risk 483 assessment. 484

485 Number of Samples per Site (Treated and Controls)

64 A minimum of one sample per treated plot per sample matrix is required to be 486 collected and analysed at each crop field trial site. In addition to the treated sample(s), one 487 sample of each matrix should be collected from the control plot and analysed for each field 488 489 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 490 for each matrix at each site in case problems arise during shipping or residue analysis. 491 Specific cases where certain regulatory authorities require two samples per treated plot are 492 detailed in paragraph 65. Analysis of a second sample would also be useful in cases where 493 the results at a particular site are suspicious or are inconsistent with results from other trial 494 sites. Another factor that could promote the analysis of a second sample is the presence of 495 high residues due to late-season foliar use (as opposed to early season use with residues 496 <LOQ where analysis of a second sample adds very little data value). 497

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.

504 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.

507 Composite versus Single Unit Samples

50866Composite samples are adequate for crop field trials. Applicants may also wish to509generate replicate single unit samples from a field to aid defining unit-to-unit variation,510which is needed for the purposes of acute dietary intake assessment. To derive a variability511factor from a residue trial, at least 119 single units should be sampled and analysed512separately (Hamilton 2004).

513 Minimum Field Sample Size (Number and Weight)

- 514 67 Codex guidelines on minimum field sample sizes should be followed and are 515 included in Annex 1. A control crop sample should also be collected from each crop field 516 trial site and for each crop commodity (e.g., cereal forage, cereal fodder, cereal grain, and 517 straw) for analysis. Control samples of each matrix are often larger than treated samples, 518 in order to provide the needed amount for spiking with known amounts of active ingredient 519 (and other components of the residue definition) and to determine the calibration curves for 520 the concurrent method validation during the analytical phase of the study.
- 521 68 For commodities not included in Annex 1, applicants are advised to use the 522 guidance on minimum field sample size for a crop part having a similar form (e.g., another 523 seed, leafy material, root or tuber).

524 General Sampling Procedures

69 The sample should be representative of all portions of the crop from the field and 525 samples should be collected without bias. Standardised procedures such as the use of the 526 Latin squares for a forage crop, selection of tree fruits from the upper, middle, and lower 527 levels of opposing quadrants of the tree, the use of grain triers for taking core samples of 528 commodities in bulk quantities, and sample reduction by quartering of samples from a field 529 are desirable. It is noted that JMPR recommends not to cut or break units of fresh plant 530 products or whole eggs unless the tested pesticides can be considered stable in the halved 531 or quartered portions or if there is potential for cross-contamination of residues from 532 inedible to edible parts of the commodity (e.g., melons) (FAO 2016). See text starting in 533 paragraph 79 and Annex 1 for crop specific sampling procedures. 534

53570Although samples should be collected in an unbiased fashion, whenever possible,536avoid edges and ends of plots, which may be influenced by turning the boom or other537sprayer type on and off (ends) or where spray nozzle may be designed for spray overlap538(edge effect). In cases where more than one pass is made, it may also be advisable to avoid539the center of the plot to avoid the possibility of high residues from improper spray overlap.

540 Subsampling

It is acceptable to subsample large commodities (e.g., head cabbage, melons, etc.) 71 541 with procedures in the field such as quartering and collecting opposing quarters. However, 542 if analyses are planned on matrices such as pulp and peel (e.g., for dietary risk assessment 543 refinement), the whole commodity should be shipped to the sample preparation facility to 544 avoid cross contamination of peel and pulp. It is acceptable to ship these samples overnight, 545 with coolant such as "blue ice", to the sample preparation facility as long as they are 546 "peeled" or "pitted", or otherwise prepared for analyses and frozen immediately upon 547 arrival. 548

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549 Shelling and seed removal

550 72 Shelling, removing seeds or beans from pods, etc. is acceptable in the field provided 551 that procedures are used which eliminate the possibility of contamination. For example, 552 using clean implements and changing gloves between plots. In cases where commodities 553 such as peel and pulp or stone and pulp are separated for analyses, weights should be 554 determined for each part.

555 Hand versus mechanical harvesting

55673Unless specifically directed otherwise (e.g., cotton gin byproducts), plant samples557for residue analyses may be collected by hand. There is no general requirement for558mechanical harvesting in crop field trials. However, in order to define a realistic residue at559harvest, some mechanically harvested samples may be useful.

560 *Washing, brushing*

56174Apart from superficial cleansing, i.e., removal of any extraneous matter, no562intrusive cleaning should be attempted. In the case of root crops recovered with soil, where563light brushing is not sufficient to remove soil, gentle minimal rinsing under cold running564water may be used. (See "Detailed Sampling Procedures" for additional information.)

565 *Contamination*

56675To avoid contamination, it is strongly recommended to take samples from the567control plot before taking samples from the treated plot. Care should be taken to ensure that568such samples are truly representative and that possible contamination or spoilage through569decay is avoided.

570 Storage, shipping conditions and duration

571 76 Samples should be frozen as soon as possible following collection to avoid sample 572 deterioration and decomposition of the residue(s). It is not advisable to allow samples to 573 thaw once frozen; therefore shipment of frozen samples should be either by freezer truck 574 or packed in dry ice. It is however acceptable to ship samples overnight with coolant such 575 as "blue ice" immediately after collection provided the samples are frozen upon arrival at 576 the laboratory or processing facility as appropriate for each matrix.

577 77 Normal frozen storage may not be appropriate for some pesticides (e.g., fumigants) 578 and arrangements may be necessary for immediate residue analysis.

579 Form to be stored (homogenate, whole RAC)

58078Samples should be stored prior to analyses according to how the storage stability581study was conducted and the analytical method for the active ingredient and relevant582metabolites. For example, some methods indicate that sample homogenisation should be583performed on the same day as extraction. As noted in the OECD Guideline "Stability of584Pesticide Residues in Stored Commodities, TG 506" storage of homogenates is likely to585represent a worse case (i.e., more degradation) compared to the storage of a whole586commodity.

587 Detailed Sampling Procedures

58879Additional details regarding recommendations for the sampling of mature crops at589normal harvest time, specifics on commodity sample size and the portions to be analysed590are provided in Annex 1.

591 *Fruits and tree nuts*

59280Circle each tree or bush and select fruit from all segments of the tree or plant, high593and low, exposed and protected by foliage. For small fruits grown in a row, select fruit594from both sides, avoiding the ends of the row. Select the quantity of the fruit according to595its density on the tree or plant, i.e., take more from the heavily laden parts. Take both large596and small fruits where appropriate, as long as all samples are marketable (except when597taking immature samples for a residue decline study).

598 Bulb vegetables, root vegetables, tuber vegetables:

- 59981Take samples from all over the plot, excluding the edges of the plot and the ends of600the rows to avoid edge effect. The number of sampling points depends on the sample size601of the crop.
- 60282To provide a representative sample of the raw commodity, adhering soil should be603removed. This may be done by brushing and, if necessary, gentle rinsing with cold running604water.
- 60583Trim off tops according to local agricultural and/or commercial practice. Details of606any trimming should be recorded. Where the tops are not used as animal feed (carrots,607potatoes) or for human consumption, they should be discarded; otherwise (e.g., turnips,608beets) they should be bagged separately.

609Brassica vegetables, leafy vegetables, stalk and stem vegetables, legume610vegetables, fruiting vegetables and fungi:

- 61184Take the sample from all parts of the plot, avoiding the edges and ends of rows.612The number of sampling points depends on the sample size of the crop.
- 61385Sample items of crops such as peas or beans protected from the spray by foliage614and also from parts exposed to the spray.
- 61586To provide a representative sample of the raw commodity, adhering soil should be616removed. This may be done by brushing and, if necessary, gentle rinsing with cold running617water.
- 61887For Brassica and leafy vegetables, do not trim except for the removal of obviously619decomposed or withered leaves. Details of any trimming should be recorded. The fate of620wrapper or outer leaves should be clearly described (i.e., included with sample or discarded621in the field).

622 Cereals

- 62388If the plot is small, collect the entire yield as needed. If the plot is large but624mechanical harvesting is not carried out, cut not less than twelve short lengths of row625chosen from all over the plot. Cut stalks 15 cm above the ground and remove the grain from626the straw.
- 627 89 Care should be taken to avoid contamination when mechanical methods are used to 628 separate the parts of the crop. The operation is best carried out in the laboratory.

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90 629 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 630 sample each for grain and straw. 631

Cereals/Legumes/Grasses/Oilseeds/Pulses - forage, hay, stover, vines, straw and 632 other animal feed 633

91 Cut and/or collect these commodities according to the commercial practice. If the 634 plots are harvested mechanically, take not less than 12 grab samples from the harvester at 635 uniform intervals over the plot. However, care should be taken to avoid contamination (e.g., 636 harvest control prior to treated plots). For crops that are windrowed, the samples should be 637 taken from the windrow at the time corresponding to the point when used for animal feed. 638 In the case of cutting green plant material for the production of hay, this timing would 639 normally be when the moisture content has decreased to the typical level for hay in 640 commercial practice. In the case of plant material which has dried before the plant is cut 641 (e.g., stover, straw), collect the sample after cutting and not after windrowing in the field. 642

Sugar cane and cane tops 643

92 Select whole canes from 12 areas of the plot and take short (e.g., 20 cm) sections 644 from all parts of the length of the canes. Collect samples of green cane tops, approximately 645 2 kg from each plot. 646

Pulses, Oilseeds, Coffee, Cocoa 647

93 Collect samples of mature seed from at least twelve parts of the plot. Where the 648 649 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 650 should normally be supplied. Take samples from the entire plot, avoiding the edges of the 651 plot. For coffee and cacao, circle each tree or bush and select pods or fruit from all segments 652 of the tree or plant, high and low, exposed and protected by foliage. Select the quantity of 653 the pods or fruit according to its density on the tree or plant, i.e., take more from the heavily 654 laden parts. 655

- 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.
- 661 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 662 after drying or fermentation without the pod and after removal of the shell. For 663 coffee sample the whole green bean after removal of the pulp and parchment 664 surrounding the bean. The removal process (dry or wet) should be recorded 665
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Herbs and spices; tea leaves; hops

- 94 Take samples in a manner reflecting common practice. Use only those plant parts 667 which are representative of consumption. 668
- For hops select cones from all parts of the plant and from both sides of the rows, 669 95 670 high and low, exposed and protected by foliage.

67196Take samples from the entire plot, avoiding the edges of the plot. Herbs, such as672parsley and chives, and hops should be sampled fresh. As fresh hop cones are not marketed,673dried cones should be produced immediately, using drying procedure reflecting the usual674practices.

675 Special cases

67697Tree nuts and olives for oil production are often harvested by shaking the tree and677collecting the product in a net on the ground. In such cases the sampling procedure should678ensure the harvest procedure in order to take account of the transfer of residues to the679product when the cGAP is for application to the orchard floor.

680 *Stored commodities*

681 98 Trials reflecting post-harvest treatments of stored products should be carried out 682 over a wide range of storage facilities, and the sampling technique should be carefully 683 chosen if valid samples are to be obtained. Procedures for taking valid samples from most 684 commodities in storage units should reflect or simulate commercial practices. Such 685 procedures are acceptable in sampling for pesticide residue analysis and may be used if 686 adequate references are given. The sampling procedures are usually designed for three 687 kinds of storage conditions as described below.

688 Sampling from bulk

99 689 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 690 stream during transfer into another container. A probe sample is not representative but may 691 692 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 693 sample. However, it is also important for the sampling procedure to generate samples from 694 only that portion of the store having the highest residues. For example, pesticide residues 695 are normally higher in the surface layer of a pile of potatoes and this should be recognised 696 697 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. 698

699 Sampling bagged commodities

700100Sampling of the commodity within a bag should be random. A representative701sample from a large stack of bags can be obtained only if every bag is accessible. This is702not always possible in practice and the alternative is to obtain a sample from a number of703randomly chosen bags by probing. Since pesticide treatments are often directed to the704surface of the bag, selective sampling to show the effect of the position of the bag in the705stack and the penetration of the pesticide into the bag may be necessary. As with bulk706containers, at least three samples should be collected and analysed.

707 Sampling fruit and vegetables in packing houses

708101Where post-harvest treatments are applied to fruit and vegetables in packing709houses, an adequate number of samples should be taken to determine the range of residue710levels resulting from variations in the treatment process. The effects on residue levels of711dip or spray concentration, temperature, duration of treatment, drying (after dip treatments)712and subsequent handling may need to be considered.

713102Post-harvest treated fruit and vegetables should be kept in, or packed in,714commercial containers or punnets and stored at ambient or cool-room temperature

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715according to normal commercial practice. Day zero samples should be taken once the716commodity is dried. Samples should then be drawn for analysis from the commercial717containers at suitable intervals representing the time expected between treatment and718subsequent marketing. The rate of disappearance or degradation of some residues depends719on whether the commodity is held in a sealed or partly sealed container or is open to the720air.

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RESIDUE ANALYSIS

723103The analytes relevant for risk assessment and enforcement should be quantified by724an appropriate analytical method (Refer to OECD Guidance Document on Pesticide725Residue Analytical Methods, ENV/JM/MONO(2007)17). Method recovery validation726studies should be run concurrently with the residue analyses of crop field trial samples from727each individual field trial in order to provide information on the recovery levels of the test728compounds from the test substrates at various fortification levels using the residue729analytical methods, and to establish a validated limit of quantitation.

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NUMBER OF CROP FIELD TRIALS

732 Combination of Data Sets for a Given Commodity

Individual OECD member countries or political regions typically require a 104 733 geographic distribution of a specified finite number of crop field trials conducted at the 734 critical GAP to generate data for the estimation of the STMR, HR and MRL. The same 735 practice would apply to estimation of the STMR, HR and MRL when trials conducted at 736 the same GAP are considered from more than one country or region. Provided the GAP is 737 comparable, the results of trials conducted in two or more countries or regions should be 738 considered in deriving the STMR, HR and MRL for a given commodity. The general rules 739 as described in paragraph 8 or by the proportionality principles (see chapter 3 of the OECD 740 Guidance Document on Crop Field Trials) apply. 741

742105Current guidelines in OECD countries or regions specify numbers of crop field743trials based on consideration of the following factors:

7441)Crop production regions, often defined or identified by the crop production745practices (e.g., irrigation – beneath crop canopy vs. overhead sprinkler; planting densities746of 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.

751 3) Significance in the diet.

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752106Having taken these factors into account, regulatory authorities in different OECD753countries have each determined the minimum number of crop field trials required for754registration of a use on a crop and establishment of a suitable MRL. More details can be755found in table 3 of OECD Guidance Document on Crop Field Trials756[ENV/JM/MONO(2011)50/REV1].

107 Geographic distribution of field trials within a country or region serves to ensure 757 that data will be available for trials in key crop production areas, and a sufficient variety of 758 horticultural practices, environmental (like soil) and weather conditions may be represented 759 in a crop field trial data set. Specific analyses of the influence of climate and ecology on 760 residue levels have been performed (FAO/OECD and USA). For more information see 761 paragraphs 61 and 62 in OECD Guidance Document on Crop Field Trials as well as added 762 documents in section references by D. Miller (2018) and J. Nguyen et al from 2019. 763 According to the publication from 2019 the investigations can be considered as completed. 764 The authors concluded, that their "assessment supports the concept of exchangeability of 765 pesticide residue values across geographic regions and opens the possibility of improving 766 harmonization of pesticide regulatory standards by establishing more globally aligned 767 MRLs". Regulatory authorities should be consulted to determine which residue data are 768 769 required.

770 Comprehensive Submissions

108 In the case of a comprehensive submission to all OECD member countries where 771 the desired GAP is uniform, a 40% reduction in the total number of trials is feasible, 772 compared to the total number of trials determined by summation of individual country 773 requirements. The assumption is that the number of trials specified in each crop production 774 region reflects the economic (acreage) importance and/or dietary significance of the crop 775 within that production region. Therefore, there is no need to further consider acreage or 776 dietary intake for a crop/commodity or to determine whether a crop is major or minor in 777 terms of acreage, diet, or trade on a global basis for the purpose of determining a minimum 778 number of crop field trials for a comprehensive submission. 779

- 780109The reduction in the total number of trials within any OECD country or crop781production region is compensated for by the total number of crop field trials making up the782comprehensive submission data set and the wider geographic distribution of these data.783With this 40% reduction, regulatory authorities may receive fewer crop field trials in their784specific country or region; however they will actually receive a greater number of trials in785total with a more comprehensive geographical distribution. There are precedents in OECD786member countries and regions for this approach.
- 787 110 To qualify for this comprehensive submission approach, all crop field trials should
 788 meet the following criteria:
- 7891)Field trials are conducted according to the uniform cGAP. At least 50% of the790trials should be conducted at or above (within 25%) the cGAP. For this purpose, trials791whose intended application rates match the cGAP but actual rates fall up to 10% below the792cGAP (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).

7952)The trials span a range of representative crop production practices for each crop796including those likely to lead to the highest residues (e.g., irrigated vs. non-irrigated, trellis797vs. non-trellis production, fall-planted vs. spring-planted, etc.).

Any reduction in the number of crop field trials should be distributed proportionally 798 111 among the crop production regions as shown in the example for a 40% reduction below. A 799 table with trial numbers for crops grown throughout OECD member countries is available 800 the OECD Guidance Document Crop Field Trials 801 in on 802 [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. 803

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

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

807112The minimum total number of trials for any crop in a comprehensive submission is808eight. In addition, the total number of trials to be conducted must not be less than the809requirement for any given individual region. For example, upon calculation of the 40%810reduction, some crops such as dried lima beans have fewer total trials (14) than required in811one region (16 in the EU). Therefore, at least 16 trials are needed for dried lima beans in a812comprehensive submission. (For more details see OECD Guidance Document on Crop813Field Trials, ENV/JM/MONO(2011)50/REV1).

- It is important to keep in mind that this comprehensive strategy would only apply 113 814 to an OECD-wide submission. If, for example, the MRL submission is originally submitted 815 to the US and Canada, the crop field trial guidelines, with respect to the number of trials, 816 for those countries should be followed. Subsequently, if MRLs in additional OECD 817 countries are pursued, the regulatory authorities in the additional countries should be 818 consulted to determine what residue data are required. For example, following 819 establishment of an MRL in the US and Canada, if an MRL for the same use is pursued in 820 the EU, the applicant may consult with EU regulatory authorities about the possibility of 821 using residue data from the US/Canadian data submission and performing fewer crop field 822 trials in the EU. 823
- 824 114 The table of trial numbers in the OECD Guidance Document on Crop Field Trials 825 [ENV/JM/MONO(2011)50/REV1] addresses only outdoor crop field trials and not 826 greenhouse (glasshouse) or post-harvest treatments. For a comprehensive submission to 827 OECD countries, with similar critical GAPs, a minimum of eight greenhouse trials is 828 needed. For such greenhouse trials, geographic distribution typically is not an issue; 829 however for active ingredients which are susceptible to photodegradation, consideration 830 should be given to locations at different latitudes and winter/summer periods.

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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.

835GENERAL INFORMATION ON CROP GROUPS AND836EXTRAPOLATION

837 Extrapolation and Principles of Representative Commodities

National authorities use targeted data sets and data extrapolation to provide 838 116 sufficient data for exposure assessment or for setting MRLs for both individual major and 839 minor crop commodities, and crop commodity groups. It provides the mechanism for 840 extending field trial data from several (typically two or three) representative commodities 841 842 to related commodities in the same crop group or subgroup. Crop grouping and the identification of representative commodities are also critical for maximising the 843 applicability of a targeted data set determined for representative commodities for minor 844 uses. The representative commodity (within the group) has the following properties: 845

- 846 1) major in terms of production and consumption and
- 847 2) most likely to contain highest residue.

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- 848117A number of different crop and commodity grouping systems have been developed849within OECD countries to identify which commodities are likely to contain similar850residues, and where group or subgroup MRLs can be considered. Characteristics of crop851and 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.

856 118 It may be recognised that a major crop within a crop group may not have the highest
857 residue. From a dietary exposure standpoint, using a major crop commodity as
858 representative of the group is acceptable to some regulatory authorities because of the small
859 consumption of minor commodities. However, particularly with regard to regional acute
860 intake figures, this may not be the case.

861 119 If necessary groups can be further divided into subgroups that better reflect
862 grouping criteria. Codex uses the following characteristics for crop grouping:

- 863 1) commodity' s similar potential for pesticide residues,
- 864 2) similar morphology,
- similar production practices, growth habits, etc.,
- 866 4) similar edible portion,

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867 5) similar GAP for pesticides uses, 6) similar residue behaviour, and 868 869 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 870 group MRL. For example, under Codex, citrus crops are divided into four subgroups. One 871 commodity from each subgroup would be needed for a group MRL. In this case these are: 872 Subgroup 001A, Lemons and Limes with the representative crops lemon or lime 873 Subgroup 001B, Mandarin with the representative crop mandarin 874 Subgroup 001C, Oranges, Sweet, Sour with the representative crop orange 875 • 876 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 877 appropriate to set a group MRL or if it is preferable to set specific MRLs for the individual 878 879 subgroups. 880 120 The commodity consumed may also be reflected in the sub grouping. For example, 881 bulb vegetables are sub grouped into Subgroup 009A, Bulb Onions with the representative crop bulb onion covering 882 883 inter alia garlic, onion and shallots Subgroup 009B, Green Onions with the representative crops spring onion or leek 884 covering inter alia chives, leek and spring onions. 885 The distinction is that only the bulb on those in subgroup 1 is consumed, whereas the bulb 886 and aerial portions of the subgroup 2 may be eaten. Different residue levels might be 887 expected on the two sub groupings for most pesticide applications. Thus, it might be 888 possible to extrapolate from bulb onion to garlic and shallot, but not from bulb onion to 889 890 spring onion. 891 121 Under mutual support, trials from two related commodities showing similar residue concentrations may be considered together in order to establish MRLs for both 892 commodities when there may be an inadequate number of trials for one or both 893 commodities. For example, there may be 8 trials for apples and 4 trials for pears, where 894 both are conducted under the same GAP and have similar residues. Four trials would be 895 considered to be too few for pears, but an MRL for pears could be estimated by considering 896 both the apple and pear trials. 897 898 Applicants are advised to contact individual regulatory authorities for details on 122 their policies with regard to crop groups and extrapolation of data. 899

900 Beyond the Crop Group or Wider Extrapolation

123 Extrapolation beyond a crop group may also be possible under special 901 circumstances. A pesticide because of its use pattern, e.g., foliar application early season 902 before edible portions form, seed treatments, or application as a directed herbicide, or 903 because of its properties, e.g., non-systemic and rapid degradation, will consistently yield 904 no or low concentrations of residue (< LOQ to just above the LOQ) on a wide variety of 905 commodities. Under such circumstances it is possible to extrapolate to establish MRLs for 906 many commodities or crop commodity groups beyond those for which field trial data have 907 been generated. 908

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.

- 912 125 Considerations of expanded crop group MRLs should be undertaken on a case-by-913 case basis and should be based on the following factors:
- Use pattern

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

919126Determination of the sameness of the GAP should take into account not only the920label instructions (rate, application method, timing, PHI) but also local agronomic practices921that might impact the residue level. For example, wheat is generally grown under similar922practices around the world, but grapes may be grown under widely varying practices. For923the latter, care should be taken to ascertain if the relevant GAPs are actually the same. If924adequate data are available, a test of the lack of difference of the data populations would925be useful.

DATA REPORTING

127 Regulatory authorities recognise there are sections in the guideline, which do not 927 928 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 929 treatments and post-harvest applications will have elements, which are not applicable to 930 other types of treatments or need to be modified to address the unique characteristics of 931 these uses. For example, soil characteristics are not applicable to post-harvest applications. 932 It is proposed to use the specific OECD Harmonised Template 85-5 as standard data format 933 for reporting information. This template can be downloaded from the OECD webpage. 934

935128OECD Harmonised Templates (OHTs) were developed to be used for the risk936assessment of chemicals, mainly studies done on chemicals to determine their properties or937effects on human health and the environment, but also for storing data on use and exposure.938They are aimed at developers of database systems, as they prescribe the formats by which939information can be entered into and maintained in a database. By using these templates,940governments and industry are easily able to electronically exchange study summary941information.

942129The templates can be used to report summary test results for any type of chemical943(e.g., pesticides, biocides, industrial chemicals). The OECD Harmonised Templates cover944endpoints and reporting elements which are grouped as follows:

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946	Administra	tive Data/Data Source
947	130	This section contains the following elements.
948	1)	Reference, Study ID, Title, Author(s), Publication date, Report No., Study dates
949	2)	Testing Laboratory
950	3)	Test Guideline, including deviations
951	4)	Purpose of studies
952	5)	GLP Compliance
953	Materials a	nd Methods (see below for more details)
954	Results and	Discussion (see below for more details)
955		
956 957 958 959	grow	Results (including raw data on individual field trials and explanations for rently aberrant or atypical values, discussion of geographical representation (major ing areas), seasonal variation (summer/winter, wet/dry, etc.) and representative nature bes and varieties of the raw agricultural commodity).
960 961	2) in sto	Storage stability / Storage period for samples should be compared to those utilised brage stability study.
962 963 964 965	defin	Discussion (including Quality Control measures taken; GLP compliance; tical treatments of data; and information on the levels of the components of the residue ition in or on the RAC (specific plant parts) arising from the use of the pesticide ulated product on the test crop under specific use conditions and storage stability).
966	Overall ren	narks/Attachments
967 968	131 "Org	Concerning data tables and other graphic representations it is referred to the section ganisation of data tables and forms".
969	Applicant's	Summary and Conclusion
970 971	132 expec	In addition to a textual summary/conclusion, the following maps/tables are ted to be reported in this section.
972	1)	Summary map of crop field study sites (by crop)
973	2)	Summary tables of residue results of individual field trials
974	3)	Graphic representations (e.g., residue decline, figures, flowcharts, etc.)
975	4)	Summary tables of recovery data via the analytical methodology
976	5)	Summary tables of storage stability validation data
977	6)	Chromatograms (as applicable)
978	133	In the following more details are provided concerning the information expected in
		ey chapters "Materials and Methods" and "Results".

980 Information/raw data on individual field trials (specifically, each individual field 981 trial report should include the following information):

982 *Test substance (pesticide)*

- 983 134 For the description of the test substance (pesticide) the following information 984 should be provided.
- 9851)Identification of the test pesticide active ingredient(s) (a.i.), including CAS and986IUPAC chemical name, common name (e.g., BSI, ISO), and company developmental or987experimental name.
- 9882)Identification of the pesticide formulated products used in the field trial, including989trade name, type (EC, WP, G, etc.), and amount of active ingredient per gallon, pound,990liter, kg, etc., and manufacturer.
- 9913)Information on other relevant parameters, as pertinent, (e.g., tank mates, spray992additives, carrier (encapsulating polymer, etc.)).
- 9934)Other. Any and all additional information the applicant considers appropriate and994relevant to provide a complete and thorough description of the test substance.

995 *Test commodity (RAC).*

- 996135For the description of the test commodity (raw agricultural commodity (RAC)) the997following information should be provided.
- 1) Identification of the RAC, including type/variety.
- 999
 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.
- 10023)The developmental stages, general condition (immature/mature, green/ripe,1003fresh/dry, etc.) and sizes of the RAC at time of pesticide application(s) and at harvestings.
- 10044)Other. Any and all additional information the applicant considers appropriate and1005relevant to provide a complete and thorough description of the RAC.
- 1006 Test procedures
- 1007136A detailed description of the experimental design and procedures followed in the1008growing of the RAC, applications of the pesticide formulated products, and harvestings of1009samples is expected. The information provided, which may be presented on standardised1010field sheets, should include (in addition to a description of the test substance and test1011commodity):
- 1012 1) Trial identification number.
- 1013 2) Cooperator (name, address), test location (e.g., state, country) and year.
- 10143)Field trial lay-out (e.g., size and number of control and experimental plots; number1015of plants per plot/unit area, number of rows per plot, length of rows and row spacing).
- 10164)Cultural treatments farming practice (cultivation, irrigation, etc.) and cropping1017system.
- 10185)Methods of application (air or ground) of the pesticide formulated products,1019description of the application equipment, type of application (band/broadcast, soil/foliar/

	28	
1020 1021		directed, ULV/concentrate/dilute, other), and calibration of pesticide application equipment, including methods and dates.
1022 1023		6) Application rates (amount of active ingredient and formulated product per acre, row, volume, etc.) and spray volumes per acre or hectare.
1024 1025 1026		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)).
1027 1028 1029		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).
1030 1031		9) Meteorological data (record of temperature and rainfall during the growing season from the nearest weather station, and wind speed during application).
1032 1033		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).
1034 1035 1036 1037 1038 1039		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.
1040 1041		12) Quality control (control measures/precautions followed to ensure the fidelity of the crop field test).
1042 1043 1044		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.
1045 1046 1047 1048		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):
1049		1) Sample identification (means of labelling/coding).
1050 1051		2) Conditions (temperatures, container types/sizes, sample sizes, form (e.g., whole commodity; chopped), etc.) and duration of storage before shipping.
1052 1053		3) Methods of packaging for shipment (container types/sizes, sample sizes, ambient/iced, labelling/coding, etc.).
1054		4) Means of transport from the field to the laboratory.

- 1055 5) Dates (harvest, pre-shipping storage, shipping, and receipt in the laboratory).
- 10566)Quality control (control measures/precautions followed to ensure the integrity of1057harvested samples during handling, pre-shipping storage, and shipping operations).

10587)Other. Any and all additional information the applicant considers appropriate and1059relevant to provide a complete and thorough description of the handling, pre-shipping1060storage, and shipping procedures for harvested samples.

1061138A detailed description of the conditions and length of storage of harvested RAC1062samples following their receipt in the laboratory is necessary (see section "Storage1063Stability").

1064139A detailed description of the residue analytical methods used for field trial and1065storage stability samples should be provided (this is detailed below in the section "1066Analytical Methodology"). If the specified information is provided elsewhere within the1067overall data submission package, it need not be reiterated here. In that case, a reference to1068the relevant analytical methodology would be sufficient.

1069140Method recovery validation studies should be run concurrently with the residue1070analyses of crop field trial samples from each individual field trial in order to provide1071information on the recovery levels of the test compounds from the test substrates at various1072fortification levels using the residue analytical methods, and to establish a validated limit1073of quantification. The following information specific to the method validations, which may1074be presented on a standardised form, should include:

- 1075 1) Experimental design: Identity of test substrates (specific plant parts) and test 1076 compounds (parent/specific metabolites). Number and magnitude of fortification levels, 1077 number of replicate samples per test compound per fortification level, sample coding, 1078 control samples, etc.
- 10792)Fortification procedure: Detail the preparation of the test compounds and test1080substrates and the manner in which the test compounds were introduced to the test1081substrates.
- 10823)Dates: Test sample preparation (maceration/extraction/etc.), test compounds1083preparation (standard solutions of known concentration), residue analyses.
- 10844)Residue results: Raw data, ppm or mg/kg found uncorrected (corrected values may1085also be reported but the basis of correction should be explained), procedures for calculating1086percent recoveries, recovery levels (range), and limits of quantitation and detection.
- 10875)Other. Any and all additional information the applicant considers appropriate and1088relevant to provide a complete and thorough description of analytical methodology1089validation procedures.
- 1090 Organisation of data tables and forms.
- 1091 141 The following elements are expected in this section.
- 10921)Tables of residue assay data for specific plant parts analysed. Residue levels1093should be reported uncorrected. Corrected values may also be presented but the procedure1094needs to be explained with sample calculations.
- 1095 2) Tables on residue recovery values.
- 1096 3) Graphs, as pertinent (e.g., residue decline).
- 1097 4) Forms containing field trial history information.
- 1098 5) Forms containing harvesting, shipping, storage information.
- 1099 6) Tables of weather data if unusual conditions claimed to result in aberrant residues.
- 1100 Trial Information
- 1101142Geographic Location (Trial Specific information should be provided for all trial1102locations):
- 11031)Trial ID No (Trial Specific, unequivocal identification code (e.g., Company Internal1104Code)

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1105	1.1 Trial Deviation (List any deviations which may impact the trial results or study conclusions)
1106	2) Year (the year in which the first GLP data are collected in trial)
1107	3) Country
1108	4) Geographic Region (e.g., EU – N, EU – S, CANADA/MEXICO/USA
1100	1CANADA/MEXICO/USA 14)
1110	5) State/Province (e.g., Bavaria/Germany)
1111	6) County
1112	7) City
1113	8) GPS Coordinates (Optional)
1114	9) Crop
1115	Derived from EPPO plant thesaurus, can be updated by EPPO code members. In the case
1116	of post- harvest treatment of a harvested commodity, list the crop from which the harvested
1117 1118	commodity was derived. The same applies for seed treatment. e.g., Sweet orange is written in EPPO code as CIDSI.
1119	9.1 Crop Variety (e.g., Blood orange)
1120	Crop Code
1121	Codes can be obtained from www.eppo.org, utilise lowest (most detailed) level
1122	143 Plot (Information should be provided for all plots):
1123 1124	1) Plot ID (Unequivocal Plot Identification; e.g., consecutive number). Numerical field or combination
1125	2) Control Plot (yes or no)
1126	3) Plot Description
1127 1128	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
1129 1130 1131	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.
1132 1133 1134	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.
1135	5) Environmental Conditions
1136	Describe abnormal weather conditions, if applicable, any other environmental effect
1137 1138	that might have had an impact on the results observed in this study; for storage protection or glasshouse application give room/glasshouse temperatures/humidities
1139 1140 1141	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
1142 1143 1144	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

1145	8) Application
1146	(a) Application No (1, 2,)
1147 1148	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.
1149 1150	(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.
1151	(c) Date of Application (dd/mm/yyyy)
1152 1153 1154	(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
1155	(e) Method of Application
1156 1157	(f) Seeding Rate (Used in conjunction with seed treatment. Using this, combined with no. seeds/ Unit, one can determine TGW (Thousand Grain Weight), etc.)
1158	(g) Number of seeds/unit (no. seeds/kg, no. seeds/lb)
1159	(h) Test Item/Test Material (Pesticide(s) tested in this study)
1160 1161	The term 'test item' is identical to the term 'test material', which is used in OHT 85-5.
1162 1163	 Description of tested Pesticide Product, End-Use Product, formulation, treated/dressed seed, etc. used in the test
1164	 Test Item Formulation Type
1165	 Test Item Trade Name
1166	- Test Item Active Ingredient Code/unique identifier (e.g., Company Internal Code)
1167	 Test Item Active ingredient name(s)
1168	 Test Item Nominal active ingredient content (e.g., grams a.i./liter)
1169 1170 1171	 Test Item actual amount active ingredient applied (e.g., grams a.i./ha); for storage protection uses: application rate (e.g., kg a.i./m³), duration of treatment (h), duration of ventilation (h)
1172 1173	 Test Item actual amount active ingredient/seed if seed treatment (e.g., g a.i./100 kg seed)
1174	 Test Item cumulative amount applied
1175 1176	 Adjuvant Added including Adjuvant Type, Adjuvant Name, Adjuvant amount in Spray Volume (%)
1177	 Amount of water used in spray application (actual)
1178	9) Sampling
1179	(a) Sampling No.
1180	Consecutive numbering of sampling events
1181	(b) Sample ID – Unique sample identification code
1182	(c) Sampling Timing: Provide any information regarding the timing of the sampling,

e.g.,

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1183	relation to application events, days after last application, etc.
1184	PHI – pre-harvest interval
1185	DALA - Days after last application
1186	Days Before Harvest
1187	(d) Growth Stage (BBCH) at sampling
-	
1188	(e) Date of Sampling (dd/mm/yyyy)
1189	(f) Sampling Information (Optional)
1190	Description of sampling method, special remarks (e.g., cabbage was harvested according to
1191	agricultural practice, 1st set of outer leaves were removed), sample handling (e.g., samples
1192	were frozen within 24 hours)
1193	(g) Sampled Material/Commodity (Field RAC Sample)
1194	- Analysis Sample (Description of Analysis sample)
1195	Field Sample may be separated into several analysis samples, e.g., whole orange may be
1196	separated into a peel sample and a pulp sample for analysis (in that case also give weights
1197	of peel and pulp), aspirated grain fractions are separated from grain. In OHT 85-5 this is
1198	called 'reference portion'.
1199	 Analysis Sample ID
1200	 Analysis Sample Description (Optional)
1201	 Analyte measured
1202	– Analyte ID
1203	 Extraction Date (dd/mm/yyyy)
1204	 Actual date of extraction
1205	 Analysis Date (dd/mm/yyyy)
1206	 Actual date of analysis
1207	– Method ID
1208	- Recovery - Residue Level (e.g., mg/kg). Some regulatory authorities do not
1209	allow this value to be corrected for recovery and rely on the measured level of
1210 1211	the analyte. Additionally give calculated residue if appropriate (e.g., residue xy calculated/expressed as yz or acid calculated/expressed as carboxylic ester,
1211	sum of a.i. and metabolites x and y, expressed as a.i)
1213	 Number of analytical replicates
1214	Analytical Methodology
1215	144 Describe basic principle of analytical method(s) and their LOQ(s),
	Mathed D on encourse reference to analytical memory (c) and then DOQ(0),

1215144 Describe basic principle of analytical method(s) and their LOQ(s),1216Method ID or cross-reference to relevant method template

- 1217 1) Analytical Method Information
- 1218 2) Fortification Level
- 1219 3) Recovery (%)
- 1220

1221 Storage Stability

1222 145 Describe all storage intervals between sampling in the field and analysis in 1223 the laboratory, and cross-reference to storage stability study, as applicable.

REFERENCES - CITATIONS - LINKS

US and Canada

1226	EPA - OPPTS 860.1000 Residue Chemistry Test Guidelines and 860.1500 Crop Field
1227	Trials, <u>https://www.epa.gov/test-guidelines-pesticides-and-toxic-</u>
1228	substances/series-860-residue-chemistry-test-guidelines
1229	PMRA - Residue Chemistry Guidelines Section 9, Crop Field Trials, Regulatory Directive
1230	98-02 at https://www.canada.ca/en/health-canada/services/consumer-product-
1231	safety/reports-publications/pesticides-pest-management/policies-guidelines.html
1232	Joint Canada/United States Field Trial Requirements, Science Policy Note SPN2017-02,
1233	Pest Management Regulatory Agency, Health Canada, 11 July 2017. Actual version at
1234	https://www.canada.ca/en/health-canada/services/consumer-product-
1235	safety/reports-publications/pesticides-pest-management/policies-
1236	guidelines/science-policy-notes/2017/guidance-joint-canada-united-states-field-
1237	trial-requirements-spn2017-02.html
1238	Reduced Residue Chemistry Data Requirements for Seed-Treatment Uses, Memo, US
1239	EPA, 26 January 2018. Actual Version at https://www.epa.gov/sites/production/files/2018-
1240	01/documents/final-chemsac-seed-treatment-signed-012518.pdf
1241	

1242

EU

1243 1244 1245	European Commission, 1997. General Recommendations for the Design, Preparation and Realization of Residue Trials. SANCO 7029/VI/95 rev.5. Actual version at <u>https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en</u>
1246 1247 1248	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
1249	

1250

New Zealand

1224

1251	Data Requirements for A Food of Feed Use Clearance Plant Compounds, 41 ACVM 06/03
1252	http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/pc-food-
1253	<u>clearance.pdf</u>

1254

1255

Australia

1256Australian Pesticide Veterinary Medicine data guideline: Residue trials to obtain1257permanent maximum residue limits for crops 1 July 20141258https://apvma.gov.au/node/1028

1259 Brazil (non-OECD country included for reference only)

1260 Sindicato Nacional da Industria de Produtos Para Defesa Agricola, Sao Paulo, December 18,1261 2006

1262

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)

- 1269A Survey Report to Follow-up the Development of the Concept of Minimum Data1270Requirements for Establishing Maximum Residue Limits (MRLs) Including Import1271Tolerances for Pesticides (2004)
- 1272 Report of the OECD/FAO Zoning Project (2004)
- 1273 OECD Guidance Document on Overview of Residue Chemistry Studies (as revised in 1274 2009) [ENV/JM/MONO(2009)31]. Environment, Health and Safety Publication, series on 1275 Testing and Assessment, No. 64; series on Pesticides, No. 32; 2009.

36 |

- 1276OECD Guidance Document on Crop Field Trials, Second Edition, Series on Pesticides -1277No. 66 and Series on Testing & Assessment No. 164, ENV/JM/MONO(2011)50/REV1,12787th September 2016
- 1279OECD Guidelines for the Testing of Chemicals, TG 506: Stability of Pesticide Residues in1280Stored Commodities. Organisation for Economic Co-operation and Development, 161281October 2007.
- 1282OECD Guidance Document on Pesticide Residue Analytical Methods1283[ENV/JM/MONO(2007)17]. Environment, Health and Safety Publication, series on1284Testing and Assessment No. 72; 2007.
- 1285 OECD Guidance Document on the Definition of Residue [ENV/JM/MONO(2006)31]. 1286 Environment, Health and Safety Publication, series on Testing and Assessment, No. 63; 1287 series on Pesticides, No. 31, 2006. (under revision).
- 1288 OECD Harmonised Templates for Reporting Chemical Test Summaries. 1289 https://www.oecd.org/ehs/templates/
- 1290FAO, 2016. Submission and evaluation of pesticide residues data for the estimation of1291maximum residue levels in food and feed (FAO Manual, 3rd Edition). FAO Plant1292Production and Protection Paper, 225.
- 1293Julius Kühn-Institut (JKI), 2018. Growth stages of mono-and dicotyledonous plants -
BBCH1294BBCH
- 1295 https://www.julius-
- 1296kuehn.de/media/Veroeffentlichungen/bbch%20epaper%20en/page.pdf;1297https://www.openagrar.de/receive/openagrar_mods_00042351
- 1298European and Mediterranean Plant Protection Organization, Dose expression for plant1299protection products, EPPO General Standard PP1/239(2), Bulletin OEPP/EPPO Bulletin1300(2012) 42 (3), 409–415. https://pp1.eppo.int/standards/general
- 1301Miller D., North American International Harmonization Efforts for Pesticides: an update1302on current status and activities. 48th Codex Committee on Pesticide Residues (CCPR48)1303Chongqing, China 25 30 April, 2016. <a href="http://www.fao.org/fao-who-1304codexalimentarius/sh-
- 1305proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%2130652Fcodex%252FMeetings%252FCX-718-
- 130748%252FCCPR48%2Bmeeting%2Bpresentation%2BApril 2016 DMiller send3.1308pdf
- 1309James Nguyen, Carmen Tiu, Jane Stewart, and David Miller, Global Zoning and1310Exchangeability of Field Trial Residues Between Zones: Are There Systematic Differences1311in Pesticide Residues Across Geographies? Statistics and Public Policy 2019, Vol. 6, No 1,131214–23, https://doi.org/10.1080/2330443X.2018.1555068
- 1313Denis Hamilton, Árpád Ambrus, Roland Dieterle, Allan Felsot, Caroline Harris, Barbara1314Petersen, Ken Racke, Sue-Sun Wong, Roberto Gonzalez, Keiji Tanaka, Mike Earl, Graham1315Roberts and Raj Bhula. Pesticide residues in food—acute dietary exposure, Pest Manag1316Sci. 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	Сгор	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	Сгор	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	<u>Cherry, sweet</u>			Small stone fruit e.g., cherries: 1 kg from several places on 4 trees
		Cherry, sour			
	003B Plums	Plum			
		<u>Prune Plum</u>			
	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	Сгор	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
		<u>Currants, black, red or</u> white	Berry		
	004C Large shrub/tree berries	Elderberry	Berry		1 kg from 12 separate areas or bushes
	004D Small fruit vine climbing	<u>Grape</u> (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	<u>Strawberry</u>	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		
sub-t	005B Assorted tropical and sub-tropical fruits - edible peel – medium to large	Fig	Fruit		
		<u>Guava</u>	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	Сгор	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
	005C Assorted tropical and sub-tropical fruits - edible peel – palms	<u>Date</u>	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	<u>Avocado</u>	Fruit		
		<u>Mango</u>	Fruit		
		Pomegranate	Fruit		
		Banana	Fruit		24 fruits. Take two fingers each from top, middle and lowest hand of four harvestable bunches
		<u>Papaya</u>	Fruit		

Codex Commodity Group	Codex Subgroups	Сгор	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	<u>Kiwifruit</u>	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	<u>Onion, bulb</u>	Bulb		12 bulbs from 12 plants.(the sample should weigh at least 2 kg - where necessary, take a

Codex Commodity Group	Codex Subgroups	Сгор	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	Сгор	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					from at least two levels on each plant
		<u>Head cabbage</u> (white cabbage; red cabbage; Savoy cabbage) or <u>Chinese cabbage (type</u> <u>Pe-tsai)</u>	Fresh heads, with wrapper leaves		12 plants
	010C Stem Brassicas	<u>Kohlrabi</u>	Globe without leaves		12 plants
011 Fruiting vegetables, Cucurbits				Whole commodity after removal of stems	
	011A Fruiting vegetables, Cucurbits – Cucumbers and Summer squashes	<u>Cucumber</u>	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)
		<u>Squash, summer</u>	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,	<u>Melon (Cucumis melo)</u>	Fruit		12 fruits from 12 separate plants

Codex Commodity Group	Codex Subgroups	Сгор	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	<u>Tomato</u> <u>(large and small</u> <u>variety)</u>	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
		<u>Sweet pepper</u>	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.)
		<u>Chili pepper</u>	Fruit		24 fruits from small- fruiting varieties, 12 from large fruiting varieties. From 12

Codex Commodity Group	Codex Subgroups	Сгор	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	<u>Eggplant</u> (= 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)
		<u>spinach</u>	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)
		<u>Kale</u> , 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	Сгор	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	<u>Kangkung</u>	Leaves and stems		0.5 kg from 12 plants (or sites in plot)
		<u>Water mimosa or</u> <u>watercress</u>	Leaves and stems		0.5 kg from 12 plants (or sites in plot)
		<u>Watercress</u>	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	Сгор	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
	014D Succulent peas without pods	<u>Garden pea</u>	Succulent (green) seeds		1 kg
	014E Underground immature beans and peas	<u>Bambara groundnut</u> (immature seeds)			
015 Pulses			Dry seeds	Whole commodity	1 kg
	015A Dry beans	Bean, dry ² (Phaseolus spp.)	Dry seeds		
		<u>Soya bean, dry</u>			
		Cowpea	Seed		
		Lupine	Seed		
		Mung bean ³	Bean		
	015B Dry peas	<u>Pea, dry (Pisum spp.)</u>	Dry seeds		
		Lentil, dry	Seed		
		Pea, field ⁴	Seed		
	015C Dry underground pulses	<u>Bambara groundnut (dry)</u>			
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	<u>Beet, sugar</u>	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	Сгор	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	<u>Celery</u>	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	Сгор	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	<u>Artichoke, globe</u>	Flower head	Whole commodity after removal of obviously decomposed or withered leaves.	12 flowerheads
018 Edible Fung		<u>Mushroom</u>	Cap and stem	Whole commodity after removal of soil and growing medium	
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	mechanically can be sampled from the

Codex Commodity Group	Codex Subgroups	Сгор	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	<u>Barley</u>	Grain		
		Buckwheat	Grain		
		Oats	Grain		
	020C Rice Cereals	Rice	Grain		
	020D Sorghum Grain and Millet	<u>Sorghum</u>	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		
		<u>Sugarcane</u>	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	Сгор	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
					from all parts of the length of the canes.
		<u>Sorgo</u>			
		Sorghum, sweet			
022 Tree nuts				Whole commodity after removal of shell.	1 kg
		Almond	Nutmeat		
		<u>walnut</u>	Nutmeat		
		pecan	Nutmeat		
		<u>chestnut</u>	Nutmeat		
		<u>pistachio</u>	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 = <u>rape seed</u> = oilseed rape = canola	Seed		
		Flax = linseed	Seed		

Codex Commodity Group	Codex Subgroups	Сгор	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
		Sesame	Seed	Whole commodity	
	023B Sunflower seeds	<u>Sunflower</u>	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		<u>Cacao bean</u>	Bean	Whole commodity.	1 kg
		<u>Coffee</u>	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		
		<u>Mint</u> (Spearmint and, Peppermint) <u>or Basil [or</u> 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	Сгор	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 028H Citrus peel	Mace Any commodity in this subgroup			
	028I Dried Chili Peppers	Any commodity in this subgroup			
	The	following groups are unde	r 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	Сгор	Raw Agricultural Commodity	Commodity To Be Analysed	Field Sample Size
				Analyseu	proceeds through the crop.)
			Нау		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.)
			Нау		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		

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	Sorghum	n Sto	over ⁷		
	Grass (land)	pasture & range- For	rage	Whole commodity	1 kg
	Grass (j land)	pasture & range- Hay	у	Whole commodity	0.5 kg
052 Miscellaneous Fodder and Forage crops			dder		2 kg from 12 separate areas of plot. (Crops harvested mechanically can be sampled from the harvester as it proceeds through the crop.)
		Hay	у		0.5 kg from 12 separate areas of plot
		Stra	aw		0.5 - 1 kg from 12 separate areas of plot
		For	age		1kg from 12 separate areas of plot
	Almond	Hul	lls	Whole commodity after removal of shell and nutmeat	1 kg
	Cotton s		tton gin products ⁸		
057 Dried herbs	Hops	Ној	ps 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 ar leaves	nd dried	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