Adopted:
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OECD GUIDELINE FOR THE TESTING OF CHEMICALS

Crop Field Trial

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 to (1) quantify the expected range of residue(s) in crop commodities following treatment according to the proposed or established good agricultural practice (GAP); (2) to determine, when appropriate, the rate of decline of the residue(s) of plant protection product(s) on commodities of interest; (3) to determine residue values such as the Supervised Trial Median Residue (STMR) and Highest Residue (HR) for conducting dietary risk assessment; and (4) to derive maximum residue limits (MRLs). Crop field trials may also be useful for selecting residue definitions by providing information on the relative and absolute amounts of parent pesticide and metabolites.

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

3. This Crop Field Trial test guideline provides a harmonized approach to conducting and reporting crop field trials in OECD countries. This guideline, along with the Guidance Document on Overview of Residue Chemistry Studies, provides for generation of complete field trial data sets for pesticide uses on crops in comprehensive submissions to all OECD countries.

GENERAL CONSIDERATIONS

4. A complete data set in the context of this guideline is the number of crop field trials matching the critical GAP (*c*GAP) 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 *c*GAP 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 harmonized approach to formulation changes, new formulations, and different application methods**.** A bridging study normally involves a comparison of different formulations or application methods for the purpose of data extrapolation, but may or may not involve side-by-side comparisons. If bridging trials are deemed necessary and a

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Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
(Sub)tropical fruits with inedible peel Note: For all tropical or sub-tropical fruits with inedible peel, analyze peel and pulp separately; calculate and express the residue (MRL) on the whole commodity			
Avocado, Lychee (= lithi), Mango	Fruit	Whole commodity after removal of stone but calculated 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) Record weight ratio of stone and flesh.
Banana, Plantain	Whole fruit	Whole commodity including peel after removal of crown tissues and stalks.	24 fruits. Take two fingers each from top, middle and lowest hand of four harvestable bunches. Field residue data on both bagged and unbagged bananas should be provided.
Kiwifruit, Passion fruit, Papaya (= paw paw), Pomegranate, Guava	Fruit	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
Pineapple	Fruit	Whole commodity after removal of crown.	12 fruits
Tree nuts			
Almond	Nutmeat	Whole commodity after removal of hull and shell.	1 kg from all parts of the tree, top and bottom, exposed and covered by foliage
	Hulls	Whole commodity after removal of shell and nutmeat	1 kg
Other tree nuts (hazelnut, walnut, pecan, chestnut, pistachio)	Nutmeat	Whole commodity after removal of shell, husk or hull. Chestnuts are analyzed whole in the skin.	1 kg from all parts of the tree or bush, top and bottom, exposed and covered by foliage

Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Coconut	Coconut (meat and liquid combined)	Whole commodity after removal of shell. Analyze meat (= flesh) and liquid (=milk) separately; calculate and express the residue on the whole edible portion (meat and liquid).	12 nuts
Roots and tubers Roots or tubers 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.			
Beet, fodder (= beet), mangel, Beet, sugar,	Root Tops (leaves)	Leaves with heads are separated from the roots.	12 plants
Beet, garden (= Beetroot)	Root Tops (leaves)	Whole commodity after removal of obviously decomposed or withered leaves. Leaves are separated from the roots	12 plants
Carrot	Root	Tops are carefully cut off with a knife by cutting through the bottom of the stem at the lowest point of attachment of the outer petioles. If an annulus of root tissue is thereby severed from hollow-crown roots, the material should be recombined with the roots.	12 roots (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)

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Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Cassava = tapioca	Roots	Whole commodity after removing tops. .	12-24 roots from at least 6 plants (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Celeriac	Root	Remove adhering soil	12 plants
Chicory, Salsify	Root Tops (leaves)	Whole commodity after removal of obviously decomposed or withered leaves.	12 roots (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Horseradish	Root	Whole commodity after removal of soil.	12 roots (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Jerusalem artichoke	Tuber	Whole commodity after removing tops.	12 tubers (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Parsnip, Rutabaga (= swede),	Root	Whole commodity after removing tops.	12 roots (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Potato, sweet potato, yam	Tuber	Whole commodity after removing tops.	12 large tubers or 24 small tubers from at least 6 plants (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Radish, Turnip	Root tops (leaves)	Whole commodity after removing tops.	12 roots (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Taro	Corm foliage	Whole commodity after removing tops	12 corm (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)

Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
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.			
Onion, bulb, garlic, Shallot	Bulb	Whole commodity after removal of roots (and foliage) and whatever parchment skin is easily detached.	12 bulbs from 12 plants.(the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Onion, green (= spring onions)	Whole plant, without roots	Whole vegetable after removal of roots.	24 plants (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Fruiting vegetables			
Cucumber	Fruit	Whole commodity after removal of stems.	12 fruits from 12 separate plants
Eggplant (= aubergine)	Fruit	Whole commodity after removal of stems.	12 fruits from 12 separate plants, min 1 kg (in case of small varieties)
Gherkin	Fruit	Whole commodity after removal of stems.	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)
Muskmelon (= melon and includes cantaloupe, casaba, crenshaw, etc., but not watermelon), Pumpkin, Watermelon, Squash, winter	Fruit	Whole commodity after removal of stems. Analyze peel and pulp separately; calculate and express the residue on the whole commodity	12 fruits from 12 separate plants
Squash, summer	Fruit	Whole commodity after removal of stems.	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)

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Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Tomato, pepper, bell and non-bell (= sweet pepper and chili pepper)	Fruit	Whole commodity after removal of stems.	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.)
Okra	Fruit (pods)	Whole commodity after removal of stems.	1 kg
Brassica			
Broccoli	Flower head and stem	Analyze flower head and stems discarding leaves.	1 kg from 12 plants
Brussels sprouts	Leaf sprouts	Analyze "buttons" only.	1 kg from 12 plants. Buttons to be taken from at least two levels on each plant
Head cabbage (white cabbage; red cabbage; Savoy cabbage)	Fresh heads, with wrapper leaves	Whole commodity after removal of obviously decomposed or withered leaves.	12 plants
Cauliflower	Flower head and stem	Analyze flower head and stems discarding leaves.	12 plants
Collards	Greens	Whole commodity after removal of obviously decomposed or withered leaves.	1 kg from 12 plants

Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Kale	Leaves	Whole commodity after removal of obviously decomposed or withered leaves.	2 kg from 12 plants sampled from two levels on the plant
Kohlrabi	Globe without leaves	Whole commodity after removal of tops and obviously decomposed or withered leaves.	12 plants
Leafy vegetables			
Cress	Leaves and stems	Whole commodity	1 kg
Lettuce, leaf, endive/escarole/scarole	Leaves	Whole commodity after removal of obviously decomposed or withered leaves	12 plants
Lettuce, head	Fresh head, with wrapper leaves	Whole commodity after removal of obviously decomposed or withered leaves.	12 plants
Shouldard greens, spinach, swiss chard	Greens (leaves)	Whole commodity after removal of obviously decomposed or withered leaves	1 kg from at least 12 plants
Watercress	Leaves and stems	Whole commodity after removal of obviously decomposed or withered leaves.	0.5 kg from at least 12 plants
Lambs' lettuce	Leaves and stems	Whole commodity	1 kg
Rape greens	Greens (leaves)	Whole commodity.	1 kg

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Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Herbs			
Parsley	Leaves, fresh	Whole commodity after removal of obviously decomposed or withered leaves	0.5 kg fresh 0.2 kg dry
Mint (Spearmint and, Peppermint)	Tops (leaves and stems)	Whole commodity	0.5 kg fresh 0.2 kg dry
Other herbs	Leaves, fresh	Whole commodity	0.5 kg from at least 12 plants
Stem and stalk vegetables			
Artichoke, globe	Flower head	Whole commodity after removal of obviously decomposed or withered leaves.	12 flowerheads (the sample should weigh at least 2 kg - where necessary, take a larger number to produce a 2 kg sample)
Asparagus, Rhubarb	Spears (stems) Asparagus stems should be washed thoroughly in cold water	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)
Celery	Untrimmed leaf stalk (petiole)	Whole commodity	12 plants
Leek	Whole plant	Whole commodity	12 plants, min 2 kg
Fungi			
Mushroom	Cap and stem	Whole commodity after removing adhering soil.	12 items (the sample should weigh at least 0.5 kg - where necessary take a larger number of items to produce a 0.5 kg sample)
Fresh legumes and pulses			
Bean, fresh[1]	Beans (green) with pods; Succulent (green) seeds	Whole commodity (either whole bean with pods or without depending on target crop).	Beans with pods: 24 units or 0.5-1 kg ; succulent (green) seeds: 1 kg
	Bean fodder and hay	Whole commodity	0.5-1 kg
Bean, dry [2]	Dry seeds	Whole commodity (without pods)	1 kg
	Straw	Whole commodity	0.5-1 kg straw

Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Cowpea	Seed	Whole commodity.	1 kg
	Hay		0.5 kg
	Forage		1.0 kg
Lentil, dry, Lupine	Seed	Whole kernel after removal of shell.	1 kg
	Fodder and straw	Whole commodity	0.5-1 kg
Mung bean[3]	Bean Bean sprouts	Whole commodity	1 kg
	Fodder	Whole commodity	0.5-1 kg
Pea, fresh	Peas (green) with pods	Whole commodity (either whole pea with pods or without depending on target crop).	24 units or min 0.5 kg
	Succulent (green) seeds		1 kg succulent (green) seeds
	Pea fodder and hay	Whole commodity	0.5-1 kg
Pea, dry	Dry seeds	Whole commodity (without pods).	1 kg dry seeds
	Vines	Whole commodity	0.5-1 kg
Pea, field[4]	Seed	Whole commodity.	1 kg
	Vines		1 kg
	Hay		0.5 kg
Cereal grains			
Barley	Grain	Whole commodity (kernel plus hull).	1 kg
	Hay	Whole commodity.	0.5 kg
	Straw	Whole commodity.	0.5 kg
Buckwheat	Grain	Whole commodity – seed plus hull	1 kg

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Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Corn, field (= maize)	Grain	Whole commodity (grain without husk or cob)	1 kg
	Aspirated grain fractions[5]	North American requirement – Refer to OPPTS 860.1500 and Directive 98-02	
	Fodder, Stover[6]	Whole commodity	12 plants. (Cut each stem into three equal lengths (with leaves attached). Take top portion from stems 1 to 4, middle portion from stems 5 to 8 and bottom portion from stems 9 to 12, thus ensuring that parts of all 12 stems are included in the sample.)
	Forage		Forage (green or silage maize): 12 plants or min 1 kg. (Cut each stem and subsample as in previous item, retaining any cobs present on the appropriate portions of stem.)
Corn, pop	Grain	Whole commodity (grain without husk or cob)	1 kg
	Stover[6]	Whole commodity	see corn, field
Corn, sweet	Sweet corn (K + CWHR = kernels plus cob with husk removed)	Kernels plus cob without husk.	12 ears from 12 plants (the sample should weigh at least 2 kg - where necessary take a larger number of items to produce a 2 kg sample.)
	Stover[6]	Whole commodity	see corn, field
Oats, rye, millet	Forage	Whole commodity.	1 kg
	Hay		0.5 kg
	Straw		0.5 kg
	Grain		1 kg
Rice	Straw	Whole commodity.	0.5 kg
	Grain		1 kg
Sorghum	Grain	Whole commodity.	1 kg
	Forage		1 kg
	Stover[7]		1 kg
	Aspirated grain fractions[5]	North American requirement – Refer to OPPTS 860.1500 and Directive 98-02	
Sorghum, sweet	Stalk	Whole commodity	0.5 kg

Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Sorghum forages, Sudan grass	(See Grass)	Whole commodity	1 kg
Triticale	Grain	Whole commodity.	1 kg
	Forage		1 kg
	Hay		0.5 kg
	Straw		0.5 kg
Wheat	Grain	Whole commodity	1 kg
	Forage		1 kg
	Hay		0.5 kg
	Straw		0.5 kg
	Aspirated grain fractions[5]	North American requirement – Refer to OPPTS 860.1500 and Directive 98-02	
Oilseeds			
Rape = rape seed = oilseed rape = canola	Seed	Whole commodity.	0.5 kg
	Fodder and straw	Whole commodity	0.5-1 kg
Cotton	Undelinted seed	Whole commodity.	1 kg, with or without fibre from 12 points in the plot.
	Cotton gin byproducts[8]		0.5 kg
Flax = linseed	Seed	Whole commodity.	0.5 kg from at least 12 separate areas of each plot
Peanut	Nutmeat	Whole commodity.	1 kg
	Hay		0.5 kg
Safflower	Seed	Whole commodity.	0.5 kg
Sesame	Seed	Whole commodity	1-2 kg from 12 separate areas of plot.
Soybean	Forage	Whole commodity	1 kg
	Hay	Whole commodity	0.5 kg
	Seed, dry	Whole commodity.	0.5 kg
	aspirated grain fractions[5]	North American requirement – Refer to OPPTS 860.1500 and Directive 98-02	
Sunflower	Seed, dry	Whole commodity	0.5 kg
Seeds beverages			
Cacao bean	Bean	Whole commodity.	1 kg
Carob bean	Bean, green		1 kg
Coffee	Bean		1 kg

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Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Others			
Ginseng	Root, dried	Whole commodity.	12 roots (the sample should weigh at least 2 kg; where necessary, take a larger number to produce a 2 kg sample
Hops	Hops cones, dried	Whole commodity.	Take green cone samples from at least 4 hop plants. Select cones from all parts of the plant, top and bottom, exposed and protected by foliage. Final product is at least 0.5 kg dried cones
Pimento = allspice	Fruit	Whole commodity after removal of stems.	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.)
Spices[9]	Fresh (as marketed)	Whole commodity	0.5 kg (0.2 kg dry)
Sugarcane and cane tops	Cane	Whole commodity	Min 2 kg. Select whole canes from 12 areas of the plot and take short (e.g. 20 cm) sections from all parts of the length of the canes.
Tea[10] (*Camellia sinensis*)	Plucked and dried leaves	Whole commodity.	0.2 kg dry leaves
Animal forage and fodder			
Alfalfa	Forage	Whole commodity.	1-2 kg
	Hay		0.5 kg
Clover	Forage	Whole commodity.	1 kg
	Hay		0.5 kg
Crown vetch	Forage	Whole commodity .	1 kg
	Hay		0.5 kg
Grass (pasture & range-land)	Forage	Whole commodity	1 kg
	Hay		0.5 kg
Lespedeza	Forage	Whole commodity.	1-2 kg
	Hay		0.5 kg
Sainfoin	Hay	Whole commodity	1 kg
	Forage		0.5 kg
Trefoil	Forage	Whole commodity.	1 kg
	Hay		0.5 kg

Crop	Raw Agricultural Commodity	Commodity To Be Analyzed	Field Sample Size
Vetch	Forage	Whole commodity.	1 kg
	Hay		0.5 kg

[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.

RESIDUE ANALYSIS

99. The analytes included in the residue definition for risk assessment and enforcement that have been previously identified in the plant metabolism studies and defined using the OECD Guidance Document on the Definition of Residue should be quantified by an appropriate analytical method (Refer to OECD Guidance Document on Pesticide Residue Analytical Methods). Method recovery validation studies should be run concurrently with the residue analyses of crop field trial samples from each individual field trial in order to provide information on the recovery levels of the test compounds from the test substrates at various fortification levels using the residue analytical methods, and to establish a validated limit of quantitation.

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NUMBER OF CROP FIELD TRIALS

Combination of Data Sets for a Given Commodity

100. Individual OECD countries or political regions typically require a geographic distribution of a specified finite number of crop field trials conducted at the critical GAP to generate data for the estimation of the STMR, HR and MRL. The same practice would apply to estimation of the STMR, HR and MRL when trials conducted at the same GAP are considered from more than one country or region. Provided the GAP is comparable, the results of trials conducted in two or more countries or regions would be considered in deriving the STMR, HR and MRL for a given commodity.

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

1. Crop production regions, often defined or identified by the crop production practices (e.g., irrigation – beneath crop canopy vs. overhead sprinkler; planting densities of fruit trees) and the soils and climatic properties of the region.

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

3. Significance in the diet.

102. Having taken these factors into account, regulatory authorities in different OECD countries have each determined the minimum number of crop field trials required for registration of a use on a crop and establishment of a suitable MRL.

103. Geographic distribution of field trials within a country or region serves to ensure that data will be available for trials in key crop production areas, and a sufficient variety of horticultural practices may be represented in a crop field trial data set. Specific analyses of the influence of climate and ecology on residue levels have been performed (FAO/OECD) or are still ongoing in the US and Canada. Until these investigations are completed, the degree of importance of geographic zones remains uncertain. Preliminary results however indicate that crop production practices may have more impact on residue levels than geographic zones.

104. Although crop field trials in countries or regions should be performed up to the *c*GAP for each area, to date there are no definitive analyses that would allow trials with widely varying application rates or PHIs to be combined. However, variation of +/- 25% of PHI, application rate or number of applications is currently deemed acceptable (i.e., 25% rule).

Comprehensive Submissions

105. In the case of a comprehensive submission to all OECD countries where the desired GAP is uniform (i.e., maximum 25% deviation in one of the key parameters), a 40% reduction in the total number of trials is feasible, compared to the total number of trials determined by summation of individual country requirements. The assumption is that the number of trials specified in each crop production region reflects the economic (acreage) importance and/or dietary significance of the crop within that production region. Therefore there is no need to further consider acreage or dietary intake for a crop/commodity or to determine whether a crop is major or minor in terms of acreage, diet, or

trade on a global basis for the purpose of determining a minimum number of crop field trials for a comprehensive submission.

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

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

(1) Field trials are conducted according to the *c*GAP (within +/- 25% of the application rate, number of applications or PHI). At least 50% of the trials should be conducted at or above (within 25%) the *c*GAP. For this purpose, trials whose intended application rates match the cGAP but actual rates fall up to 10% below the cGAP (e.g., due to the normal variability in preparing spray solutions) are considered acceptable. In addition, for some authorities at least 50% of the trials need to be decline studies (see paragraphs 49-52).

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

108. Any reduction in the number of crop field trials should be distributed proportionally among the crop production regions as shown in the example for a 40% reduction for barley below. A table with trial numbers for crops grown throughout OECD countries is available in the OECD Guidance Document on Overview of Residue Chemistry Studies. In the event that the number of required trials changes in any given region, the total number and reduced number should be adjusted accordingly.

Country or Region	US/CAN	EU	JP	AUS	NZ	Total
Number without reduction	24	16	2	8	4	54
Number with 40% reduction	14	10	2	5	2	33

In no case may the number of trials in a given crop production region be reduced below 2. Thus, in the example the 40% reduction does not apply in Japan and therefore the total number of trials is 33 rather than 32, which is the actual 40% reduction from 54.

109. The minimum total number of trials for any crop in a comprehensive submission is eight. In addition, the total number of trials to be conducted may not be less than the requirement for any given individual region. For example, some crops such as dried lima beans have fewer total trials (14) than required in the EU alone (16). (For more details see OECD Guidance Document on Overview of Residue Chemistry Studies).

110. It is important to keep in mind that this comprehensive strategy would only apply to an OECD-wide submission. If, for example, the MRL submission is originally submitted to the US and Canada, the crop field trial guidelines, with respect to the number of trials, for those countries should

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be followed. Subsequently, if MRLs in additional OECD countries are pursued, the regulatory authorities in the additional countries should be consulted to determine what residue data are required. For example, following establishment of an MRL in the US and Canada, if an MRL for the same use is pursued in the EU, the applicant may consult with EU regulatory authorities about the possibility of using residue data from the US/Canadian data submission and performing fewer crop field trials in the EU.

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

112. 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 96-97, at least three samples should be collected and analyzed in studies on bulk and bagged commodities.

GENERAL INFORMATION ON CROP GROUPS AND EXTRAPOLATION

Extrapolation and Principles of Representative Commodities

113. National authorities use targeted data sets and data extrapolation to provide sufficient data for exposure assessment or for setting MRLs for both individual major and minor crop commodities, and crop commodity groups. It provides the mechanism for extending field trial data from several (typically two or three) representative commodities to related commodities in the same crop group or subgroup. Crop grouping and the identification of representative commodities are also critical for maximizing the applicability of a targeted data set determined for representative commodities for minor uses. The representative commodity (within the group) has the following properties: (1) major in terms of production and consumption and (2) most likely to contain highest residue.

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

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

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

116. Subgroups are primarily indicative of form and growth habit, and normally data for at least one commodity would be needed from each subgroup to set a group MRL. For example, citrus crops are sometimes divided into large diameter (orange, grapefruit) and small diameter (lemon, lime,

mandarin) subgroups. One commodity from each subgroup (e.g., orange + mandarin) would be needed for a group MRL. Likewise, orange might be extrapolated to grapefruit (same subgroup).

117. The commodity consumed may also be reflected in the sub grouping. For example, bulb vegetables are often sub grouped thusly (1) garlic, onion, shallot and (2) spring onions. The distinction is that only the bulb on those in subgroup 1 is consumed, whereas the bulb and aerial portions of the subgroup 2 may be eaten. Different residue levels might be expected on the two sub groupings for most pesticide applications. Thus, it might be possible to extrapolate from bulb onion to garlic and shallot, but not from bulb onion to spring onion.

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

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

Beyond the Crop Group or Wider Extrapolation

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

121. 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, in Australia, data for apple, peach, and nectarine may be translated to persimmon, a subtropical fruit.

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

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

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

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DATA REPORTING

124. Regulatory authorities recognize there are sections in the guideline which do not apply in all cases. Therefore, applicants should exercise scientific judgment in deciding which portions are germane to a specific data submission. In particular, uses such as seed treatments and post-harvest applications will have elements which are not applicable to other types of treatments or need to be modified to address the unique characteristics of these uses. For example, soil characteristics are not applicable to post-harvest applications.

(1) Summary/introduction

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

(2) Data tables and other graphic representations.

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

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

(A) Test substance (pesticide).
(i) Identification of the test pesticide active ingredient (a.i.), including CAS and IUPAC chemical name, common name (e.g., BSI, ISO), and company developmental or experimental name.
(ii) Identification of the pesticide formulated products used in the field trial, including trade name, type (EC, WP, G, etc.), and amount of active ingredient per gallon, pound, liter, kg, etc., and manufacturer.

(iii) Information on other relevant parameters, as pertinent, (e.g., tank mates, spray additives, carrier (encapsulating polymer, etc.)).
(iv) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the test substance.

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

(4) Test procedures.

(A) A detailed description of the experimental design and procedures followed in the growing of the RAC, applications of the pesticide formulated products, and harvestings of samples. The information provided, which may be presented on standardized field sheets, should include (in addition to a description of the test substance and test commodity):

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

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(xiv) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the growing of the RAC, applications of the pesticide formulated products, and harvesting of samples.

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

(i) Sample identification (means of labeling/coding).
(ii) Conditions (temperatures, container types/sizes, sample sizes, form (e.g., whole commodity; chopped), etc.) and duration of storage before shipping.
(iii) Methods of packaging for shipment (container types/sizes, sample sizes, ambient/iced, labeling/coding, etc.)).
(iv) Means of transport from the field to the laboratory.
(v) Dates (harvest, pre-shipping storage, shipping, and receipt in the laboratory).
(vi) Quality control (control measures/precautions followed to ensure the integrity of harvested samples during handling, pre-shipping storage, and shipping operations).
(vii) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of the handling, pre-shipping storage, and shipping procedures for harvested samples.

(C) A detailed description of the conditions and length of storage of harvested RAC samples following their receipt in the laboratory.

(D) A detailed description of the residue analyses used in determining the components of the residue definition in field trial RAC and storage stability samples. If the specified information is provided elsewhere within the overall data submission package, it need not be reiterated here. In that case, a reference to the relevant analytical methodology would be sufficient.

(E) Method recovery validation studies should be run concurrently with the residue analyses of crop field trial samples from each individual field trial in order to provide information on the recovery levels of the test compounds from the test substrates at various fortification levels using the residue analytical methods, and to establish a validated limit of quantification. The following information specific to the method validations, which may be presented on a standardized form, should include:

(i) Experimental design: Identity of test substrates (specific plant parts) and test compounds (parent/specific metabolites). Number and magnitude of fortification levels, number of replicate samples per test compound per fortification level, sample coding, control samples, etc.
(ii) Fortification procedure: Detail the preparation of the test compounds and test substrates and the manner in which the test compounds were introduced to the test substrates.
(iii) Dates: Test sample preparation (maceration/extraction/etc.), test compounds preparation (standard solutions of known concentration), residue analyses.
(iv) Residue results: Raw data, ppm or mg/kg found uncorrected (corrected values may also be reported but the basis of correction should be explained), procedures for calculating percent recoveries, recovery levels (range), and limits of quantitation and detection.
(v) Other. Any and all additional information the applicant considers appropriate and relevant to provide a complete and thorough description of analytical methodology validation procedures.

(5) Organization of data tables and forms.

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

(B) Tables on residue recovery values.

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

(D) Forms containing field trial history information.

(E) Forms containing harvesting, shipping, storage information.

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

(6) Trial Information

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

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

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

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

(iii) Country

(iv) Geographic Region (e.g., EU – N, EU – S, NAFTA 1….NAFTA 14)

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

(vi) County

(vii) City

(viii) GPS Coordinates (Optional)

(ix) Agricultural Practice of Crop Production or GAP (Optional)

Describe the agricultural practice of producing this crop in this region

(x) Crop Grouping (Optional)

(xi) Crop

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

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

(xii) Crop Code

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

(xiii) Soil Characterization (e.g., sandy loam, sandy clay loam, etc.)

(B) Plot (Information should be provided for all plots)

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

(ii) Control Plot (yes or no)

(iii) Plot Description - Describe plot specific information: e.g., plot size or area, row spacing, plant spacing, plants/area, crop height, seeding rates, number of seeds/area, exaggerated application rate, type of protection in case of a protected crop scenario, in case of a storage protection use give type, size and volume of store, also type and size of package of stored products (e.g., bulk, paper, plastic bag) etc.

(iv) Environmental Conditions

Describe abnormal weather conditions, if applicable, soil properties, any other environmental effect that might have had an impact on the results observed in this study ; for storage protection or glasshouse application give room/glasshouse temperatures/humidities

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(v) Describe crop maintenance on the plot, e.g., all procedures used in planting, maintenance, and harvest, including irrigation, application of fertilizers and other maintenance chemicals

(vi) Date of planting/sowing (for permanent crops year of planting is sufficient); in case of seed treatment give date of seed treatment and date of sowing, beginning and end of flowering, beginning and end of commercial harvest

(vii) Application

(a) Application No (1, 2, ...)

Consecutive numbers of the applications. i.e., 1st application = 1, 2nd application = 2

In the case of seed treatment, the sowing of the seeds is the first application.

(b) Growth stage (BBCH) at application, height of plants at application in case of "tall crops" (e.g., vines) and both height and crown height of plants in case of tree crops

(c) Date of Application (dd/mm/yyyy)

In case of seed treatment, state the date of sowing, in case of post-harvest dip, state the date of dip. In case of storage treatment give beginning and end of treatment together with beginning and end of ventilation

(d) Method of Application

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

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

(f) Test Item (Pesticide(s) tested in this study)

- Description of Test Item; information regarding tested Pesticide Product, End-Use Product, formulation, treated/dressed seed, etc. used in the test item applied to the trial plot, crop, and/or the harvested commodity
- Test Item Formulation Type
- Test Item Trade Name
- Test Item Active Ingredient Code/unique identifier (e.g., Company Internal Code)
- Test Item Active ingredient name(s)
- Test Item Nominal active ingredient content (e.g., grams a.i./liter)
- Test Item actual amount active ingredient applied (e.g., grams a.i./ha); for storage protection uses: application rate (e.g., kg a.i./m³), duration of treatment (h), duration of ventilation (h)
- Test Item actual amount active ingredient/seed if seed treatment (e.g., g a.i./100 kg seed)
- Test Item cumulative amount applied
- Adjuvant Added
  - Adjuvant Type
  - Adjuvant Name
  - Adjuvant amount in Spray Volume (%)
- Amount of water used in spray application (actual)

(viii) Sampling

(a) Sampling No.

Consecutive numbering of sampling events

(b) Sample ID – Unique sample identification code

(c) Sampling Timing: Provide any information regarding the timing of the sampling, e.g., relation to application events, days after last application, etc.

PHI – pre-harvest interval

DALA - Days after last application

Days Before Harvest

(d) Growth Stage (BBCH) at sampling

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

(f) Sampling Information (Optional)

Description of sampling method, special remarks (e.g., cabbage was harvested according to agricultural practice, 1st set of outer leaves were removed), sample handling (e.g., samples were frozen within 24 hours)

(g) Sampled Material/Commodity (Field RAC Sample)

- Analysis Sample (Description of Analysis sample)

Field Sample may be separated into several analysis samples, e.g., whole orange may be separated into a peel sample and a pulp sample for analysis (in that case also give weights of peel and pulp), aspirated grain fractions are separated from grain.

- Analysis Sample ID
- Analysis Sample Description (Optional)
- Analyte measured
- Analyte ID.
- Extraction Date (dd/mm/yyyy)
- Actual date of extraction
- Analysis Date (dd/mm/yyyy)
- Actual date of analysis
- Method ID
- Recovery
- Residue Level (e.g., mg/kg). Some regulatory authorites do not allow this value to be corrected for recovery and rely on the measured level of the analyte. Additionally give calculated residue if appropriate (e.g., residue xy calculated/expressed as yz or acid calculated/expressed as carboxylic ester, sum of a.i. and metabolites x and y, expressed as a.i….)
- Number of analytical replicates

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

(A) Analytical Method Information
(B) Fortification Level
(C) Recovery (%)

(8) Storage Stability: Describe longest storage interval between sampling in the field and analysis in the laboratory, and cross-reference to storage stability study, as applicable.

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ESSENTIAL DEFINITIONS

Active ingredient(s) is the component(s) of a formulation responsible for the direct or indirect biological activity against pests or diseases, or in regulating metabolism/growth, etc. A single active ingredient may be comprised of one or more chemicals or biological entities which may differ in relative activity. A formulation may contain one or more active ingredients. (FAO Specifications)

Adjuvant refers to any product added to the spray tank for the purpose of improving the performance of the test substance/active ingredient. Adjuvants may be characterized for example as wetting agents, spreader-stickers, compatibility agents, buffering agents, de-foamers, non-ionic surfactants, crop oil concentrates, etc.

Applicant refers to a company and/or person who applies for a registration, amended registration, re-registration or MRL.

Commodity group: Commodities within a commodity group are intended to have similar residue characteristics and to be suitable for setting group MRLs. Commodity groups (e.g., pome fruits, cereal grains) within the Codex Classification for Foods and Feeds are suitable for establishing group MRLs. Note that a given crop may be included in more than one commodity group. For example, wheat is a crop, and the commodities are grain (cereal grain commodity group) and straw (straw, fodder and forage of cereal grains and grasses commodity group).

Crop Field Trial – see "**Supervised Field Trial**"; these terms are considered synonymous for purposes of this guideline.

Crop field trial site is a geographically defined address/location within a country/region/state of a field, space, greenhouse or other area in/on which a pesticide field trial is conducted. A site may consist of several *plots* (areas with defined boundaries on which a crop is grown), including control and one or more treated plots, each of which receives a specific pesticide application regimen. The trial location for a post-harvest application is defined as the location where the post-harvest treatment takes place (for example treatment room or storage location). Additionally, the trial location for a seed treatment crop field trial is defined as the location where the seed is planted or sown.

Crop Group refers to a group of crops in which the expected residues on the commodities are likely to be similar (from treatment under similar GAP) and where group or subgroup MRLs can be considered. Crop grouping is based on similarities in appearance, harvestable commodity, edible portions and/or growth habits etc.

End-use product is a product containing active ingredient(s), and usually formulant(s), that is labeled with instructions for direct pest control use or application (See also 'Product')

Extrapolation refers to a system projection of data from one system to another system. In this sense, data received from one formulation can be extrapolated to another formulation under certain circumstances. In some instances, extrapolation of field trial data obtained from one commodity are used to predict the residue behaviour of another similar commodity under described circumstances and thus proposing the same MRLs for both commodities.

Formulant is any substance or group of substances other than an *active ingredient* that is intentionally added to a pest control product to improve its physical characteristics, e.g., sprayability, solubility, spreadability and/or stability.

Good Agricultural Practice in the use of Pesticides (GAP) includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable.

Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

Actual conditions include any stage in the production, storage, transport, distribution of food commodities and animal feed. (CAC, 1995) (FAO Manual)

Critical Good Agricultural Practice (*c*GAP) is the GAP selected to represent the worst-case use scenario within the context of national, regional, or global uses that will be producing the highest possible field residues on crop commodities. It usually includes the maximum use-rate and number of applications and the minimum re-treatment and pre-harvest intervals.

Good experimental field practice is the formalized process for designing and recording the practices used in the performance of field investigations with pesticides, and which assure the reliability and integrity of the data. See Good laboratory practice. (Draft IUPAC Glossary of Terms Related to Pesticides)

Good laboratory practice (GLP) is **t**he formalized process and conditions under which laboratory studies on pesticides are planned, performed, monitored, recorded, reported and audited. Studies performed under GLP are based on the national regulations of a country and are designed to assure the reliability and integrity of the studies and associated data. The U.S. Environmental Protection Agency GLP definition also covers field experiments (see Good experimental field practice). (after OECD, 1992) (Draft IUPAC Glossary of Terms Related to Pesticides)

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

Limit of detection (LOD) is the lowest concentration of a pesticide residue in a defined matrix where positive identification can be achieved using a specified method. (Draft IUPAC Glossary of Terms Related to Pesticides)

Limit of quantitation (LOQ) is the lowest concentration of a pesticide residue in a defined matrix where positive identification and quantitative measurement can be achieved using a specified method. (Draft IUPAC Glossary of Terms Related to Pesticides)

Maximum Residue Limit (MRL) is the maximum concentration of a residue that is legally permitted or recognized as acceptable in, or on, a food, agricultural commodity or animal feedstuff as set by Codex or a national regulatory authority. The term tolerance used in some countries is, in most instances, synonymous with MRL. It is normally expressed as mg/kg fresh weight.(after FAO, 1986) (Draft IUPAC Glossary of Terms Related to Pesticides)

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The **maximum residue level** is estimated as the maximum concentration of residues (expressed as mg/kg) which may occur in a food or feed commodity following Good Agricultural Practices. The estimated maximum residue level is considered by regulatory agencies to be suitable for establishing MRLs. (FAO Manual, 2002)

Pre-harvest interval (PHI) is the time interval between the last application of a pesticide to the next normal harvest**.** (Draft IUPAC Glossary of Terms Related to Pesticides)

Post-harvest treatment refers to a pesticide application to the harvested crop, which may occur before or during storage.

Product is a formulation containing one or more active constituent(s), and possibly non-active constituent(s), which is intended for application and administration, with or without dilution before use, and which is labeled with directions for use. (Australia Sec.4 Data Requirements)

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

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

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

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

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

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

REFERENCES – CITATIONS – LINKS

US and Canada
EPA – OPPTS 860.1000 Residue Chemistry Test Guidelines and 860.1500 Crop Field Trials http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1000.pdff

http://www.epa.gov/opptsfrs/publications/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1500.pdff

PMRA – Residue Chemistry Guidelines Section 9, Crop Field Trials, Regulatory Directive 98-02
http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802b-e.pdff

EU
91/414, Appendix B, General Recommendations for the Design, Preparation and Realization of Residue Trials http://ec.europa.eu/food/plant/protection/resources/app-b.pdff

91/414, Appendix D, Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs http://ec.europa.eu/food/plant/protection/resources/app-d.pdff
[now revision 8]

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

Australia
Australia Residue Guideline No. 24 – Residue Trials to Obtain Permanent MRLs for Crops
December 2000

Brazil (non-OECD country included for reference only)
Sindicato Nacional da Industria de Produtos Para Defesa Agricola, Sao Paulo, December 18, 2006

Other documents:

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

A Survey Report to Follow-up the Development of the Concept of Minimum Data Requirements for Establishing Maximum Residue Limits (MRLs) Including Import Tolerances for Pesticides (2004)
http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/DOWNLOAD/survey_min_data_req_mrls.pdff

Report of the OECD/FAO Zoning Project (2004)
http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.htm

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OECD Guidance Document on Overview of Residue Chemistry Studies [ENV/JM/MONO(2006)32]. Environment, Health and Safety Publication, series on Testing and Assessment, No. 64; series on Pesticides, No. 32; 2006 (under revision).

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

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

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

FAO Manual 2002. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. Food and Agriculture Organization of the United Nations. Rome, 2002. First edition

Growth stages of mono-and dicotyledonous plants - BBCH Monograph
http://www.bba.de/veroeff/bbch/bbcheng.pdf