L.N. 479 of 2004

PESTICIDES CONTROL ACT, 2001
(ACT NO.XI OF 2001)

European Community Methods of sampling for official Control of pesticide residues in and on Products of Plant and Animal origin Regulations, 2004

IN exercise of the powers conferred by article 5 of the Pesticides Control Act 2001, the Minister for Rural Affairs and the Environment has made the following regulations:-

Title and scope.

1. (1) The title of these regulations is the European Community Control of Pesticide Residues in and Products of Animal and Plant Origin Regulations, 2004 and they shall come into force on

(2) The scope of these regulations is to implement the rules found under European Union Council Directive 2002/63/EEC establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and in accordance with the provisions of article 5 of the Pesticide Control Act. The aforementioned Directive's provisions apply to the sampling of products of plant and animal origin in order to determine the level of pesticide residues for the purposes of European Union Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC and do not affect the sampling strategy, sampling levels and frequency as specified in Annexes III and IV to European Union Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products:

Provided that European Union Council Directives 76/895/EEC, 86/362/EEC and 90/642/EEC were transposed under the Maximum Residue Level of Pesticides in Produce of Plant Origin Regulations, 2004, L.N 199 of 2004.

Sampling for checks.

2. The territory of Malta shall require that sampling for the checks provided for in Article 6 of Directive 76/895/EEC, in Article 8 of Directive 86/362/EEC, in Article 8 of Directive 86/363/EEC and in Article 6 of Directive 90/642/EEC, be carried out in accordance with the methods described in the Schedule to these regulations.

SCHEDULE

METHODS OF SAMPLING PRODUCTS OF PLANT AND ANIMAL ORIGIN FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR CHECKING COMPLIANCE WITH MRLS

1. OBJECTIVE

Samples intended for the official control of the levels of pesticide residues in and on fruit and vegetables and in products of animal origin shall be taken according to the methods described below.

The objective of these sampling procedures is to enable a representative sample to be obtained from a lot for analysis to determine compliance with maximum residue levels (MRLs) for pesticides.

2. PRINCIPLES

Community MRLs are based on good agricultural practice data and raw commodities as well as foods derived from them that comply with the MRLs are intended to be toxicologically acceptable.

A MRL for a plant, egg or dairy product takes into account the maximum level expected to occur in a composite sample, which has been derived from multiple units of the treated product and which is intended to represent the average residue level in a lot. A MRL for meat and poultry takes into account the maximum level expected to occur in the tissues of individual treated animals or birds.

In consequence, MRLs for meat and poultry apply to a bulk sample derived from a single primary sample, whereas MRLs for plant products, eggs and dairy products apply to a composite bulk sample derived from one to ten primary samples.

3. DEFINITION OF TERMS

Analytical portion

A representative quantity of material removed from the analytical sample, of proper size for measurement of the residue concentration.

Note: A sampling device may be used to withdraw the analytical portion.

Analytical sample

The material prepared for analysis from the laboratory sample, by separation of the portion of the product to be analysed and then by mixing, grinding, fine chopping, etc., for the removal of analytical portions with minimal sampling error.

Note: Preparation of the analytical sample must reflect the procedure used in setting MRLs and thus the portion of the product to be analysed may include parts that are not normally consumed.

Bulk sample/aggregate sample

For products other than meat and poultry, the combined and well-mixed aggregate of the primary samples taken from a lot. For meat and poultry, the primary sample is considered to be equivalent to the bulk sample.

Notes: a) The primary samples must contribute sufficient material to enable all laboratory samples to be withdrawn from the bulk sample.

b) Where separate laboratory samples are prepared during collection of the primary sample(s), the bulk sample is the conceptual sum of the laboratory samples, at the time of taking the samples from the lot.

Laboratory sample

The sample sent to, or received by, the laboratory. A representative quantity of material removed from the bulk sample.

Notes:

a) The laboratory sample may be the whole or a part of the bulk sample.
b) Units should not be cut or broken to produce the laboratory sample(s), except where subdivision of units is specified in Table 3.
c) Replicate laboratory samples may be prepared.

Lot:

A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc. A suspect lot is one which, for any reason, is suspected to contain an excessive residue. A non-suspect lot is one for which there is no reason to suspect that it may contain an excessive residue.

Note: a) Where a consignment is comprised of lots which can be identified as originating from different growers, etc, each lot should be considered separately.

b) A consignment may consist of one or more lots.

c) Where the size or boundary of each lot in a large consignment is not readily established, each one of a series of wagons, lorries, ships bays, etc., may be considered to be a separate lot.

d) A lot may be mixed by grading or manufacturing processes, for example.

Primary sample/incremental sample:

One or more units taken from one position in a lot.

Notes: a) The position from which a primary sample is taken in the lot should preferably be chosen randomly but, where this is physically impractical, it should be from a random position in the accessible parts of the lot.

b) The number of units required for a primary sample should be determined by the minimum size and number of laboratory samples required.

c) For plant, egg and dairy products, where more than one primary sample is taken from a lot, each should contribute an approximately similar proportion to the bulk sample.

d) Units may be allocated randomly to replicate laboratory samples at the time of collecting the primary sample(s), in cases where the units are of medium or large size and mixing the bulk sample would not make the laboratory sample(s) more representative, or where the units (e.g. eggs, soft fruit) could be damaged by mixing.

e) Where primary samples are taken at intervals during loading or unloading of a lot, the sampling ‘position’ is a point in time.

f) Units should not be cut or broken to produce the primary sample(s), except where subdivision of units is specified in Table 3.

Sample:

One or more units selected from a population of units, or a portion of material selected from a larger quantity of material. For the purposes of these recommendations, a representative sample is intended to be representative of the lot, the bulk sample, the animal, etc., in respect of its pesticide residue content and not necessarily in respect of other attributes.

Sampling:

The procedure used to draw and constitute a sample.

Sampling device:

(i) A tool such as a scoop, dipper, borer, knife or spear, used to remove a unit from bulk material, from packages (such as drums, large cheeses) or from units of meat or poultry which are too large to be taken as primary samples.

(ii) A tool such as a riffle box, used to prepare a laboratory sample from a bulk sample, or to prepare an analytical portion from an analytical sample.

Notes: a) Specific sampling devices are described by ISO [1] [2] [3]and IDF [4] standards.

b) For materials such as loose leaves, the hand of the sampling officer may be considered to be a sampling device.

Sampling officer

A person trained in sampling procedures and, where required, authorised by the appropriate authorities to take samples.

Note: The sampling officer is responsible for all procedures leading to and including preparation, packing and shipping of the laboratory sample(s). The officer must understand that consistent adherence to the specified sampling procedures is necessary, must provide complete documentation for samples, and should collaborate closely with the laboratory.

Sample size

The number of units, or quantity of material, constituting the sample.

Unit

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[1] International Organisation for Standardisation, 1979. International standard ISO 950: Cereals - sampling (as grain).

[2] International Organisation for Standardisation, 1979. International standard ISO 951: Pulses in bags - sampling.

[3] International Organisation for Standardisation, 1980. International standard ISO 1839: Sampling - tea.

[4] International Dairy Federation, 1995. International IDF standard 50C: Milk and milk products - methods of sampling.

The smallest discrete portion in a lot, which should be withdrawn to form the whole or part of a primary sample.

Notes: Units should be identified as follows.

a) Fresh fruit and vegetables. Each whole fruit, vegetable or natural bunch of them (e.g. grapes) should form a unit, except where these are small. Units of packaged small products may be identified as in (d). Where a sampling device may be used without damaging the material, units may be created by this means. Individual eggs, fresh fruit or vegetables must not be cut or broken to produce units.

b) Large animals or parts or organs of them. A portion, or the whole, of a specified part or organ should form a unit. Parts or organs may be cut to form units.

c) Small animals or parts or organs of them. Each whole animal or complete animal part or organ present may form a unit. Where packaged, units may be identified as in (d), below. Where a sampling device may be used without affecting residues, units may be created by this means.

d) Packaged materials. The smallest discrete packages should be taken as units. Where the smallest packages are very large, they should be sampled as bulk, as in (e). Where the smallest packages are very small, a pack of packages may form the unit.

e) Bulk materials and large packages (such as drums, cheeses, etc) which are individually too large to be taken as primary samples. The units are created with a sampling device.

4. SAMPLING PROCEDURES [5]

4.1. Precautions to be taken

Contamination and deterioration of samples must be prevented at all stages, because they may affect the analytical results. Each lot to be checked for compliance must be sampled separately.

4.2. Collection of primary samples

The minimum number of primary samples to be taken from a lot is determined from Table 1, or Table 2 in the case of a suspect lot of meat or poultry. Each primary sample should be taken from a randomly chosen position in the lot, as far as practicable. The primary samples must consist of sufficient material to provide the laboratory sample(s) required from the lot.

Note: Sampling devices required for grain[6], pulses[7] and tea[8] are described in ISO recommendations and those required for dairy products [9] are described by the IDF.

Table 1

[5] ISO recommendations for sampling of grain or other commodities shipped in bulk may be adopted, if required.

[6] International Organisation for Standardisation, 1979. International standard ISO 951: Cereals - sampling (as grain).

[7] International Organisation for Standardisation, 1979. International standard ISO 951: Pulses in bags - sampling.

[8] International Organisation for Standardisation, 1980. International standard ISO 1839: Sampling - tea.

[9] International Dairy Federation, 1995. International IDF standard 50C: Milk and milk products – methods of sampling

Minimum number of primary samples to be taken from a lot

	Minimum number of primary samples to be taken from the lot
a) Meat and poultry	
A non-suspect lot	1
A suspect lot	Determined according to Table 2
	Minimum number of primary samples to be taken from the lot
b) Other products	
i) Products, packaged or in bulk, which can be assumed to be well mixed or homogenous	1 (A lot may be mixed by grading or manufacturing processes, for example)
ii) Products, packaged or in bulk, which may not be well mixed or homogeneous	For products comprised of large units, being primary food commodities of plant origin only, the minimum number of primary samples should comply with the minimum number of units required for the laboratory sample (see Table 4)
Either	
Weight of lot, kg	
< 50	3
50-500	5
> 500	10
Or:	
Number of cans, cartons or other containers in the lot	
1-25	1
26-100	5
> 100	10

Table 2

Number of randomly selected primary samples required for a given probability of finding at least one non-compliant sample in a lot of meat or poultry, for a given incidence of non-compliant residues in the lot

Incidence of non-compliant residues in the lot	Minimum number of samples required to detect a non-compliant residue with a probability of		
%	90%	95%	99%
90	1	-	2
80	-	2	3
70	2	3	4
60	3	4	5
50	4	5	7
40	5	6	9
35	6	7	11
30	7	9	13
25	9	11	17
20	11	14	21
15	15	19	29
10	22	29	44
5	45	59	90
1	231	299	459
0,5	460	598	919
0,1	2 301	2995	4 603

Notes: a) The table assumes random sampling.

b) Where the number of primary samples indicated in Table 2 is more than about 10% of the units in the total lot, the number of primary samples taken may be fewer and should be calculated as follows:

$$n = n_o/((1+(n_o-1))/N)$$

where
n = minimum number of primary samples to be taken
n_o = number of primary samples given in Table 2
N = number of units, capable of yielding a primary sample, in the lot.

c) where a single primary sample is taken, the probability of detecting a non-compliance a similar to the incidence of non-compliant residues.

d) For exact or alternative probabilities, or for a different incidence of non-compliance, the number of samples to be taken may be calculated from:

$$1- p = (1- i)^n$$

Where p is the probability and i is the incidence of non-compliant residues in the lot (both expressed as fractions, not percentages), and n is the number of samples.

4.3. Preparation of the bulk sample

The procedures for meat and poultry are described in Table 3. Each primary sample is considered to be a separate bulk sample.

The procedures for plant products, eggs or dairy products are described in Tables 4 and 5. The primary samples should be combined and mixed well, if practicable, to form the bulk sample.

Where mixing to form the bulk sample is inappropriate or impractical, the following alternative procedure may be followed. Where units may be damaged (and thus residues may be affected) by the processes of mixing or subdivision of the bulk sample, or where large units cannot be mixed to produce a more uniform residue distribution, the units should be allocated randomly to replicate laboratory samples at the time of taking the primary samples. In this case, the result to be used should be the mean of valid results obtained from the laboratory samples analysed.

Table 3

Meat and poultry: description of primary samples and minimum size of laboratory samples

	Commodity classification	Examples	Names of primary samples to be taken	Minimum size of each laboratory sample
Primary food commodities of animal origin				
1.	Mammalian meats *Note:* for enforcement of MRLs for fat-soluble pesticides samples must be taken according to part 2 below			
1.1	Large mammals, whole or Half carcass, usually 10 kg	Cattle, sheep, pigs	Whole or part of diaphragm, supplemented by cervical muscle, if necessary	0.5 kg
1.2	Small mammals, whole carcass	Rabbits	Whole carcass or hind quarters	0.5 kg after removal of skin and bone
1.3	Mammal meat parts, loose fresh/chilled/frozen packaged or otherwise	Quarters, chops, steaks, shoulders	Whole unit(s) or a portion of a large unit	0.5 kg after removal of bone
1.4	Mammal meat parts, bulk frozen	Quarters, chops	*Either* a frozen cross-section of a container *or* the whole (or portions) of individual meat parts	0.5 kg after removal of bone
2.	Mammalian fats, including carcass fat Note: samples of fat taken as described in parts 2.1, 2..2 and 2.3 may be used to determine compliance of the fat, or the whole product, with the corresponding MRLs			
2.1	Large mammals, at slaughter, whole or half carcass, usually > 10 kg	Cattle, sheep, pigs	Kidney, abdominal or subcutaneous fat cut from one animal	0.5 kg
2.2	Small mammals at slaughter, whole or half carcass, < 10 kg		Abdominal or subcutaneous fat cut from one animal	0.5 kg
2.3		Legs, chops, steaks	*Either* visible fat, trimmed from unit(s) *Or* whole unit(s) Or portions of whole unit(s), where fat is not trimmable	0.5 kg 2 kg
2.4	Mammal bulk fat tissue		Units taken with a sampling device from at least three positions	0.5kg

3.	Mammalian offal			
3.1	Mammal liver fresh, chilled, frozen		Whole liver(s), or part of liver	0.4 kg
3.2	Mammal kidney fresh, chilled, frozen		One or both kidneys, from one or two animals	0.2 kg
3.3	Mammal heart fresh, chilled, frozen		Whole heart(s), or ventricle portion only, if large	0.4 kg
3.4	Other mammal offal fresh, chilled, frozen		Part or whole unit from one or more animals, or a cross-section taken from bulk frozen product	0.5 kg
4.	Poultry meats Note: for enforcement of MRLs for fat-soluble pesticides, samples must be taken according to Part 5 below.			
4.1	Bird, large-sized carcase > 2 kg	Turkey, goose, cocks, capons and ducks	Thighs, legs and other dark meat	0.5 kg after removal of skin and bone
4.2	Bird, medium-sized carcase 500 g – 2kg	Hens, guinea fowl, Young chicken	Thighs, legs or other dark meat from at least three birds	0.5 kg after removal of skin and bone
4.3	Bird, small-sized carcase < 500 g carcase	Quail, pigeon	Carcasses from at least six birds	0.2 kg of muscle tissue
4.4	Bird parts fresh, chilled, frozen retail or wholesale packaged	Legs, quarters, breasts and wings	Packaged units or individual units	0.5 kg after removal of skin and bone
5.	Poultry fats, including carcase fat Note: samples of fat taken as described in parts 5.1 and 5.2 may be used to determine compliance of the fat, or the whole product, with the corresponding MRLs			
5.1	Birds, at slaughter, whole or part carcase	Chickens, turkeys	Units of abdominal fat from at least 3 birds	0.5 kg
5.2	Bird meat parts	Legs, breast muscle	*Either* visible fat, trimmed from unit(s) *Or* whole unit(s) or portions of whole	0.5 kg

			unit(s) where fat is not trimmable	2 kg
5.3	Bird fat tissue in bulk		Units taken with a sampling device from at least three positions	0.5 kg
6	Poultry offal			
6.1	Edible bird offal, except goose and dark fat liver and similar high-value products		Units from at least six birds, or a cross-section form a container	0.2 kg
6.2	Goose and duck fat liver and similar high-value products		Unit from one bird or container	0.05 kg
Processed foods of animal origin				

7	Secondary food commodities of animal origin, dried meats Derived edible products of animal origin, processed animal fats, including rendered or extracted fats Manufactured food (single ingredient) of animal origin, with or without packin medium or minor ingredients such as flavouring agents, spices and condiments, and which is normally pre-packed and ready for consumption, with or without cooking Manufactured food (multi-ingredient) of animal origin, a multi-ingredient food consisting of ingredients of both animal and plant origin will be included here if the ingredient(s) of animal origin is (are) predominant			
7.1	Mammal or bird, comminuted, cooked, canned, dried rendered, or otherwise processed products, including multi-ingredient products	Ham, sausage, minced beef, chicken paste	Packaged units, or a representative cross-section from a container or units (including juices, if any) taken with a sampling device	0.5 kg or 2 kg if fat content < 5%

Table 4

Plant products: description of primary samples and minimum size of laboratory samples

	Commodity classification	Examples	Nature of primary samples to be taken	Minimum size of each laboratory sample
Primary food commodities of plant origin				
1.	All fresh fruits All fresh vegetables including potatoes and sugar beets and excluding herbs			
1.1	Small sized fresh Products units generally < 25g	Berries, peas, olives	Whole units, or packages, or units taken with a sampling device	1 kg
1.2	Medium sized fresh products, units Generally 25 to 250 g	Apples, oranges	Whole units	1 kg (at least 10 units)
1.3	Large sized fresh products, units generally > 250 kg	Cabbages, cucumbers, grapes (bunches)	Whole unit(s)	2 kg (at least 5 units)
2.	Pulses	Beans, dried; peas, dried		1 kg
	Cereal grains	Rice, wheat		1 kg
	Tree nuts	Except coconuts		1 kg
		Coconuts		5 units
	Oilseeds	Peanuts		0.5 kg
	Seeds for beverages and sweets	Coffee beans		0.5 kg
3.	Herbs	Fresh parsley	Whole units	0.5 kg
		Others, fresh		0.2 kg
	(for dried herbs see part 4 of this table)			
	Spices	Dried	Whole units or taken with a sampling device	0.1 kg
Processed foods of plant origin				
4.	Secondary food commodities of plant origin, dried fruits, vegetables, herbs, hops, milled cereal products Derived products of plant origin, teas, herb teas, vegetable oils, juices and miscellaneous products e.g. processed olives and citrus molasses Manufactured foods (single ingredient) of plant origin, with or without packing medium or minor ingredients, such as flavouring agents, spices and condiments and which is normally pre-packed and ready for consumption with or without cooking Manufactured foods (multi-ingredient) of plant origin, including products with ingredients of animal origin where the ingredient(s) of plant origin predominate(s), breeds and other cooked cereal products			
4.1	Products of high-unit value		Packages or units taken with a sampling device	0.1 kg

4.2	Solid products of low bulk	Hops, tea, herb tea	Packaged units or units taken with a sampling device	0.2 kg
4.3	Other solid products	Bread, flour, dried fruit	Packages or units taken with a sampling device	0.5 kg
4.4	Liquid products	Vegetable oils, juices	Packaged units or units taken with a sampling device	0.5 l or 0.5 kg

Table 5

Egg and dairy products: description of primary samples and minimum size of laboratory samples

	Commodity classification	Examples	Nature of primary sample to be taken	Minimum size of each laboratory sample
Primary food commodities of animal origin				
1.	Poultry eggs			
1.1	Eggs, except quail and similar		Whole eggs	12 whole chicken eggs, 6 whole goose or duck eggs
1.2	Eggs, quail and similar		Whole eggs	24 whole eggs
1.3	Milks		Whole units, or units taken with a sampling device	0.5 l

Processed foods of animal origin

3.	Secondary food commodities of animal origin, secondary milk products such as skimmed milks, evaporated milks and milk powders Derived edible products of animal origin, milkfats derived milk products such as butters, butteroils, creams, cream powders, caseins etc Manufactured food (single ingredient) of animal origin, manufactured milk products such as yogurt, cheeses Manufactured food (multi-ingredient) of animal origin, manufactured milk products (including products with ingredients of plant origin where the ingredient(s) of animal origin predominate (s) such as processed cheese products, cheese preparations, flavoured yogurt, sweetened condensed milk			
			Packaged unit(s) or unit(s) taken with a sampling device	0.5 l (liquid) or 0.5 kg (solid)

i) Evaporated milks and evaporated creams in bulk must be mixed thoroughly before sampling, scraping adhering material from the sides and bottom of containers and stirring well. About 2 to 3 l should be removed and again stirred well before removing the laboratory sample.

ii) Milk powders in bulk should be sampled aseptically, passing a dry borer tube through the powder at an even rate.

iii) Creams in bulk should be mixed thoroughly with a plunger before sampling but foaming, whipping and churning must be avoided.

3.2	Butter and butteroils	Butter, whey butter, low fat spreads containing butter fat, anhydrous butteroil, anhydrous milkfat	Whole or parts of packaged unit(s) or unit (s) taken with a sampling device	0.2 kg or 0.5 l
3.3	Cheeses, including processed cheeses			
	Units 0.3 kg or greater		Whole unit(s) or unit(s) cut with a sampling device	0.5 kg
	Units < 0.3 kg			0.3 kg

	Note: Cheeses with a circular base should be sampled by making two cuts radiating from the centre. Cheeses with a rectangular base should be sampled by making two cuts parallel to the sides			
3.4	Liquid, frozen or dried egg products		Unit(s) taken aseptically with a sampling device	0.5 kg

4.4. Preparation of the laboratory sample

Where the bulk sample is larger than is required for a laboratory sample, it should be divided to provide a representative portion. A sampling device, quartering, or other appropriate size reduction process may be used but units of fresh plant products or whole eggs should not be cut or broken. Where required, replicate laboratory samples should be withdrawn at this stage or they may be prepared using the alternative procedure described above. The minimum sizes required for laboratory samples are given in Tables 3, 4 and 5.

4.5. Sampling record

The sampling officer must record the nature and origin of the lot; the owner, supplier or carrier of it; the date and place of sampling; and any other relevant information. Any departure from the recommended method of sampling must be recorded. A signed copy of the record must accompany each replicate laboratory sample and a copy should be retained by the sampling officer. A copy of the sampling record should be given to the owner of the lot, or a representative of the owner, whether or not they are to be provided with a laboratory sample. If sampling records are produced in computerised form, these should be distributed to the same recipients and a similar verifiable audit trail maintained.

4.6. Packaging and transmission of the laboratory sample

The laboratory sample must be placed in a clean, inert container which provides secure protection from contamination, damage and leakage. The container should be sealed, securely labelled and the sampling record must be attached. Where a bar code is utilised, it is recommended that alphanumeric information is also provided. The sample must be delivered to the laboratory as soon as practicable. Spoilage in transit must be avoided, e.g. fresh samples should be kept cool and frozen samples must remain frozen. Samples of meat and poultry should be frozen prior to despatch, unless transported to the laboratory before spoilage can occur.

4.7. Preparation of the analytical sample

The laboratory sample should be given a unique identifier which, together with the date of receipt and the sample size, should be added to the sample record. The part of the commodity to be analysed[10] i.e. the analytical sample, should be separated as soon as practicable. Where the residue level must be calculated to include parts which are not analysed [11], the weights of the separated parts must be recorded.

[10] Part of products to which maximum limits apply

[11] For example, the stones of stone fruit are not analysed but the residue level is calculated assuming that they are included but contain no residue.

4.8. Preparation and storage of the analytical portion

The analytical sample should be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn. The size of the analytical portion should be determined by the analytical method and the efficiency of mixing. The methods for comminution and mixing should be recorded and should not affect the residues present in the analytical sample. Where appropriate, the analytical sample should be processed under special conditions, e.g. at sub-zero temperature, to minimise adverse effects. Where processing could affect residues where practical alternative procedures are not available, the analytical portion may consist of whole units, or segments removed from whole units. If the analytical portion thus consists of few units or segments, it is unlikely to be representative of the analytical sample and sufficient replicate portions must be analysed, to indicate the uncertainty of the mean value. If analytical portions are to be stored before analysis, the method and length of time of storage should be such that they do not affect the level of residues present. Additional portions must be withdrawn for replicate and confirmatory analyses, as required.

5. CRITERIA FOR DETERMINING COMPLIANCE

Analytical results must be derived from one or more laboratory samples taken from the lot and received in a fit state for analysis. The results must be supported by acceptable quality control data. Where a residue is found to exceed a MRL, its identity should be confirmed and its concentration must be verified by analysis of one or more additional analytical portions derived from the original laboratory sample(s). The MRL applies to the bulk sample. The lot complies with a MRL where the MRL is not exceeded by the analytical result(s). Where results for the bulk sample exceed the MRL, a decision that the lot is non-compliant must take into account:

(i) the results obtained from one or more laboratory samples, as applicable, and
(ii) the accuracy and precision of analysis, as indicated by the supporting quality control data.

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