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ANNEX

ANNEX

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

on the methods of sampling and analysis, and on the interpretation of results for the official control of pesticide residues in and on food and feed of plant and animal origin, and repealing Directive 2002/63/EC

ANNEX

PROCEDURE FOR SAMPLING AND ANALYSIS FOR FOOD AND FEED OF PLANT AND ANIMAL ORIGIN FOR THE DETERMINATION OF PESTICIDE RESIDUES FOR CHECKING COMPLIANCE WITH MRLS

PART A
GENERAL PROVISIONS FOR FOOD

Sampling shall be performed by a sampling officer.

The sampling officer shall:

(a) be responsible for procedures, including preparation, packing and shipping of the laboratory sample(s);

(b) ensure consistent adherence to the specified sampling procedures;

(c) complete documentation for samples and collaborate closely with the relevant laboratory;

(d) take precautions to avoid any effect on the levels of residues and avoid any adverse effect on the analytical determination or avoid making the samples unrepresentative in the course of sampling and transfer of the sample to the laboratory;

(e) sample separately each lot or sublot which is to be examined;

(f) in cases where a consignment consists of more than one lot, consider each lot separately and decide what is to be included in the sample.

Where the size or boundary of each lot in a large consignment is not readily established, the sampling officer may consider that other physical barriers, such as wagons, lorries or ships bays, form a separate lot or sublot.

Samples taken at growers shall be collected at farm-gate, from products ready to be placed on the market.

PART B
SAMPLING PROCEDURES FOR FOOD

B.1 Division of lots into sublots

Where necessary and possible, the sampling officer shall divide larger lots into sublots to ensure all parts are represented, on condition that the sublot may be separated physically. The sampling officer shall ensure that each sublot is physically separated and identifiable.

For food traded in bulk consignments (e.g. cereals) Table 1 shall apply.

For food not traded in bulk Table 2 shall apply.

Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the sublot may exceed the weight mentioned in Tables 1 and 2 by a maximum of 20 %.

Table 1
Subdivision of lots into sublots for food traded in bulk

Lot weight (ton)	Maximum weight or number of sublots
≥ 1500	500 tonnes
> 300 and < 1500	3 sublots
≥ 100 and ≤ 300	100 tonnes

< 100	-

Table 2
Subdivision of lots into sublots for food not traded in bulk

Lot weight (ton)	Weight of sublots
≥ 15	7,5-30 tonnes
< 15	-

B.2 Collection of incremental samples

The sampling officer shall take incremental samples from various randomly chosen and evenly distributed positions throughout the whole sampled portion; the samples shall be of approximately equal size. In exceptional cases, where this is physically not practical, the sampling officer shall take incremental samples from random positions in the accessible part of the lot/sublot. In such case the sampling officer shall record the procedure followed in the sampling report.

The sampling officer shall identify unit(s) for incremental samples as follows:

(a) Fresh fruits and vegetables

Each whole fruit, vegetable or natural medium-sized bunch (e.g. grapes) shall form a unit, except where this fruit, vegetable or bunch is small. Units of packaged small products (e.g. currants) may be identified in accordance with point (e). , If the material cannot be damaged a sampling device may be used and thus residues cannot be affected In the case of bananas and similar fruits and vegetables made available in a bunch, individual items shall be considered as a unit.

(b) Eggs

Each egg shall form a unit.

(c) Large animals or parts or organs of them

A part or whole of a large animal or of a specified organ shall form a unit. Parts or organs may be cut to form units.

(d) Small animals (except insects) 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 set out in point (e). When creating units, a sampling device may be used if the material cannot be damaged and thus residues cannot be affected.

(e) Packaged materials

The smallest discrete packages shall be taken as units from the same lot/sublot. Where the smallest packages are very large, as much as practical, they shall be sampled as bulk, as specified in point (f). Where the smallest packages are very small, a pack of packages may form a unit and the packages shall be considered as part of the same lot.

(f) Bulk materials and large packages (e.g. drums, cheeses which are individually too large to be taken as incremental samples).

The units are created with a sampling device.

The minimum number/amount of incremental samples to be taken by the sampling officer from a lot/sublot to form the aggregate sample shall be determined as set out in Table 3, or in the case of a suspect lot as set out in Table 7.

The incremental samples shall ensure sufficient quantity to enable all laboratory samples, including replicate samples, drawn for analytical purposes, to be withdrawn from the aggregate sample.

For products where more than one incremental sample is taken from a lot/sublot, each shall contribute with a similar proportion to the aggregate sample.

Where incremental samples are taken at intervals during loading or unloading of a lot/sublot, the sampling 'position' is a point in time and the number of incremental samples is determined by taking into account the size of the sampled portion.

The number of units required for incremental samples is specified in Table 3. The minimum sizes of laboratory samples are specified in Tables 4, 5 and 6. Units may be collected using sampling devices, for example:

(a) 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, poultry or fish which are too large to be taken as incremental samples;

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

For materials such as loose leaves, the sampling officer shall use gloves when sampling by hands to prevent cross-contamination.

The sampling devices shall be cleaned between uses as necessary, to prevent any cross-contamination.

Units may be allocated randomly to replicate laboratory samples at the time of collecting the incremental sample(s), in cases where the units are of medium or large size (as described in Table 5) and mixing the aggregate sample would not make the laboratory sample(s) more representative, or where the units (e.g. eggs, soft fruit) could be damaged by mixing.

Where the sampling is not carried out as set out in point B.2 due to unacceptable commercial consequences (e.g. because of packaging forms, damage to the lot), or the sampling officer applies an alternative method provided that it is sufficiently representative for the sampled lot or sublot and is fully documented, the sampling officer shall record the procedure followed in the sampling report referred to in point B.6.

Units shall not be cut or broken to produce incremental sample(s) except in accordance with the subdivision of units specified in Table 4.

Table 3

Minimum amount/number of incremental (primary) samples to be taken from a lot/sublot to form the aggregate sample

	Minimum amount/number of incremental samples to be taken from the lot/sublot
a) Suspect lot	Determined according to Table 7
b) Products, packaged or in bulk, which can be assumed to be well mixed or homogeneous	1 (A lot may be mixed, as an example, by grading or manufacturing processes); For large portions, see i) and ii)

c) Products packaged or in bulk, which may not be well mixed or homogeneous	For primary food or commodities of plant origin, for products comprised of medium sized, large-sized or very large-sized units, the minimum number of incremental samples shall comply with the minimum number of units required for the laboratory sample (see Table 5)
Either:	
Weight or volume of lot/sublot (in kilogram or litre)	
< 50	3
≥ 50 and ≤ 500	5
≥ 500 and ≤ 2,5 tonnes	10
> 2,5 tonnes	√ (20 times the number of tonnes making up the sampled portion) (*), up to 40 incremental samples * Where the number obtained is a fraction, it shall be rounded up to the next whole number For large portions, see i) and ii)

In the case of large portions (sampled portions > 500 tonnes):

i) the number of incremental samples to be taken = 40 incremental samples + √ number of tonnes in relation to the control of substances or products uniformly distributed throughout the food (e.g. in the case of a lot of 529 tonnes, 40+23=63 incremental samples are to be taken);

ii) or 100 incremental samples + √ number of tonnes in relation to the control of constituents or substances likely to be distributed non-uniformly in food (e.g. in the case of a lot of 529 tonnes of wheat, 100+23=123 incremental samples are to be taken).

Or:	
Number of packages, cans, cartons or other units in the lot/sublot	
≤ 25	1
26-100	5%, at least 2 units
>100	5%, at maximum 10 units
d) Packaged food supplements	
Number of packages in the lot/sublot	
1-50	1
51-250	2
251-1000	4
>1000	4+1 package per 1000 retail packages with a maximum of 25 retail packages
e) Miscellaneous products of unknown lot size (only applicable for e-commerce)	1

f) Fishery and sea products including shellfish and crustaceans
The minimum sample quantities shall be defined in the national residue control programme. The minimum sample quantities shall be sufficient to enable the approved laboratories to carry out the analytical procedures necessary to complete the screening and the confirmatory analyses. Specifically, for fishery and sea products including shellfish and crustaceans, a sample consists out of one or more animals, depending on the requirements of the analytical methods.

B.3 Preparation of the aggregate/reduced sample by the sampling officer

The aggregate sample shall be made up by combining the incremental samples.

The applicable requirements for meat and poultry are described in Table 4. Each incremental sample shall be considered to be a separate aggregate sample.

The applicable requirements for plant products, eggs or dairy products are described in Tables 5 and 6, respectively. The incremental samples shall be combined and mixed well, if practicable, to form the aggregate sample.

Where separate laboratory samples are prepared during collection of the incremental sample(s) from the lot/sublot, the aggregate sample shall be considered to be the combined sum of the laboratory samples.

If needed, the aggregate sample can be representatively reduced using a sample reduction method.

Where mixing to form the aggregate 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 aggregate sample, or where large units cannot be mixed to produce a more uniform residue distribution, the units may be allocated randomly to replicate laboratory samples at the time of taking the incremental samples. In this case, the result to be used shall be the means of obtaining valid analytical results from the analytical portions analysed and formed from the replicate laboratory samples.

B.4 Preparation, packaging, sealing and transport of the laboratory sample by the sampling officer

The laboratory sample is formed from the aggregate sample and may be the whole or a part of the aggregate sample. The sampling officer shall then prepare the laboratory and replicate samples from the reduced sample of approximately the same amount and conforming to the quantitative requirements of Part B. The replicate sample may also be prepared in the laboratory by the laboratory staff. Units shall not be cut or broken to produce the laboratory sample(s), except where subdivision of units is specified in Tables 4 and 5.

Where the aggregate sample is larger than the required laboratory sample, it may be reduced 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 shall not be cut or broken.

The minimum sizes required for laboratory samples are specified in Tables 4, 5 and 6.

A smaller sample size than those specified in Tables 4 and 5 may be taken from a product in duly justified cases (such as the high value of the product) and provided that the smaller sample does not result in insufficient sample material to perform appropriate analysis. The reason for doing so shall be noted in the sampling record.

The laboratory sample shall be placed in a clean, chemically inert container non-reactive with water, ensuring safe protection against environmental and atmospheric factors and preserving the homogeneity of the sample. The container shall be sealed at the place of sampling, securely and accurately labelled, and accompanied by the sampling report, if it is a paper report. In the case of paperless (digital) procedures, the sample shall be identifiably linked to the relevant digital record entry. Where a bar code is used, it is recommended that alphanumeric information is also provided.

The sampling officer shall deliver the laboratory sample to the laboratory as soon as practicable. Spoilage in transit shall be prevented, e.g. fresh samples shall be kept cool and frozen samples shall remain frozen. Samples of primary food commodities of animal origin shall be frozen prior to despatch, unless transported to the laboratory before spoilage can occur. In cases where samples of primary food commodities of animal origin are transported unfrozen decay or spoilage shall be avoided during transport.

Where a replicate sample is left with the food business operator, the food business operator shall be instructed (e.g. via a leaflet) on how to store and transfer the sample to the laboratory, to minimize degradation of residues. If the food business operator is not able to fulfil the storage requirements, the sample shall be delivered to the laboratory as soon as practicable for further processing (e.g. homogenisation) as required by Member State's procedures and to store it at a low temperature until the decision for analysis is taken.

Table 4

Food of animal origin: description of incremental (primary) samples and minimum size of laboratory samples

#	Commodity classification[1]	Examples	Part of incremental sample to be taken	Minimum size of each laboratory sample
Primary food commodities of animal origin				
1	Mammalian muscle – Categories: 1011010, 1012010, 1013010, 1014010, 1015010, 1017010			
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 hindquarters	0,5 kg after removal of skin and bone
1.3	Mammal parts, loose fresh/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 parts, bulk	Quarters,	Either a frozen cross-section of a	0,5 kg

[1] In accordance with the classification of products in Annex I to Regulation (EC) 396/2005.

	frozen	chops	container or the whole (or portions) of individual muscle parts	after removal of bone
2	Mammalian fats, including carcass fat – Categories: 1011020, 1012020, 1013020, 1014020, 1015020, 1017020			
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 <10kg		Abdominal or subcutaneous fat from one or more animals	0,5 kg
2.3	Mammal parts	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, where feasible in practice	0,5 kg
3	Mammalian offal – Categories: 1011030, 1012030, 1013030, 1014030, 1015030, 1017030 1011040, 1012040, 1013040, 1014040, 1015040, 1017040 1011050, 1012050, 1013050, 1014050, 1015050, 1017050			
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 muscle – Category: 1016010			
4.1	Bird, large-sized carcass > 2kg	Turkey, goose, cocks, capons and ducks	Thighs, legs and other dark muscle	0,5 kg after removal of skin and bone
4.2	Bird, medium-sized carcass 500g-2kg	Hens, guinea fowl, young	Thigh, legs or other dark muscle from at least three birds	0,5 kg after removal of skin and bone

		chicken		
4.3	Bird, small-sized carcass < 500g carcass	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 carcass fat – Category: 1016020.			
5.1	Birds at slaughter, whole or part carcass	Chickens, turkeys	Units of abdominal fat from at least 3 birds, where feasible in practice	0,5 kg
5.2	Bird parts	Legs, breast, muscle	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 0,5 kg or 2 kg if fat content <5%
5.3	Bird fat tissue in bulk		Units taken with a sampling device from at least three positions	0,5 kg
6	Poultry Offal – Categories: 1016030, 1016040, 1016050			
6.1	Edible bird offal, except goose and duck fat liver and similar high-value products		Units from at least six birds, or a cross-section from a container, where feasible in practice	0,2 kg
6.2	Goose and duck fat liver and similar high-value products		Unit from one bird or container	0,1 kg
7	Honey – Category: 1040000			
7.1	Honey		Packaged units	0,5 kg
8	Amphibians and Reptiles – Category: 1050000 [1]			
8.1	Muscle	Crocodile, lizard	Units from tail, body, legs	0,5 kg
8.2		Frogs	Legs	0,5 kg
8.2		Snake	Units from body	0,5 kg
9	Terrestrial invertebrate animals – Category: 1060000			
9.1	Snails	Roman snail	Whole snails	12 snails

9.2	Insects	Crickets	Whole insects	10 whole insects or 0.2 kg
		Larvae of locusts, mealworms	Larvae	0,5 kg
10	Wild Terrestrial vertebrate animals – Category: 1070000			
10.1	The rules set for domesticated animals under categories 1-3 of this table shall apply for the corresponding tissue.			
Processed foods of animal origin				
11	Secondary food commodities of animal origin, dried meats. Derived edible products of animal origin, processed animal fats, including rendered or extracted fats, food supplements. Manufactured food (single ingredient) of animal origin, with or without packing medium or minor ingredients such as flavouring agents, colorants (e.g. carmine), spices and condiments, insect powder 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, including baby food.			
11.1	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
11.2	Food Supplements	Collagen	Packaged units	0,1 l or 0,1 kg

Table 5

Plant products: description of incremental (primary) samples and minimum size of laboratory samples

	Commodity classification[1]	Examples[2]	Part of incremental sample to be taken	Minimum size of each laboratory sample
Primary food commodities of plant origin				
1	Fruits, fresh or frozen – Category: 0100000			

[2] The commodities that are listed as examples could potentially fall into a different category if the average unit size is larger or smaller. For example, cucumbers and potatoes can range from small to large sizes.

	Vegetables, fresh or frozen – Category: 0200000, including mushrooms (0280000)			
1.1	Small-sized product units <25 g	Berries, peas, olives	Whole units, or packages, or units taken with a sampling device	1 kg
1.2	Medium-sized products, units 25-250 g	Apples, oranges	Whole units	1 kg but at least 10 units
1.3	Large-sized fresh products, units 250-1000 g	Cucumbers, grapes (bundles, bunches)	Whole unit(s)	2 kg but at least 5 units
1.4	Very large-sized fresh products, units > 1000g	Pumpkins, melons	Whole unit(s)	2 kg but at least 5 units
1.5	Tree nuts (0120000)	Except coconuts	Packages, or units taken with a sampling device	1 kg
		Coconuts	Whole units	5 units
1.6	Herbs (0256000)	Parsley, sage	Whole units	0,2 kg
2	Pulses (0300000)	Beans, Peas	Packages, or units taken with a sampling device	1 kg
3	Oilseeds (0401000)	Linseeds	Packages, or units taken with a sampling device	0,5 kg
4	Cereal grains (0500000)	Rice, wheat	Packages, or units taken with a sampling device	1 kg
5	Seeds for beverages and sweets	(Green) coffee beans	Packages, or units taken with a sampling device	0,5 kg
6	Sugar Plants (0900000)	Sugar beets	Whole units	2 kg at least 2 units

Processed foods of plant origin

7	Secondary food commodities of plant origin, dried fruits, dried vegetables, dried herbs, herbal infusions (0630000), hops (0700000), spices (0800000), milled cereal products, extracts. Derived products of plant origin, teas, herb teas, vegetable oils and drinks, juices, food supplements 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, colorants, 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), breads and other cooked cereal products, including cereal-based baby food.			
7.1	Spices (0800000)	Nutmeg	Packages of units taken with a sampling device	0,1 kg
7.2	Products of high unit value	Rose petals, saffron	Packages of units taken with a sampling device	0,1 kg [2]
7.3	Solid products of low bulk	Hops, tea, herb tea	Packaged units or units taken with a sampling device	0,1kg[2]
7.4	Other solid products	Bread, flour, dried fruit	Packages or other whole units, or units taken with a sampling device	0,5 kg
7.5	Liquid products	Vegetable oils, juices	Packaged units or units taken with a sampling device	0,5 l or 0,5 kg
7.6	Food Supplements	Ashwagandha, acai, spirulina	Packaged units	0,1 l or 0,1 kg[2]
7.7	Baby food	Ready to eat, fruit / vegetable based	Packaged units or units taken with a sampling device	0,5 l or 0,5 kg

Table 6

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

	Commodity classification[4]	Examples	Part of incremental sample to be taken	Minimum size of each laboratory sample
Primary food commodities of animal origin				
1	Poultry eggs – Category: 1030000			
1.1	Eggs, large	Goose, duck or similar	Whole eggs	6 whole eggs
1.2	Eggs, medium	Chicken and similar	Whole eggs	10 whole eggs
1.3	Eggs, small	quail and similar	Whole eggs	24 whole eggs
2	Milks – Category: 1020000			
2.1	Milks		Whole units, or units taken with a	0,5 l

			sampling device	
Processed foods of animal origin				
3	Secondary food commodities of animal origin, secondary milk products such as skimmed milks, evaporated milks, milk powders, including infant formulae, and egg powder. 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 yoghurt, 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 predominates(s)) such as processed cheese products, cheese preparations, flavoured yoghurt, sweetened condensed milk.			
3.1	Liquid milks, milk powders, evaporated milks and creams, dairy ice creams, creams yoghurts		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 shall be mixed thoroughly before sampling, scraping adhering material from the sides and bottom of containers and stirring well. About 2 to 3 l shall be removed and again stirred well before removing the laboratory sample (ii) Milk powders in bulk shall be sampled aseptically, passing a dry borer tube through the powder at an even rate. (iii) Creams in bulk shall be mixed thoroughly with a plunger before sampling but foaming, whipping and churning shall be avoided.			
3.2	Butter and butteroils	Butter, whey butter, low fat spreads containing butter fat, anhydrous butteroil, anhydrous fat	Whole or parts of packaged unit(s) or unit(s) taken with a sampling device	0,2 kg or 0,2 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 shall be sampled by making two cuts radiating from the centre. Cheeses with a rectangular base shall 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

Table 7

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

Incidence of non-compliant residues in the lot/sublot	Minimum number of samples (n_0) required to detect non-compliant residues with a probability of:		
	90%	95%	99
90%	2	2	3
80%	2	3	4
70%	3	4	5
60%	3	4	6
50%	4	6	8
40%	6	7	11
30%	8	10	15
20%	12	16	24
10%	25	32	49
5%	51	66	101
1%	255	332	510

Note: values in the table are based on an assumed 90% sensitivity of the test.

The above table is based on the following formula:

$$n = \frac{\ln(1-p)}{\ln(1-i*Se)}$$

n = number of samples required

p = desired probability of detecting at least one non-compliant sample

i = estimated incidence rate (proportion of the lot expected to be non-compliant)

Se = sensitivity

B.5 Replicate sample

The replicate sample shall be taken from the well-mixed aggregate sample or from the laboratory or analytical sample by the laboratory staff or by the sampling officer. Replicate samples are prepared in the same way as laboratory samples.

B.6 Sampling report

A report shall be produced after each sampling procedure and include, at least, the following data:

(1) Declaration that sampling was performed in accordance with the rules laid down in Implementing Regulation (EU) ..../.... *[Publication Office: please insert the reference to this Regulation];*

(2) Address of the competent authorities;

(3) Name of the sampling officer or identification code;

(4) (Official) identification number of the sample;

(5) Sampling date;

(6) Name and address of the food business operator;

(7) Name and address of the farm of origin (when sampling on farm);

(8) Registration number of the establishment or slaughterhouse number, where relevant;

(9) Animal, plant or product description or name of the food;

(10) Lot size;

(11) Lot identification;

(12) Where relevant, medication within the last four weeks before sampling (when sampling on farm);

(13) Sampling programme, where relevant;

(14) Particular remarks, where relevant.

The sampling officer shall:

(a) sign or authenticate a paper or electronic copy of the sampling report;

(b) provide a copy of the sampling report to the food business operator of the lot/sublot, or his, her or its representative, regardless of whether that business operator is to be provided with a replicate sample.

Where sampling records are in paper form, the competent authority shall keep the original of the sampling report or the sampling officer shall send the original sampling report to the laboratory.

Confidentiality shall be ensured in accordance with Article 8 of Regulation (EU) 2017/625.

Any deviation from the specified method of sampling shall be recorded in detail in the sampling report.

Where sampling records are in paper form, a signed copy of the record shall accompany each replicate laboratory sample. Where sampling records are produced in a paperless (digital) form, arrangements shall be made ensuring a similar verifiable audit trail.

B.7 Preparation of the analytical sample by the laboratory

Laboratory samples which are not analysed immediately shall be stored in the laboratory under conditions that minimise decay. Fresh products, drinks, oils shall be stored in the refrigerator, but typically no longer than five days. Dried, preserved and canned products may be stored at room temperature, but if storage time is expected to exceed four weeks, they shall be sub-sampled and stored in the freezer.

The laboratory shall prepare the analytical sample from the laboratory sample by separating the portion of the product to be analysed, i.e. the part of the product to which the MRL applies[3], and then by mixing, grinding, fine chopping, comminuting etc., for the removal of analytical portions with minimal subsampling bias. The preparation of the analytical sample shall 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.

If needed, the laboratory sample can be representatively reduced using a sample reduction method.

[3] Annex I to Regulation (EC) 396/2005.

The part of the product to be analysed, i.e. the analytical sample, shall be separated as soon as practicable. Where the residue level is required to be calculated to include parts which are not analysed[4], the weights of the separated parts shall be recorded.

B.8 Preparation and storage of the analytical portion by the laboratory

The analytical sample shall be comminuted, if appropriate, and mixed well, to enable representative analytical portions to be withdrawn by the laboratory. A device may be used to withdraw the analytical portion. The size of the analytical portion shall be determined by the analytical method and the efficiency of mixing. The methods for comminution and mixing shall be recorded and shall not affect the residues present in the analytical sample. Where appropriate, the analytical sample shall be processed under special conditions, e.g. frozen, to minimise adverse effects.

Where processing could affect residues and 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 shall be analysed, to indicate the uncertainty of the mean value.

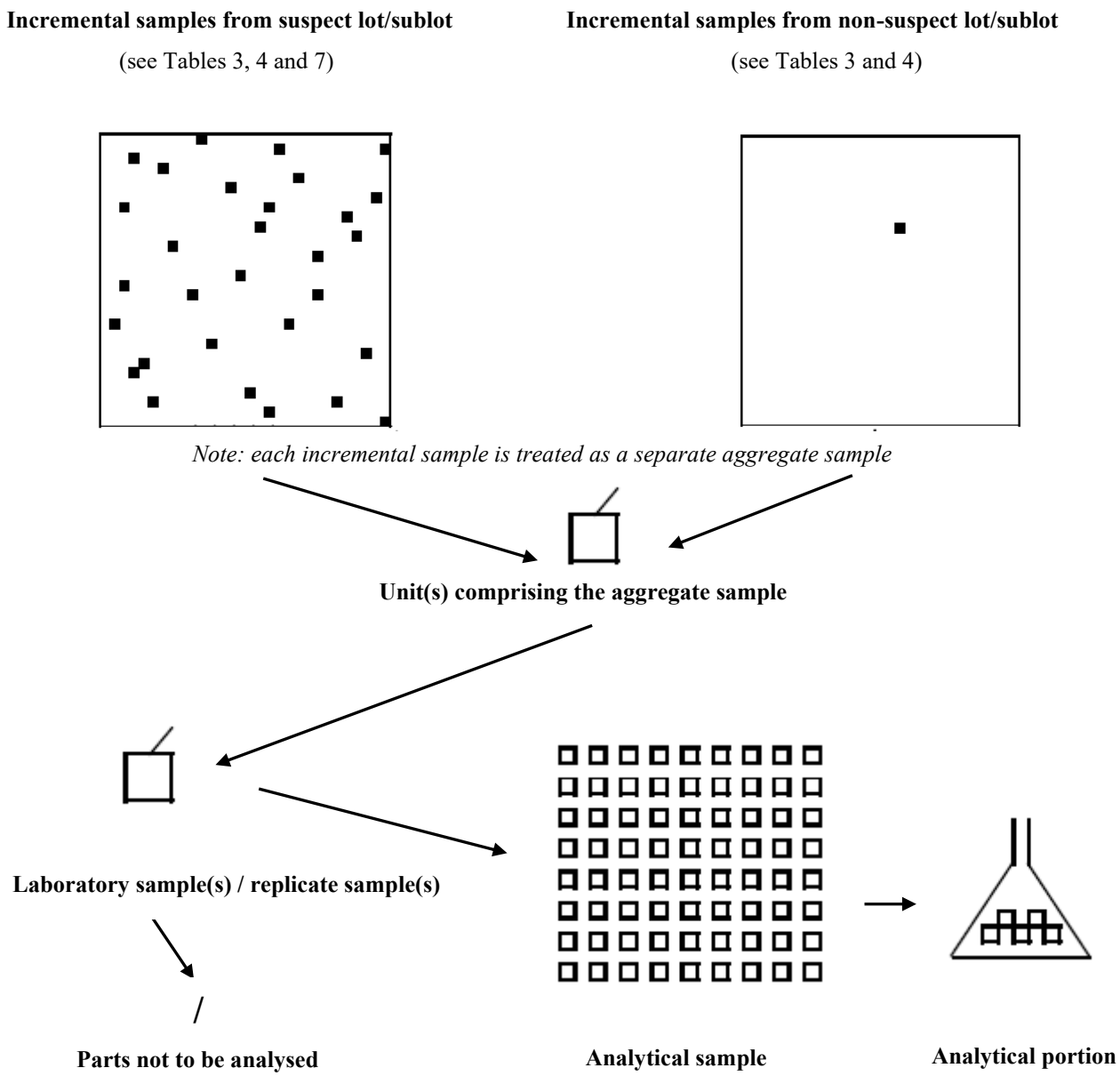
Depending on available storage stability data, it might be possible to store analytical portions before analysis. In this case, the method, the duration of storage time and the temperature during storage shall be such that they do not affect the level of residues present.

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

B.9 Schematic presentations

Schematic presentations of the sampling procedures described in points B.2, B.3 and B.4:

B.9.1. Sampling products of meat and poultry



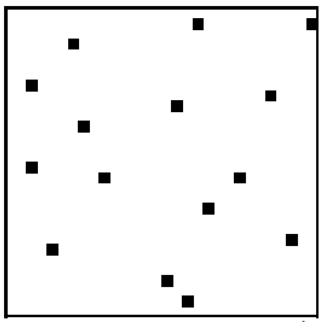
B.9.2. Sampling products other than meat and poultry

Incremental samples from suspect lot/sublot

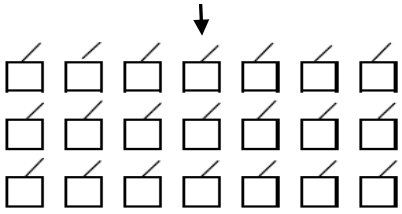
(see Tables 3, 5, 6 and 7)

Incremental samples from non-suspect lot/sublot

(see Tables 3, 5 and 6)

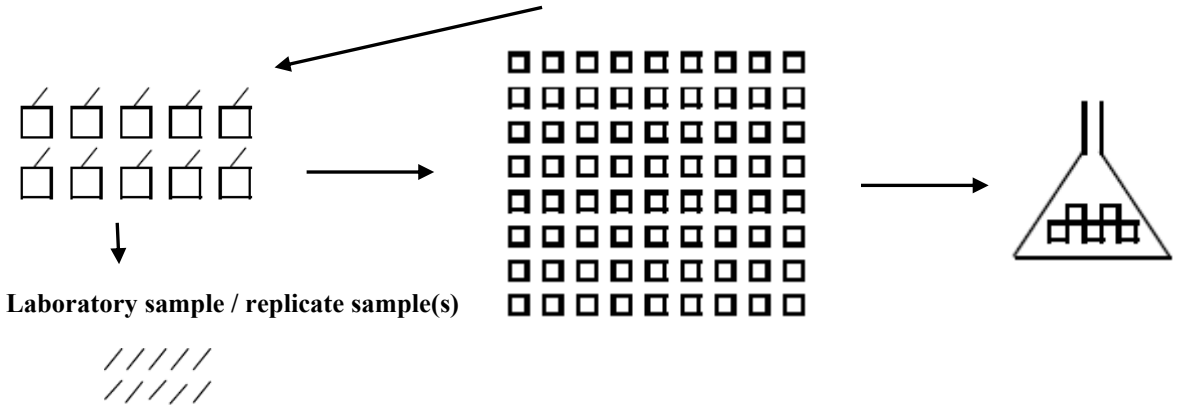


Note: incremental samples are combined to form the aggregate sample



Units comprising the aggregate sample

Note: where laboratory samples are prepared directly from the lot/sublot, the aggregate sample is the conceptual sum of the laboratory samples



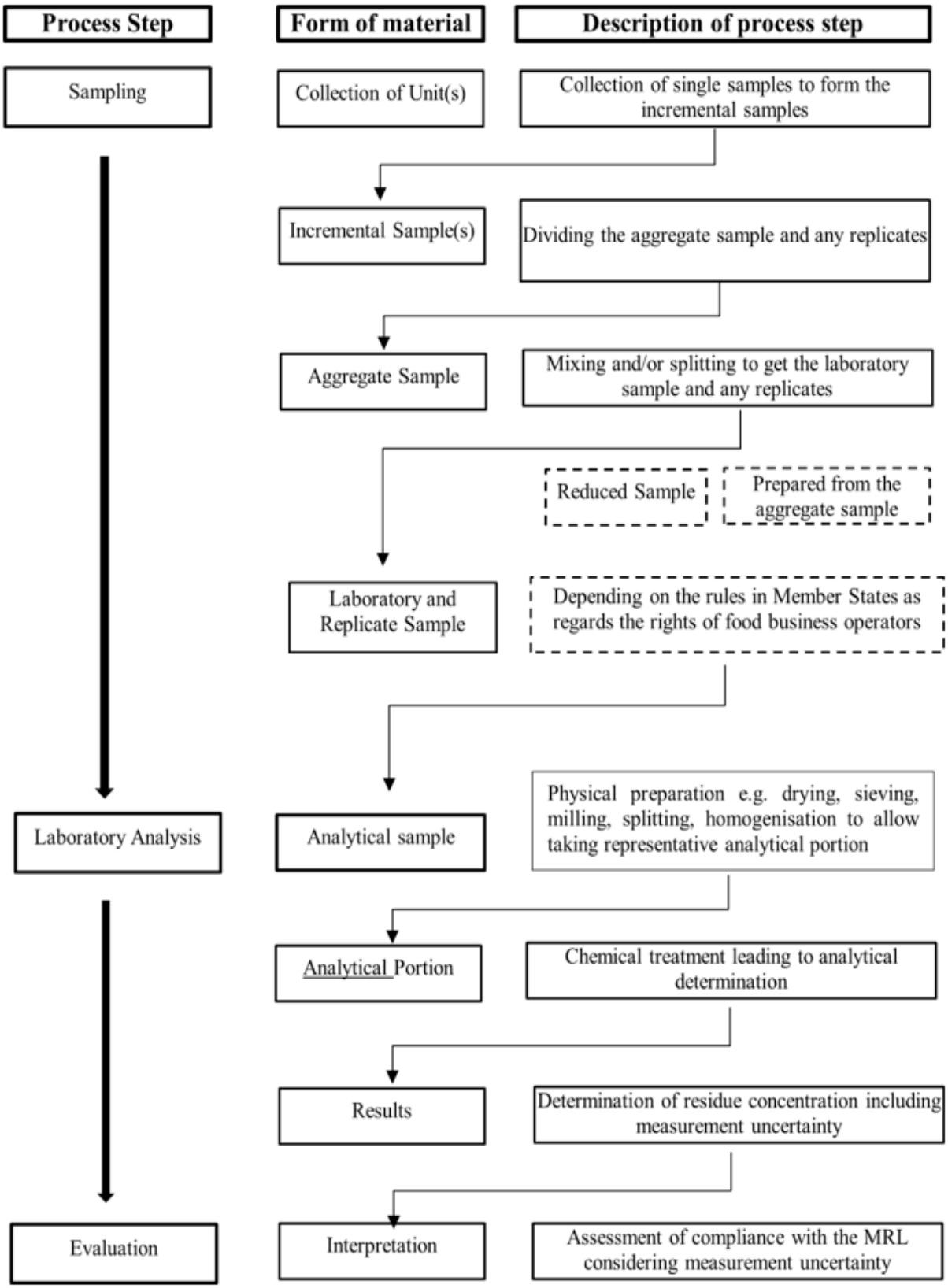
Laboratory sample / replicate sample(s)

Parts not to be analysed

Analytical sample

Analytical portion

B.9.3. Typical sampling and analytical process



PART C

METHODS OF ANALYSIS, MEASUREMENT UNCERTAINTY AND INTERPRETATION OF RESULTS

C.1 Methods of analysis and deriving the analytical results

C.1.1 Methods of analysis shall be supported by quality control data and shall be validated for the specific substance/commodity group combination. As a minimum, one representative commodity from each commodity group must be validated, depending on the intended scope of the method. When the method is applied to a wider variety of matrices, complementary validation data should be acquired.

Analytical results shall be derived from one or more laboratory samples taken from the lot/sublot and provided that the analytical sample contains the correct part(s) of the product as laid down in Annex I to Regulation (EC) No 396/2005. Where a residue is found to exceed an MRL, its identity shall be confirmed and its concentration shall be verified by analysing at least one additional analytical portion.

C.1.2. The analytical result shall be reported as x+/- U whereby 'x' is the analytical result and 'U' is the expanded measurement uncertainty and shall be reported in the same units and with the same number of decimal figures as the result.

C.2 Measurement uncertainty and interpretation of results

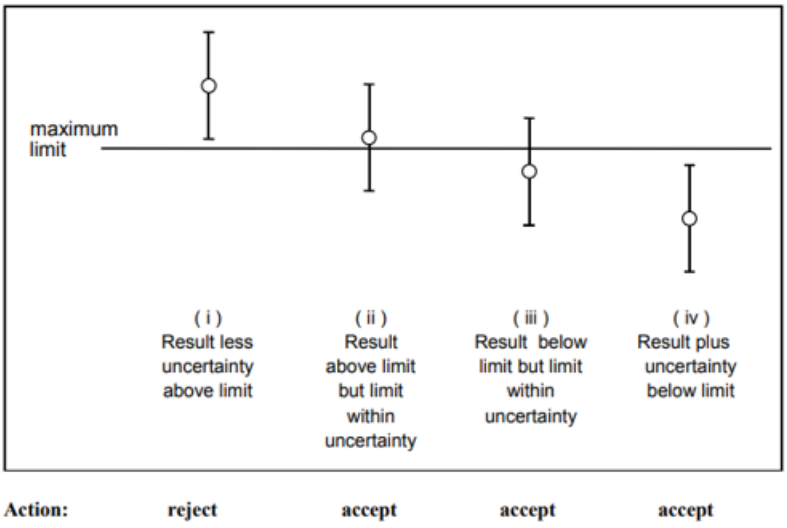
C.2.1. The MRL shall apply to the analytical sample derived from the aggregate sample through the laboratory or replicate sample. The result of the laboratory sample shall be considered representative for the lot/sublot and it applies to the entire lot/sublot.

C.2.2. When checking exceedances of the MRL, official laboratories and enforcement authorities shall apply a default expanded measurement uncertainty[5] that was calculated from long-term data of EU inter-laboratory comparative tests applying a coverage factor of 2 (confidence level of95 %). The expanded measurement uncertainty is 50% with the exception of copper, where a value of 20% applies, to enforce MRLs. The analytical laboratory shall demonstrate that its own expanded measurement uncertainty for the specific analytical method/substance/commodity group combination is equal or lower than the above stated default values In the case of MRL-exceedances, the harmonised default expanded measurement uncertainty shall be reported by the laboratory.

Where the level found in a sample leads to an International Estimate of Short-term Intake (IESTI) that exceeds the Acute Reference Dose (ARfD), as a precautionary measure, the competent authority may apply a lower expanded measurement uncertainty, based on the laboratory's own estimated measurement uncertainty (if supported by sufficient intra- and inter-laboratory evidence) and/or a lower confidence level (lower coverage factor, k).

C.2.3. Interpretation of the analytical result taking into account the expanded measurement uncertainty

[5] BIPM, 'JCGM 100:2008 – Guide to the expression of uncertainty in measurement', 2008.



C.2.4. A lot/sublot shall be considered:

(a) compliant with the MRL if the analytical sample complies with the MRL, taking into account the expanded measurement uncertainty and if necessary, the correction for recovery. This means the sample is compliant if the measured value is below or equal to the MRL when subtracting the expanded uncertainty ($x - U \leq MRL$);

(b) non-compliant with the MRL if the analytical sample exceeds the MRL beyond reasonable doubt taking into account the expanded measurement uncertainty and if necessary, the correction for method bias where indicated. This means the sample is not compliant if the measured value exceeds the MRL when subtracting the expanded uncertainty ($x-U > MRL$)[6].

C.2.5. Acceptance and rejection of consignment consisting of more than one lot

Any lot sampled in accordance with this Regulation and where the analytical result shows exceedance of the MRL shall be regarded as non-compliant as specified in point C.2.4.b. in its entirety and shall be rejected.

The sampling officer shall determine the sampled lot of a consignment, that can be different from the lot of the food business operator. The sampled lot can be one lot, or a group of lots sharing the same properties (date of production, origin, description, etc.).

If one lot, part of a group of lots sharing the same properties, has been found to be non-compliant and there is a reasonable doubt that the other similar lots are in MRL exceedance, these other similar lots shall be regarded as suspect lots.

[6] Example: in case the MRL = 1, the result x = 2.2 and U=50 %, then x - U = 2.2 – 1.1 (= 50 % of 2.2)=1.1, which is >MRL.