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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2782

of 14 December 2023

laying down the methods of sampling and analysis for the control of the levels of mycotoxins in food and repealing Regulation (EC) No 401/2006

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([1]), and in particular Article 34(6) thereof,

Whereas:

(1) Commission Regulation (EU) 2023/915 ([2]) sets maximum levels for certain mycotoxins and ergot sclerotia in foods.

(2) Commission Regulation (EC) No 401/2006 ([3]) lays down the methods of sampling and analysis to be used for the official control of the levels of mycotoxins in foodstuffs.

(3) The sampling methods provided for in Regulation (EC) No 401/2006 for the different foods should apply to the control of all mycotoxins instead of specifically mentioned mycotoxins, in those foods. It is furthermore appropriate to update the sampling method for food supplements and to provide for a sampling method for dried herbs, herbal infusions and teas.

(4) Official controls can be performed on foods for which no specific maximum level has been established for mycotoxins and for which no specific sampling procedure has been established. It is therefore appropriate to provide criteria to determine which sampling procedure should be applied in such cases.

(5) On the basis of the best available scientific information, the European Union Reference Laboratory on mycotoxins and plant toxins have updated the analytical performance criteria for mycotoxins. It is therefore appropriate to modify the criteria as laid down in Regulation (EC) No 401/2006.

(6) It is necessary to provide sufficient time for control laboratories to implement the new requirements introduced by this Regulation. Therefore, it is appropriate to provide for a reasonable time until this Regulation applies.

(7) In order to ensure continuity in the performance of official controls and other regulatory activities on maximum levels of mycotoxins and to allow enough time for methods of analysis to be re-validated, it is appropriate to provide that methods of analysis which have been validated before the date of application of this Regulation may remain in use for a defined period, subject to the specific requirements provided for in point 4.3 in Annex II to Regulation (EC) No 401/2006

([1]) OJ L 95, 7.4.2017, p. 1.
([2]) Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103).
([3]) Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs (OJ L 70, 9.3.2006, p. 12).

(8) Since the modifications to Regulation (EC) No 401/2006 are substantial, it is appropriate, for reasons of clarity, to repeal and replace that Regulation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

For the purposes of this Regulation, the following definitions shall apply:

(1) 'lot' means an identifiable quantity of a food commodity delivered at one time and determined by the competent authority to have common characteristics, such as origin, variety, type of package, packer, consignor or markings;

(2) 'sublot' means a physically separate and identifiable part of a large lot designated to apply the sampling method;

(3) 'incremental sample' means a quantity of material taken from a single place in the lot or sublot;

(4) 'aggregate sample' means the combined total of all the incremental samples taken from the lot or sublot;

(5) 'subsample' means a quantity of material taken from the aggregate sample for control of ergot sclerotia by visual examination;

(6) 'laboratory sample' means a representative part or quantity of the aggregate sample intended for the laboratory;

(7) 'recovery (Rec, %)' means the percentage obtained by applying the following formula x/xref × 100 % where:

x = measured concentration (for spiked samples corrected for background concentration if not blank), and

xref = reference concentration (concentration of a Certified Reference Material (CRM), Proficiency Test material, or spiked sample);

(8) 'bias' means the difference between the measured value and the reference concentration;

(9) 'repeatability relative standard deviation (RSDr)' means the relative standard deviation (%) calculated from results generated under repeatability conditions (repeatability precision): using the same method on the same sample material in one laboratory by the same operator, with the same instrument, within a short interval of time (1 day or 1 sequence);

(10) 'within-laboratory reproducibility relative standard deviation ($RSDw_R$)' means the relative standard deviation (%) calculated from results generated under within-laboratory reproducibility conditions (intermediate precision): using the same method on the same sample material in one laboratory but different days (preferably a longer time interval), and may include other conditions, such as involving different operators and/or different (equivalent) instruments;

(11) 'reproducibility relative standard deviation (RSD_R)' means the relative standard deviation (%) calculated from results generated under reproducibility conditions (interlaboratory precision), meaning the same material is analysed by different laboratories. The RSD_R may be derived from, in particular, collaborative studies and proficiency tests;

(12) 'limit of Quantification (LOQ)' means the lowest content of the analyte which can be measured with reasonable statistical certainty. In the context of this regulation this means the lowest successfully validated level: the lowest tested concentration of analyte in a sample material, for which it has been demonstrated that the criteria for recovery, precision, and identification are met ([4]);

(13) 'screening target concentration (STC)' means the concentration of interest for detection of the mycotoxin in a sample. When the aim is to test compliance with regulatory limits, the STC is equal to the applicable maximum level. For other purposes or in case no maximum level has been established, the STC is predefined by the laboratory;

(14) 'screening method' means the method used for selection of those samples with levels of mycotoxins that exceed the screening target concentration (STC), with a given certainty. For the purpose of mycotoxin screening, a certainty of 95 % is considered fit-for-purpose. The result of the screening analysis is either 'negative' or 'suspect'. Screening methods shall allow a cost-effective high sample-throughput, thus increasing the chance to discover new incidents with high exposure and health risks to consumers. These methods shall be based on bio-analytical, LC-MS or HPLC methods. Results from samples exceeding the cut-off value shall be verified by a full re-analysis from the original sample by a confirmatory method;

(15) 'negative sample' means the mycotoxin content in the sample is < STC with a certainty of 95 % (i.e. there is a 5 % chance that samples will be incorrectly reported as negative);

(16) 'false negative sample' means the mycotoxin content in the sample is >STC but it has been identified as negative;

(17) 'suspect sample' (screen positive) means the sample exceeds the cut-off value and may contain the mycotoxin at a level higher than the STC;

(18) 'false suspect sample' means a negative sample that has been identified as suspect;

(19) 'confirmatory methods' means methods that provide full or complementary information enabling the mycotoxin to be identified and quantified unequivocally at the level of interest;

(20) 'cut-off value' means the response, signal, or concentration, obtained with the screening method, above which the sample is classified as 'suspect'. The cut-off value is determined during the validation and takes the variability of the measurement into account;

(21) 'negative control (blank matrix) sample' means a sample known to be free of the mycotoxin to be screened for, by previous determination using a confirmatory method of sufficient sensitivity or by other method or, where such sample cannot be obtained, material with the lowest obtainable level as long as the level allows the conclusion that the screening method is fit for that purpose;

(22) 'sample known to be free' means a sample where the amount present of the analyte does not exceed 1/5 of the STC. If the level can be quantified with a confirmatory method, the level shall be taken into consideration for the validation assessment;

(23) 'positive control sample' means a sample containing the mycotoxin at the screening target concentration, such as a certified reference material, a material of known content (e.g. test material of proficiency tests) or otherwise sufficiently characterised by a confirmatory method. In the absence of any of the above, a blend of samples with different levels of contamination or a spiked sample prepared within laboratory and sufficiently characterised can be used, provided it can be proven that the contamination level has been verified.

Article 2

1. Sampling for the control of the levels of mycotoxins in foods shall be carried out in accordance with the methods set out in Annex I.

([4]) For risk assessment, fit-for-purpose LOQs are generally lower compared to what is required for official control for checking compliance with a ML, as the aim is to generate numerical data for the major part of the samples analysed (i.e. avoid left-censored data) in order to be able to perform accurate exposure assessments. For monitoring purposes, it can be acceptable to report levels below the LOQ as defined in the context of this Regulation.

2. In case of a food that cannot be classified in a food category for which a sampling procedure has been established in Annex I, the sampling procedure shall be determined having regard to the particle size of that food or the similarity of that food with a product that can be classified in one of the food categories in Annex I.

3. In case of a foods that cannot be classified in any food category listed in Annex I and provided that there is evidence that the mycotoxin is homogeneously distributed in such a food, the food shall be sampled using the sample procedure laid down in Part B of the Annex to Commission Regulation (EC) No 333/2007 ([5]).

Article 3

Sample preparation and methods of analysis used for the control of the levels of mycotoxins in foodstuffs shall comply with the criteria set out in Annex II.

Article 4

Regulation (EC) No 401/2006 is hereby repealed. References to the repealed Regulation shall be construed as references to this Implementing Regulation.

However, until 1 January 2029, the specific requirements provided for in point 4.3 in Annex II to Regulation (EC) No 401/2006 shall continue to apply to methods which have been validated before the entry into application of this Regulation.

Article 5

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 April 2024.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 December 2023.

For the Commission
The President
Ursula VON DER LEYEN

([5]) Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs (OJ L 88, 29.3.2007, p. 29).

ANNEX I

Methods of sampling for the control of the levels of mycotoxins in food [1]

PART I

GENERAL PROVISIONS

A.1. **General provisions**

A.1.1. *Personnel*

Sampling shall be performed by a person as designated by the competent authority of the Member State.

A.1.2. *Material to be sampled*

Each lot which is to be examined shall be sampled separately. In accordance with the specific sampling provisions for the different mycotoxins, large lots shall be subdivided into sublots to be sampled separately.

A.1.3. *Precautions to be taken*

In the course of sampling and preparation of the samples, precautions shall be taken to avoid any changes, which would:

— affect the mycotoxin content, adversely affect the analytical determination or make the aggregate samples unrepresentative;

— affect the food safety of the lots to be sampled.

Also, all measures necessary to ensure the safety of the persons taking the samples shall be taken.

A.1.4. *Incremental samples*

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from such procedure shall be recorded in the record provided for under part I. point A.1.8. of this Annex.

A.1.5. *Preparation of the aggregate sample*

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

A.1.6. *Replicate samples*

The replicate samples for enforcement, defence and reference purposes shall be taken from the homogenised aggregate sample, unless such procedure conflicts with Member States' rules as regards the rights of the food business operator.

A.1.7. *Packaging and transmission of samples*

Each sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the sample, which might arise during transportation or storage.

A.1.8. *Sealing and labelling of samples*

Each sample taken for official use shall be sealed at the place of sampling and identified following the rules of the Member State.

[1] A guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins is available at https://food.ec.europa.eu/document/download/5e7138d9-26c5-4f38-900c-9933fe605a92_en?filename=cs_contaminants_sampling_analysis-guidance-2010_en.pdf The guidance document provides additional practical information but the information contained in the guidance document is subordinate to the provisions in this Regulation.

A record of each sampling shall be kept, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

A.2. **Different types of lots**

Food commodities may be traded in bulk, containers, or individual packages, such as sacks, bags, retail/individual packages. The method of sampling may be applied to commodities put on the market in bulk, containers, or individual packages, such as sacks, bags, retail/individual packages or any other different form.

Without prejudice to the specific sampling provisions set out in other parts of this Annex, the following formula shall be used as a guide for calculating the sampling frequency of lots put on the market in individual packages, such as sacks, bags, retail/individual packages.

$$\text{Sampling frequency (SF) } n = \frac{\text{Weight of the lot x Weight of the incremental sample}}{\text{Weight of the aggregate sample x Weight of individual package}}$$

— weight: in kg

— sampling frequency (SF): every n^{th} individual package from which an incremental sample shall be taken (decimal figures shall be rounded to the nearest whole number).

A.3. **Sampling of commodities with a high volume/weight ratio**

With the exception of the food commodities falling under parts L and M of part II of this Annex, in the case of sampling food commodities which have a high volume in comparison to their weight (i.e. volume (dm^3)/weight (kg) > 5) the weight requirements can be replaced by equivalent volume requirement (i.e. 1 kg replaced by 1 dm^3).

PART II

METHODS OF SAMPLING

This part lays down the methods of sampling for the following categories of food:

A. Cereals, oilseeds other than groundnuts, cereal and oilseed products other than groundnut products

B. Dried fruit and derived/processed products with the exception of dried figs

C. Dried figs and derived/processed products

D. Groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size and derived/processed products

E. Dried spices except dried spices with large particle size and powdered spices

F. Milk and milk products, infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula

G. Coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products

H. Beverages

I. Solid processed fruit and vegetable products

J. Baby foods and processed cereal-based food for infants and young children

K. Vegetable oils

L. Food supplements, pollen and pollen products

M. Dried herbs, herbal infusions (dried product), teas (dried product) and powdered spices

N. Very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible

A. METHOD OF SAMPLING FOR CEREALS, OILSEEDS OTHER THAN GROUNDNUTS, CEREAL AND OILSEED PRODUCTS OTHER THAN GROUNDNUT PRODUCTS

A.1. **Weight of the incremental sample**

The weight of the incremental sample shall be about 100 g, unless otherwise defined in this part and except for oilseeds or cereal grains for which 1 000 seeds/grains weigh less than 10 g ('small particle oilseeds or cereal grains')

For these small particle oilseeds or cereal grains the incremental sample shall be about 25 g.

In the case of lots in retail/individual packages, the weight of the incremental sample shall depend on the weight of the retail/individual package.

In the case of retail/individual packages of more than 100 g (or 25 g in the case of small particle oilseeds or cereal grains), this will result in aggregate samples weighing more than the required weight indicated in tables 1 and 2 of point A.2. If the weight of a single retail/individual package is much more (i.e. more than double) than 100 g (or 25 g in the case of small particle oilseeds or cereal grains), 100 g (or 25 g in the case of small particle oilseeds or cereal grains) shall be taken from each retail/individual package as an incremental sample. This may be done either when the sample is taken or in the laboratory.

However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, or other reasons), an alternative method of sampling may be applied. In particular, in case where a valuable product is marketed in retail/individual packages of 500 g or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1 and 2, on the condition that the weight of the aggregate sample is equal to the required weight of the aggregate sample mentioned in those tables.

Where the retail/individual packages are less than 100 g (or 25 g in the case of small particle oilseeds or cereal grains) and if the difference is not very large (i.e. not less than half of 100 g or 25 g) one retail/individual package is to be considered as one incremental sample, resulting in an aggregate sample of less than the required weight indicated in tables 1 and 2. If the weight of the retail/individual packages are much less than 100 g (or 25 g in the case of small particle oilseeds or cereal grains), one incremental sample consists of two or more retail/individual packages, whereby the 100 g (or 25 g in the case of small particle oilseeds or cereal grains) are approximated as closely as possible.

A.2. **General survey of the method of sampling for cereals, oilseeds other than groundnuts, cereal products and oilseed products, other than groundnut products**

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
Cereals, oilseeds other than groundnuts, cereal products and oilseed products, other than groundnut products	> 300 and < 1 500	3 sublots	100	10 2,5 for small particle oilseeds or cereal grains
	≥ 100 and ≤ 300	100 tonnes	100	10 2,5 for small particle oilseeds or cereal grains

	< 100	—	3-100 (*)	1-10 0,25 – 2,5 for small particle oilseeds or cer eal grains

(*) Depending on the lot weight – see Table 2 of Point A.4.

A.3. **Method of sampling for cereals, oilseeds other than groundnuts, cereal products and oilseed products, other than groundnut products for lots ≥ 50 tonnes**

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots according to Table 1. 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 mentioned weight by a maximum of 20 %. In case the lot is not or cannot be physically separated into sublots, a minimum of 100 incremental samples is taken from the lot. For lots > 500 tonnes, the number of incremental samples is provided for in point N.2.

— Each sublot shall be sampled separately.

— Number of incremental samples: 100. Weight of the aggregate sample = 10 kg (or 2,5 kg in the case of small particle cereals and oilseeds).

— If it is not possible to carry out the method of sampling set out in this point because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented. An alternative method of sampling may also be applied in cases where it is practically impossible to apply the abovementioned method of sampling. This is the case where large lots of cereals are stored in warehouses or where cereals are stored in silos ([2]). The sampling of such lots shall be performed in accordance with the rules set out in part N.

A.4. **Method of sampling for cereals, oilseeds other than groundnuts, cereal products and oilseed products, other than groundnut products for lots < 50 tonnes**

For lots of cereals, oilseeds other than groundnuts, cereal products and oilseed products, other than groundnut products less than 50 tonnes, the sampling plan shall be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10 kg (or 0,25 – 2,5 kg in the case of small particle oilseeds or cereal grains). For very small lots (≤ 0,5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample combining all incremental samples shall also be in that case at least 1 kg (or 0,25 kg in the case of small particle cereals and oilseeds) and for the determination of ergot sclerotia, at least 1 kg.

The figures in Table 2 shall be used to determine the number of incremental samples to be taken.

Table 2

Number of incremental samples to be taken depending on the weight of the lot of cereals, oilseeds other than groundnuts, cereal products and oilseed products, other than groundnut products

Lot weight (tonnes)	Number of incremental samples	Aggregate sample weight(kg) (*)	Aggregate sample weight(kg) (*) for small particle oilseeds or cereal grains
≤ 0,05	3	1	0,25
> 0,05-≤ 0,5	5	1	0,25

([2]) The sampling of such lots shall be performed in accordance with the rules set out in part N. Guidance for sampling large lots shall be provided in a guidance document available on the following website: https://food.ec.europa.eu/system/files/2016-10/cs_contaminants_sampling_guidance-sampling-final_en.pdf

> 0,5-≤ 1	10	1	0,25
> 1-≤ 3	20	2	0,5
> 3-≤ 10	40	4	1,0
> 10-≤ 20	60	6	1,5
> 20-≤ 100	100	10	2,5

(*) In case of control for the presence of ergot sclerotia, the aggregate sample weight is at least 1 kg.

A.5. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part A.

Where that is not possible, an alternative method of sampling at retail stage may be applied provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg ([3]).

A.6. **Acceptance of a lot or sublot**

Control of ergot sclerotia

From the aggregate sample, 2 subsamples of at least 0,5 kg shall be taken for examination. One subsample shall be examined. In case the result of the subsamples is equal or below 50 % (analytical threshold) of the maximum level, the sample is compliant with the maximum level. If the result is above 50 % of the maximum level, another subsample needs to be examined and the average of the result of the 2 subsamples is used for checking compliance with the maximum level. The following outcomes shall be derived:

— acceptance if the first subsample contains less than 50 % of the maximum level of ergot sclerotia or if the average of two subsamples conforms to the maximum level;

— rejection if the average of two subsamples exceeds the maximum level.

Control of mycotoxins

The following outcomes shall be derived:

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty;

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

B. METHOD OF SAMPLING FOR DRIED FRUIT AND DERIVED/PROCESSED PRODUCTS WITH THE EXCEPTION OF DRIED FIGS

This method of sampling is of application for the official control of levels of mycotoxins in dried fruit and derived/processed products, with the exception of dried figs and derived/processed products (part II.C of this Annex).

B.1. **Weight of the incremental sample**

The weight of the incremental sample shall be about 100 g, unless otherwise defined in this part II.B

([3]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

In the case of lots in retail/individual packages, the weight of the incremental sample depends on the weight of the retail/individual package.

In the case of retail/individual packages of more than 100 g, this will result in aggregate samples weighing more than the required weight indicated in tables 1 and 2 of this part B. If the weight of a single retail/individual package is much more (more than double) than 100 g, then 100 g shall be taken from each individual retail/individual package as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail/individual packages of 500 g or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1 and 2 of this part on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1 and 2 of this part B.

Where the retail/individual packages are less than 100 g and if the difference is not very large (i.e. not less than half of 100 g) one retail/individual package shall be considered as one incremental sample, resulting in an aggregate sample of less than the required weight indicated in tables 1 and 2 of this part. If the weight of the retail/individual packages are much less than 100 g, one incremental sample shall consist of two or more retail/individual packages, whereby the 100 g are approximated as closely as possible.

B.2. General survey of the method of sampling dried fruit and derived/processed products, with the exception of figs

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample weight (kg)
Dried fruit, except dried figs	≥ 15	15-30 tonnes	100	10
	< 15	—	10-100 (*)	1-10

(*) Depending on the lot weight – see Table 2 of this part B

B.3. Method of sampling for dried fruit and derived/processed products (lots ≥ 15 tonnes), with the exception of dried figs

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots according to Table 1. 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 mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately.

— Number of incremental samples: 100. Weight of the aggregate sample = 10 kg.

— If it is not possible to carry out the method of sampling described above because of the commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

B.4. Method of sampling for dried fruit and derived/processed products (lots < 15 tonnes), with the exception of dried figs

For dried fruit lots, with the exception of figs, under 15 tonnes the sampling plan shall be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10 kg.

The figures in the following table can be used to determine the number of incremental samples to be taken.

Table 2

Number of incremental samples to be taken depending on the weight of the lot of dried fruit and derived/processed products except dried figs

Lot weight (tonnes)	Number of incremental samples	Aggregate sample weight (kg)
≤ 0,1	10	1
> 0,1-≤ 0,2	15	1,5
> 0,2-≤ 0,5	20	2
> 0,5-≤ 1,0	30	3
> 1,0-≤ 2,0	40	4
> 2,0-≤ 5,0	60	6
> 5,0-≤ 10,0	80	8
> 10,0-≤ 15,0	100	10

B.5. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part B.

Where that is not possible, another alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg ([4]).

B.6. **Specific sampling provisions for dried fruit and derived/processed products with the exception of dried figs traded in vacuum packages**

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in Table 2 of point B.4 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 2 of point B.4).

B.7. **Acceptance of a lot or sublot**

The following outcomes shall be derived:

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty;

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

C. METHOD OF SAMPLING FOR DRIED FIGS AND DERIVED/PROCESSED PRODUCTS

C.1. **Weight of the incremental sample**

The weight of the incremental sample shall be about 300 g, unless otherwise defined in part II.C.

([4]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

In the case of lots in retail/individual packages, the weight of the incremental sample depends on the weight of the retail/individual package.

In the case of retail/individual packages of more than 300 g, this will result in aggregate samples weighing more than the required weight indicated in tables 1, 2 and 3. If the weight of a single retail/individual package is much more (i.e. more than double) than 300 g, then 300 g shall be taken from each individual retail/individual package as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail/individual packages of 500 g or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1, 2 and 3, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1, 2 and 3.

Where the retail/individual packages are less than 300 g and if the difference is not very large (i.e. not less than half of 300 g) one retail/individual package shall be considered as one incremental sample, resulting in an aggregate sample of less than the required weight indicated in tables 1, 2 and 3. If the weight of the retail/individual packages are much less than 300 g, one incremental sample shall consist of two or more retail/individual packages, whereby the 300 g are approximated as closely as possible.

C.2. General survey of the method of sampling for dried figs

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
Dried figs	≥ 15	15-30 tonnes	100	30
	< 15	—	10-100 (*)	≤ 30

(*) Depending on the lot weight – see Table 2 of this part C

C.3. Method of sampling for dried figs (lots ≥ 15 tonnes)

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots according to Table 1. 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 mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately.

— Number of incremental samples: 100

— Weight of the aggregate sample = 30 kg, which shall be mixed and divided into three equal laboratory samples of 10 kg before grinding (this division into three laboratory samples is not necessary in case of dried figs subjected to further sorting or other physical treatment and availability of equipment which is able to homogenise a 30 kg sample).

— Each laboratory sample of 10 kg shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II.

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and fully described and documented.

C.4. **Method of sampling for dried figs (lots < 15 tonnes)**

The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100.

The figures in the following Table 2 may be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2

Number of incremental samples to be taken depending on the weight of the lot and number of subdivisions of the aggregate sample

Lot weight (tonnes)	No of incremental samples (for retail/individual packages see also point C.1)	Aggregate sample weight (kg) (in case of retail/individual packages, weight of aggregate sample can diverge – see point C.1)	No of laboratory samples from aggregate sample
≤ 0,1	10	3	1 (no division)
> 0,1 – ≤ 0,2	15	4,5	1 (no division)
> 0,2 – ≤ 0,5	20	6	1 (no division)
> 0,5 – ≤ 1,0	30	9 (- < 12 kg)	1 (no division)
> 1,0 – ≤ 2,0	40	12	2
> 2,0 – ≤ 5,0	60	18 (- < 24 kg)	2
> 5,0 – ≤ 10,0	80	24	3
> 10,0 – ≤ 15,0	100	30	3

— Weight of the aggregate sample ≤ 30 kg which shall be mixed and divided into two or three equal laboratory samples of ≤ 10 kg before grinding (this division into two or three laboratory samples is not necessary in case of dried figs, subjected to further sorting or other physical treatment and availability of equipment which is able to homogenise up to 30 kg samples).

  In cases where the aggregate sample weights are less than 30 kg, the aggregate sample shall be divided into laboratory samples according to the following guidance:

  — < 12 kg: no division into laboratory samples;

  — ≥ 12 – < 24 kg: division into two laboratory samples;

  — ≥ 24 kg: division into three laboratory samples.

— Each laboratory sample shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II.

— If it is not possible to carry out the method of sampling described in the previous indent, because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and fully described and documented.

C.5. **Method of sampling for derived/processed products and compound foods**

C.5.1. *Derived/processed products with very small particle size (homogeneous distribution of mycotoxin contamination)*

— In many cases, lots of fig pastes have no homogenous distribution of mycotoxin contamination and therefore in the case of fig paste, the method of sampling and acceptance as for dried figs (under points C.3 and C.4) shall be applied.

— Number of incremental samples: 100. For lots of under 50 tons the number of incremental samples shall be 10 to 100, depending on the lot weight (see following Table 3).

Table 3

Number of incremental samples to be taken depending on the weight of the lot

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)
≤ 1	10	1
> 1 – ≤ 3	20	2
> 3 – ≤ 10	40	4
> 10 – ≤ 20	60	6
> 20 – ≤ 50	100	10

— The weight of the incremental sample shall be about 100 g. In the case of lots in retail/individual packages, the weight of the incremental sample depends on the weight of the retail/individual package.

— Weight of aggregate sample = 1-10 kg sufficiently mixed.

C.5.2. *Other derived/processed products with a relatively large particle size (heterogeneous distribution of mycotoxin contamination)*

Method of sampling and acceptance as for dried figs (points C.3 and C.4).

C.6. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part C.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and fully described and documented. In any case, the aggregate sample shall be at least 1 kg ([5]).

C.7. **Specific method of sampling of dried figs and derived/processed products traded in vacuum packages**

C.7.1. *Dried figs*

For lots equal to or more than 15 tonnes, at least 50 incremental samples resulting in a 30 kg aggregate sample shall be taken, and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in Table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 2).

C.7.2. *Products derived/processed from dried figs with small particle size*

For lots equal to or more than 50 tonnes, at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 50 tonnes, 25 % of the number of incremental samples mentioned in Table 3 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 3).

C.8. **Acceptance of a lot or sublot**

The following outcomes shall be derived:

([5]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

For dried figs:

— acceptance if none of the laboratory samples exceeds the maximum level, taking into account the correction for recovery and measurement uncertainty;

— rejection if one or more of the laboratory samples exceed(s) the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

In cases where the aggregate sample is 12 kg or less

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

D. METHOD OF SAMPLING FOR GROUNDNUTS (PEANUTS), APRICOT KERNELS, TREE NUTS AND DRIED SPICES WITH LARGE PARTICLE SIZE AND DERIVED/PROCESSED PRODUCTS

This method of sampling is of application for the official control of the levels of mycotoxins in groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size and derived/processed products. This method of sampling is also of application for the official control of the level of mycotoxins in spices with a relatively large particle size, i.e. particle size comparable with peanuts or larger such as nutmeg.

D.1. **Weight of the incremental sample**

The weight of the incremental sample shall be about 200 g, unless otherwise defined in this part D.

In the case of lots in retail/individual packages, the weight of the incremental sample depends on the weight of the retail/individual package.

In the case of retail/individual packages of more than 200 g, this will result in aggregate samples weighing more than the required weight indicated in tables 1, 2 and 3. If the weight of a single retail/individual package is much more than 200 g, then 200 g shall be taken from each individual retail/individual package as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail/individual packages of 500 g or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1, 2 and 3, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1, 2 and 3.

Where the retail/individual packages are less than 200 g and if the difference is not very large (i.e. not less than half of 200 g), one retail/individual package shall be considered as one incremental sample, resulting in an aggregate sample of less than the required weight indicated in tables 1, 2 and 3. If the weight of the retail/individual packages are much less than 200 g, one incremental sample shall consist of two or more retail/individual packages, whereby the 200 g are approximated as closely as possible.

D.2. **General survey of the method of sampling for groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size**

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
Groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size	≥ 500	100 tonnes	100	20
	> 125 and < 500	5 sublots	100	20
	≥ 15 and ≤ 125	25 tonnes	100	20
	< 15	—	10-100 (*)	≤ 20

(*) Depending on the lot weight – see Table 2 of this part D.

D.3. **Method of sampling for groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size (lots ≥ 15 tonnes)**

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 1. 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 mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately.

— Number of incremental samples: 100.

— Weight of the aggregate sample = 20 kg which shall be mixed and divided into two equal laboratory samples of 10 kg before grinding (this division into two laboratory samples is not necessary in case of groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise a 20 kg sample).

— Each laboratory sample of 10 kg shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II.

— If it is not possible to carry out the method of sampling described above because of the commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

D.4. **Method of sampling for groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size (lots < 15 tonnes)**

The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100.

The figures in the following Table 2 may be used to determine the number of incremental samples to be taken and the subsequent division of the aggregate sample.

Table 2

Number of incremental samples to be taken depending on the weight of the lot and number of subdivisions of the aggregate sample

Lot weight (tonnes)	No of incremental samples (for retail/individual packages see also point D.1)	Aggregate sample weight (kg) (in case of retail/individual packages, weight of aggregate sample can diverge – see point D.1)	No of laboratory samples from aggregate sample
≤ 0,1	10	2	1 (no division)
> 0,1 – ≤ 0,2	15	3	1 (no division)
> 0,2 – ≤ 0,5	20	4	1 (no division)
> 0,5 – ≤ 1,0	30	6	1 (no division)
> 1,0 – ≤ 2,0	40	8 (- < 12 kg)	1 (no division)
> 2,0 – ≤ 5,0	60	12	2
> 5,0 – ≤ 10,0	80	16	2
> 10,0 – ≤ 15,0	100	20	2

— Weight of the aggregate sample ≤ 20 kg which shall be mixed and if necessary divided into two equal laboratory samples of ≤ 10 kg before grinding (this division into two laboratory samples is not necessary in case of groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise up to 20 kg samples).

— In cases where the aggregate sample weights are less than 20 kg, the aggregate sample shall be divided into laboratory samples according to following guidance:

  — < 12 kg: no division into laboratory samples;

  — ≥ 12 kg: division into two laboratory samples.

— Each laboratory sample shall be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Annex II.

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

D.5. **Method of sampling for derived/processed products, with the exception of vegetable oil, and compound foods**

D.5.1. *Derived/processed products (other than vegetable oil) with small particle size, i.e. flour, peanut butter (homogeneous distribution of mycotoxin contamination) and compound foods*

— Number of incremental samples: 100; for lots of under 50 tons the number of incremental samples shall be 10 to 100, depending on the lot weight (see Table 3),

Table 3

Number of incremental samples to be taken depending on the weight of the lot

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)
≤ 1	10	1
> 1 – ≤ 3	20	2
> 3 – ≤ 10	40	4
> 10 – ≤ 20	60	6
> 20 – ≤ 50	100	10

— The weight of the incremental sample shall be about 100 g. In the case of lots in retail/individual packages, the weight of the incremental sample depends on the weight of the retail/individual package,

— Weight of aggregate sample = 1-10 kg sufficiently mixed,

D.5.2. *Derived/processed products with a relatively large particle size (heterogeneous distribution of mycotoxin contamination) and compound foods*

Method of sampling and acceptance as for groundnuts (peanuts), apricot kernels, tree nuts and spices with large particle size (points D.3 and D.4).

D.6. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part D.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg ([6]).

D.7. **Specific method of sampling for groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size and derived/processed products traded in vacuum packages**

D.7.1. *Pistachios, groundnuts (peanuts), Brazil nuts*

For lots equal to or more than 15 tonnes at least 50 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots of less than 15 tonnes, 50 % of the number of incremental samples mentioned in Table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 2).

D.7.2. *Apricot kernels, tree nuts other than pistachios and Brazil nuts, dried spices with large particle size*

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 20 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in Table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 2).

D.7.3. *Products derived/processed from groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size*

([6]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

For lots equal to or more than 50 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 50 tonnes, 25 % of the number of incremental samples mentioned in Table 3 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 3).

D.8. **Acceptance of a lot or sublot**

For groundnuts (peanuts), apricot kernels and tree nuts subjected to a sorting or other physical treatment:

— acceptance if the aggregate sample or the average of the laboratory samples conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty,

— rejection if the aggregate sample or the average of the laboratory samples exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

For groundnuts (peanuts), apricot kernels, tree nuts and dried spices with large particle size placed on the market for the final consumer or for use as ingredient in foods

— acceptance if none of the laboratory samples exceeds the maximum level, taking into account the correction for recovery and measurement uncertainty,

— rejection if one or both of the laboratory samples exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

In cases where the aggregate sample is 12 kg or less:

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

E. METHOD OF SAMPLING FOR DRIED SPICES EXCEPT DRIED SPICES WITH LARGE PARTICLE SIZE AND POWDERED SPICES

This method of sampling is of application for the official control of the levels of mycotoxins in spices. However, dried spices with a relatively large particle size, i.e. particle size comparable with peanuts or larger such as nutmeg with heterogeneous distribution of mycotoxin contamination, the method of sampling provided in part D of this Annex shall apply. For powdered spices (spices in powder), the method of sampling provided in part M of this Annex shall be applied.

E.1. **Weight of the incremental sample**

The weight of the incremental sample shall be about 100 g, unless otherwise defined in this part E.

In the case of lots in retail/individual packages, the weight of the incremental sample depends on the weight of the retail/individual package.

In the case of retail/individual packages of > 100 g, this will result in aggregate samples weighing more than the required weight indicated in tables 1 and 2. If the weight of a single retail/individual package is >> 100 g, then 100 g shall be taken from each individual retail/individual package as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a

valuable product is marketed in retail/individual packages of 500 g or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1 and 2, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1 and 2.

Where the retail/individual packages are less than 100 g and if the difference is not very large (i.e. not less than half of 100 g), one retail/individual package shall be considered as one incremental sample, resulting in an aggregate sample of less than the required weight indicated in tables 1 and 2. If the weight of the retail/individual packages are much less than 100 g, one incremental sample shall consist of two or more retail/individual packages, whereby the 100 g are approximated as closely as possible.

E.2. **General survey of the method of sampling for dried spices except dried spices with large particle size and powdered spices.**

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample weight (kg)
Dried spices	≥ 15	25 tonnes	100	10
	< 15	—	5-100 (*)	0,5-10

(*) Depending on the lot weight – see Table 2 of this part E.

E.3. **Method of sampling for dried spices except dried spices with large particle size and powdered spices (lots ≥ 15 tonnes).**

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 1. 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 mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately.

— Number of incremental samples: 100. Weight of the aggregate sample = 10 kg.

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

E.4. **Method of sampling for dried spices except dried spices with large particle size and powdered spices (lots < 15 tonnes)**

For lots of dried spices less than 15 tonnes the sampling plan shall be used with 5 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 0,5 to 10 kg.

The figures in the following Table 2 can be used to determine the number of incremental samples to be taken.

Table 2

Number of incremental samples to be taken depending on the weight of the lot of dried spices

Lot weight (tonnes)	Number of incremental samples	Aggregate sample weight (kg)
≤ 0,01	5	0,5
> 0,01-≤ 0,1	10	1
> 0,1-≤ 0,2	15	1,5
> 0,2-≤ 0,5	20	2
> 0,5-≤ 1,0	30	3
> 1,0-≤ 2,0	40	4
> 2,0-≤ 5,0	60	6
> 5,0-≤ 10,0	80	8
> 10,0-≤ 15,0	100	10

E.5. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part E.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 0,5 kg ([7]).

E.6. **Specific method of sampling for dried spices except dried spices with large particle size and powdered spices traded in vacuum packages**

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in Table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 2).

E.7. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty;

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

F. METHOD OF SAMPLING FOR MILK AND MILK PRODUCTS; INFANT FORMULA, FOLLOW-ON FORMULA, FOODS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS AND YOUNG CHILDREN AND YOUNG CHILD FORMULA

F.1. **Method of sampling for milk, milk products, infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula.**

The aggregate sample shall be at least 1 kg or 1 litre except where it is not possible e.g. when the sample consists of one bottle.

([7]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 0,5 kg, the aggregate sample weight might be less than 0,5 kg.

The minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The number of incremental samples determined is function of the usual form in which the products concerned are commercialised. In the case of bulk liquid products, the lot shall be thoroughly mixed insofar as possible and insofar it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of mycotoxins is assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.

The incremental samples, which might frequently be a bottle or a package, shall be of similar weight. The weight of an incremental sample shall be at least 100 g, resulting in an aggregate sample of at least about 1 kg or 1 litre. Departure from this method shall be recorded in the record provided for under part I point A.1.8 of this Annex.

Table 1

Minimum number of incremental samples to be taken from the lot

Form of commercialisation	Volume or weight of lot (in litre or kg)	Minimum number of incremental samples to be taken	Minimum volume or weight of aggregate sample (in litre or kg)
Bulk	—	3-5	1
Bottles/packages	≤ 50	3	1
Bottles/packages	50 to 500	5	1
Bottles/packages	> 500	10	1

F.2. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part F.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented ([8]).

F.3. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty;

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

G. METHOD OF SAMPLING FOR COFFEE, COFFEE PRODUCTS, COCOA, COCOA PRODUCTS, LIQUORICE ROOT AND LIQUORICE PRODUCTS

This method of sampling is of application for the official control of levels of mycotoxins in coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products. As regards coffee, coffee products, cocoa and cocoa products the method of sampling provided in this part G is applicable to solid (dried) products. For beverages (liquid), the method of sampling provided in part H is applicable.

G.1. **Weight of the incremental sample**

The weight of the incremental sample shall be about 100 g, unless otherwise defined in this part G.

In the case of lots in retail/individual packages, the weight of the incremental sample shall depend on the weight of the retail/individual package.

([8]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

In the case of retail/individual packages of more than 100 g, this will result in aggregate samples weighing more than the required weight indicated in tables 1 and 2. If the weight of a single retail/individual package is much more than 100 g, then 100 g shall be taken from each individual retail/individual package as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail/individual packages of 500 g or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in tables 1 and 2, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in tables 1 and 2.

Where the retail/individual packages are less than 100 g and if the difference is not very large (i.e. not less than half of 100 g), one retail/individual package shall be considered as one incremental sample, resulting in an aggregate sample of less than the required weight indicated in tables 1 and 2. If the weight of the retail/individual packages are much less than 100 g, one incremental sample shall consist of two or more retail/individual packages, whereby the 100 g are approximated as closely as possible.

G.2. General survey of the method of sampling for coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (ton)	Weight or number of sublots	No incremental samples	Aggregate sample weight (kg)
Coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products	≥ 15	15-30 tonnes	100	10
	< 15	—	10-100 (*)	1-10

(*) Depending on the lot weight – see Table 2 of this part G.

G.3. Method of sampling for coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products (lots ≥ 15 tonnes)

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 1. 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 vary from the mentioned weight by a maximum of 20 %.

— Each sublot shall be sampled separately,

— Number of incremental samples: 100,

— Weight of the aggregate sample = 10 kg,

— If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

G.4. **Method of sampling for coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products (lots < 15 tonnes)**

For coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products under 15 tonnes the sampling plan shall be used with 10 to 100 incremental samples, depending on the lot weight, resulting in an aggregate sample of 1 to 10 kg.

The figures in the following Table 2 can be used to determine the number of incremental samples to be taken.

Table 2

Number of incremental samples to be taken depending on the weight of the lot of coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products

Lot weight (tonnes)	No of incremental samples	Aggregate sample weight (kg)
≤ 0,1	10	1
> 0,1 – ≤ 0,2	15	1,5
> 0,2 – ≤ 0,5	20	2
> 0,5 – ≤ 1,0	30	3
> 1,0 – ≤ 2,0	40	4
> 2,0 – ≤ 5,0	60	6
> 5,0 – ≤ 10,0	80	8
> 10,0 – ≤ 15,0	100	10

G.5. **Method of sampling for coffee, coffee products, cocoa, cocoa products, liquorice root and liquorice products traded in vacuum packages**

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 10 kg aggregate sample shall be taken and for lots less than 15 tonnes, 25 % of the number of incremental samples mentioned in Table 2 shall be taken resulting in an aggregate sample of which the weight corresponds to the weight of the sampled lot (see Table 2).

G.6. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part G.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg ([9]).

G.7. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

([9]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

H. METHOD OF SAMPLING FOR BEVERAGES

This method of sampling is of application for the official control of the levels of mycotoxins in beverages, with the exception of milk.

H.1. **Method of sampling**

The aggregate sample shall be at least one litre except where it is not possible e.g. when the sample consists of one bottle.

The minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The number of incremental samples determined is function of the usual form in which the products concerned are commercialised. In the case of bulk liquid products the lot shall be thoroughly mixed insofar as possible and insofar it does not affect the quality of the product, by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of mycotoxins can be assumed within a given lot. It is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.

The incremental samples, which might frequently be a bottle or a package, shall be of similar volume. The volume of an incremental sample shall be at least 100 millilitre, resulting in an aggregate sample of at least about 1 litre. Departure from this method shall be recorded in the record provided for under part I point A.1.8 of this Annex.

Table 1

Minimum number of incremental samples to be taken from the lot

Form of commercialisation	Volume of lot (in litres)	Minimum number of incremental samples to be taken	Minimum volume of the aggregate sample (in litres)
Bulk	—	3	1
Bottles/packages (beverages other than wine)	≤ 50	3	1
Bottles/packages (beverages other than wine)	50 to 500	5	1
Bottles/packages (beverages other than wine)	> 500	10	1
Bottles/packages wine	≤ 50	1	1
Bottles/packages wine	50 to 500	2	1
Bottles/packages wine	> 500	3	1

H.2. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part H ([10]).

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented.

([10]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 litre, the aggregate sample volume might be less than 1 litre.

H.3. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

I. METHOD OF SAMPLING FOR SOLID PROCESSED FRUIT AND VEGETABLE PRODUCTS

This method of sampling is of application for the official control of the levels of mycotoxins in solid processed fruit (with the exception of processed products from dried fruit which fall under parts B and C of this Annex) and vegetable products, including solid processed fruit and vegetable products for infants and young children.

I.1. **Method of sampling**

The aggregate sample shall be at least 1 kg, except where it is not possible e.g. when sampling a single package.

The minimum number of incremental samples to be taken from the lot shall be as given in Table 1.

The incremental samples shall be of similar weight. The weight of an incremental sample shall be at least 100 g, resulting in an aggregate sample of at least 1 kg. Departure from this method shall be recorded in the record provided for under part I point A.1.8 of this Annex.

Table 1

Minimum number of incremental samples to be taken from the lot

Weight of lot (in kg)	Minimum number of incremental samples to be taken	Aggregate sample weight(kg)
< 50	3	1
50 to 500	5	1
> 500	10	1

If the lot consists of individual packages, then the number of packages, which shall be taken to form the aggregate sample, is given in Table 2.

Table 2

Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages

Number of packages or units in the lot	Number of packages or units to be taken	Aggregate sample weight(kg)
1 to 25	1 package or unit	1
26 to 100	about 5 %, at least two packages or units	1
> 100	about 5 %, at maximum 10 packages or units	1

I.2. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part I.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented ([11]).

I.3. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the measurement uncertainty and correction for recovery,

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

J. METHOD OF SAMPLING FOR BABY FOODS AND PROCESSED CEREAL BASED FOODS FOR INFANTS AND YOUNG CHILDREN

This method of sampling is of application for the official control of the levels of mycotoxins in baby foods and processed cereal based foods for infants and young children, with the exception of beverages referred to in part H and solid processed fruit and vegetable products referred to in part I of this Annex.

J.1. **Method of sampling**

— The method of sampling for cereals and cereal products as set out in point A.4 in part II of this Annex shall apply to food intended for infants and young children. Accordingly, the number of incremental samples to be taken shall depend on the weight of the lot, with a minimum of 10 and a maximum of 100, in accordance with Table 2 at point A.4 in part II of this Annex. For very small lots (≤ 0,5 tonnes) a lower number of incremental samples may be taken, but the aggregate sample uniting all incremental samples shall be also in that case at least 1 kg.

— weight of the incremental sample shall be about 100 g. In the case of lots in retail/individual packages, the weight of the incremental sample shall depend on the weight of the retail/individual package and in case of very small lots (≤ 0,5 tonnes) the incremental samples shall have a weight as such that uniting the incremental samples results in an aggregate sample of at least 1 kg. Departure from this method shall be recorded in the record provided for under part I point A.1.8 of this Annex.

— weight of aggregate sample = 1-10 kg sufficiently mixed.

J.2. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part J.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented ([12]).

J.3. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty;

([11]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

([12]) In case the portion to be sampled is so small that it is impossible to obtain an aggregate sample of 1 kg, the aggregate sample weight might be less than 1 kg.

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

K. METHOD OF SAMPLING FOR VEGETABLE OILS

K.1. **Method of sampling for vegetable oils**

— The weight of the incremental sample shall be at least about 100 g (ml) (depending of the nature of the lot e.g. vegetable oil in bulk, at least 3 incremental samples of about 350 ml have to be taken), resulting in an aggregate sample of at least 1 kg (litre).

— On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 1. 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 mentioned weight by a maximum of 20 %. In case the lot is not or cannot be physically separated into sublots, a minimum of 3 incremental samples is taken from the lot.

— The minimum number of incremental samples to be taken from the lot shall be as given in Table 2. The lot shall be thoroughly mixed insofar possible by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of mycotoxins can be assumed within a given lot, it is therefore sufficient to take three incremental samples from a lot to form the aggregate sample.

Table 1

Subdivision of lots into sublots depending on lot weight

Commodity	Lot weight (tonne)	Weight or number of sublots	Minimum No incremental samples	Minimum aggregate sample weight (kg)
Vegetable oils	≥ 1 500	500 tonnes	3	1
	> 300 and < 1 500	3 sublots	3	1
	≥ 50 and ≤ 300	100 tonnes	3	1
	< 50	—	3	1

Table 2

Minimum number of incremental samples to be taken from the lot

Form of commercialisation	Weight of lot (in kg) Volume of lot (in litres)	Minimum number of incremental samples to be taken
Bulk (*)	—	3
packages	≤ 50	3
packages	> 50 to 500	5
packages	> 500	10

(*) On condition that the sublot can be separated physically, large bulk lots of vegetable oils shall be subdivided into sublots as foreseen in Table 2 of this part K

K.2. **Method of sampling for vegetable oils at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part K.

Where that is not possible, other effective methods of sampling at retail stage may be used provided that they ensure that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 1 kg.

K.3. **Acceptance of a lot or sublot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty,

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

L. METHOD OF SAMPLING FOR FOOD SUPPLEMENTS, POLLEN AND POLLEN PRODUCTS

L.1. **Weight of incremental sample and method of sampling**

The sampling procedure provided for food supplements, pollen and pollen products as capsules/pills is based on retail/individual packages containing usually 30 to 120 capsules/pills per retail/individual package

Lot size (number of retail/individual packages)	Number of retail/individual packages to be taken for sample	Sample size (minimum amount of the aggregate sample)
1-50	1	Food supplements as capsules/pills: Total content of the retail/individual package
		Other forms of food supplements – incremental samples of approx. 20 g or 20 ml — 100 g for food supplements containing herbal/plant based ingredients including extracts (minimum 5 incremental samples) — 50 g or 50 ml for other food supplements (minimum 3 incremental samples)
51-250	2	Food supplements as capsules/pills: total content of the two retail/individual packages
		Other forms of food supplements – incremental samples of approx. 20 g or 20 ml — 200 g for food supplements containing herbal/plant based ingredients including extracts (minimum 10 incremental samples) — 100 g or 100 ml for other food supplements (minimum 5 incremental samples)
251-1 000	4	Food supplements as capsules/pills: from each retail/individual package taken for sample, half of the capsules/pills

		Other forms of food supplements – incremental samples of approx. 20 g or 20 ml — 200 g for food supplements containing herbal/plant based ingredients including extracts (minimum 10 incremental samples) — 100 g or 100 ml for other food supplements (minimum 5 incremental samples)
> 1 000	4 + 1 retail/individual packages per 1 000 retail/individual packages with a maximum of 25 retail/individual packages	Food supplements as capsules/pills: ≤ 10 retail/individual packages: from each retail/individual package, half of the capsules/pills > 10 retail/individual packages: from each retail/individual package, an equal number of capsules/pills is taken to result in a sample with the equivalent of the content of retail/individual 5 packages
		Other forms of food supplements – incremental samples of approx. 20 g or 20 ml ≤ 10 retail/individual packages: — 200 g for food supplements containing herbal/plant based ingredients including extracts (minimum 10 incremental samples) — 100 g or 100 ml for other food supplements (minimum 5 incremental samples) > 10 retail/individual packages – per 5 retail/individual packages: — 100 g for food supplements containing herbal/plant based ingredients including extracts (minimum 5 incremental samples) — 50 g or 50 ml for other food supplements (minimum 3 incremental samples)
Unknown (only applicable for e-commerce)	1	Food supplements as capsules/pills: total content of the package

L.2. **Sampling at retail**

Sampling of food supplements, pollen and pollen products at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part L.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 0,05 kg.

L.3. **Acceptance of a lot**

— acceptance if the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty;

— rejection if the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

M. METHOD OF SAMPLING FOR DRIED HERBS, HERBAL INFUSIONS (DRIED PRODUCT), TEAS (DRIED PRODUCT) AND POWDERED SPICES

M.1. Weight of the incremental sample

The weight of the incremental sample shall be about 40 g, unless otherwise defined in this part M.

In the case of lots in retail/individual packages, the weight of the incremental sample depends on the weight of the retail/individual package.

In the case of retail/individual package of > 40 g, this will result in aggregate samples weighing more than the required weight indicated in tables 1 and 2. If the weight of a single retail/individual package is >> 40 g, then 40 g shall be taken from each individual retail/individual package as an incremental sample. This can be done either when the sample is taken or in the laboratory. However, in cases where such method of sampling would lead to unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.), then an alternative method of sampling can be applied. For example, in case where a valuable product is marketed in retail/individual packages of 500 g or 1 kg, the aggregate sample can be obtained by the aggregation of a number of incremental samples that is smaller than the number indicated in Tables 1 and 2, on the condition that the weight of the aggregate sample corresponds to the required weight of the aggregate sample mentioned in Tables 1 and 2.

Where the retail/individual packages are less than 40 g and if the difference is not very large (i.e. not less than half of 40 g), one retail/individual package shall be considered as one incremental sample, resulting in an aggregate sample of less than the required weight indicated in tables 1 and 2. If the weight of the retail/individual packages are much less than 40 g, one incremental sample shall consist of two or more retail/individual packages, whereby the 40 g are approximated as closely as possible.

M.2. General survey of the method of sampling for dried herbs, herbal infusions (dried product), teas (dried product) and powdered spices

Table 1

Subdivision of lots into sublots depending on lot weight

Commodity	Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample weight (kg)
dried herbs, herbal infusions (dried product) teas (dried product), powdered spices	≥ 15	25 tonnes	50	2
	< 15	—	3 – 50 (*)	0,1 – 2,0

(*) Depending on the lot weight – see Table 2 of this part M.

M.3. Method of sampling for dried herbs, herbal infusions (dried product), teas (dried product) and powdered spices (lots ≥ 15 tonnes)

On condition that the sublot can be separated physically, each lot shall be subdivided into sublots following Table 1. 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 mentioned weight by a maximum of 20 %.

Each sublot shall be sampled separately.

The number of incremental samples shall be50. The weight of the aggregate sample shall be 2,0 kg.

If it is not possible to carry out the method of sampling described above because of the unacceptable commercial consequences resulting from damage to the lot (because of packaging forms, means of transport or other reasons) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

M.4. **Method of sampling for dried herbs, herbal infusions (dried product) and teas (dried product) and powdered spices (lots < 15 tonnes)**

For lots of dried herbs, herbal infusions (dried product) and teas (dried product) and powdered spices less than 15 tonnes the sampling plan shall be used with 3 to 50 incremental samples, depending on the lot weight, resulting in an aggregate sample of 0,1 to 2,0 kg.

The figures in the following Table 2 may be used to determine the number of incremental samples to be taken.

Table 2

Minimum number of incremental samples to be taken depending on the weight of the lot of dried herbs, herbal infusions (dried product), teas (dried product) and powdered spices

Lot weight (tonnes)	Minimum number of incremental samples	Minimum aggregate sample weight (kg)
≤ 0,1	3	0,1
> 0,1 – ≤ 0,5	10	0,4
> 0,5 – ≤ 5,0	25	1,0
> 5,0 – ≤ 10,0	35	1,4
> 10,0 – ≤ 15,0	50	2,0

M.5. **Sampling at retail stage**

Sampling of foodstuffs at the retail stage shall be done where possible in accordance with the sampling provisions set out in this part M.

Where that is not possible, an alternative method of sampling at retail stage may be used provided that it ensures that the aggregate sample is sufficiently representative of the sampled lot and is fully described and documented. In any case, the aggregate sample shall be at least 0,1 kg.

M.6. **Acceptance of a lot or sublot**

Acceptance: where the laboratory sample conforms to the maximum level, taking into account the correction for recovery and measurement uncertainty;

Rejection: where the laboratory sample exceeds the maximum level beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty. This is the case when the analytical result (corrected for recovery if applicable) minus the expanded measurement uncertainty arising from the analysis is above the maximum level.

N. METHOD OF SAMPLING FOR VERY LARGE LOTS OR LOTS STORED OR TRANSPORTED IN A WAY WHEREBY SAMPLING THROUGHOUT THE LOT IS NOT FEASIBLE

N.1. **General principles**

In case the way of transport or storage of a lot does not enable to take incremental samples throughout the whole lot, sampling of such lots shall preferably be done when the lot is in flow (dynamic sampling).

In the case of large warehouses destined to store food, operators shall be encouraged to install equipment in the warehouse enabling (automatic) sampling across the whole stored lot.

When a sampling procedure as provided for in this part N is applied, the food business operator or his representative shall be informed of the sampling procedure. If the sampling procedure is questioned by the food business operator or his representative, the food business operator or his representative shall enable the competent authority to sample throughout the whole lot at his/her own cost.

Sampling of a portion of the lot is allowed, on the condition that the quantity of the sampled portion is at least 10 % of the lot to be sampled. If a portion of a lot of food of the same class or description has been sampled and identified as not satisfying Union requirements, it shall be presumed that the entire lot is also affected, unless further detailed assessment shows no evidence that the rest of the lot is unsatisfactory.

The relevant sampling provisions, such as weight of the incremental sample, provided for in the other parts of this Annex are applicable for the sampling for very large lots or lots stored or transported in a way whereby sampling throughout the lot is not feasible.

N.2. **Number of incremental samples to be taken in the case of very large lots**

In the case of large sampled portions (sampled portions > 500 tonnes), the number of incremental samples to be taken = 100 incremental samples + √tonnes. However, in case the lot is less than 1 500 tonnes and can be subdivided into sublots in accordance with the Table 1 of part A and on the condition that the sublots can be separated physically, the number of incremental samples as provided for in part A have to be taken.

N.3. **Large lots transported by ship**

N.3.1. *Dynamic sampling of large lots transported by ship*

The sampling of large lots in ships is preferably carried out while the product is in flow (dynamic sampling).

The sampling is to be done per hold (entity that can physically be separated). Holds are however emptied partly one after the other so that the initial physical separation no longer exists after transfer into storage facilities. Sampling can therefore be performed based on initial physical separation or based on the separation after transfer into the storage facilities.

The unloading of a ship can last for several days. Normally, sampling has to be performed at regular intervals during the whole duration of unloading. It is however not always feasible or appropriate for an official inspector to be present for sampling during the whole operation of unloading. Therefore, sampling of a portion of the lot is allowed to be undertaken (sampled portion). The number of incremental samples is determined by taking into account the size of the sampled portion.

Even if the official sample is taken automatically, the presence of an inspector is necessary. However, if the automatic sampling is done with pre-set parameters which cannot be changed during the sampling and the incremental samples are collected in a sealed receptacle, preventing any possible fraud, then the presence of an inspector is only required at the beginning of the sampling, every time the receptacle of the samples needs to be changed and at the end of the sampling.

N.3.2. *Sampling of lots transported by ship by static sampling*

In cases where the sampling is done in a static way the same procedure as foreseen for storage facilities (silos) accessible from above has to be applied (see point N.5.1).

The sampling has to be performed on the accessible part (from above) of the lot/hold. The number of incremental samples is determined by taking into account the size of the sampled portion.

N.4. **Sampling of large lots stored in warehouses**

The sampling has to be performed on the accessible part of the lot. The number of incremental samples is determined by taking into account the size of the sampled portion.

N.5. **Sampling of storage facilities (silos)**

N.5.1. *Sampling of silos (easily) accessible from above*

The sampling has to be performed on the accessible part of the lot. The number of incremental samples is determined by taking into account the size of the sampled portion.

N.5.2. *Sampling of silos not accessible from above (closed silos)*

N.5.2.1. *Silos not accessible from above (closed silos) with individual sizes > 100 tonnes*

Food stored in such silos cannot be sampled in a static way. Therefore, when the food in the silo has to be sampled and there is no possibility to move the lot, an agreement has to be made with the operator that he or she has to inform the inspector about when the silo will be unloaded, partially or completely, in order to enable sampling when the food is in flow.

N.5.2.2. *Silos not accessible from above (closed silos) with individual sizes < 100 tonnes*

Contrary to the provision in point N.1 (sampled portion at least 10 %), the sampling procedure involves the release into a receptacle of a quantity of 50 to 100 kg and taking the sample from it. The size of the aggregate sample corresponds to the whole lot and the number of incremental samples relate to the quantity of the food from the silo released into the receptacle for sampling.

N.6. **Sampling of loose food in large closed containers**

Such lots can often only be sampled when unloaded. In certain cases it is not possible to unload at the point of import or control and therefore the sampling should take place when such containers are unloaded. The operator has to inform the inspector about the place and time of unloading the containers to enable the inspector to be present.

ANNEX II

Criteria for sample preparation and for methods of analysis used for the control of the levels of mycotoxins in food

1. INTRODUCTION

1.1. **Precautions**

As the distribution of mycotoxins is generally non-homogeneous, samples shall be prepared, and especially homogenised, with extreme care.

The complete sample as received by the laboratory shall be homogenised, in case the homogenisation is performed by the laboratory.

For the analysis of aflatoxins, daylight shall be excluded as much as possible during the procedure, since aflatoxin gradually breaks down under the influence of ultra-violet light.

1.2. **Calculation of proportion of shell/kernel of whole nuts/oilseeds (peanuts and other)**

The maximum levels established in Regulation (EU) 2023/915 apply to the edible part. The level of mycotoxins in the edible part can be determined by:

— samples of nuts and oilseeds 'in shell' can be shelled and the level of mycotoxins is determined in the edible part;

— the nuts and oilseeds 'in shell' can be taken through the sample preparation procedure. The method of sampling and analysis shall estimate the weight of kernel in the aggregate sample. The weight of kernel in the aggregate sample shall be estimated after establishing a suitable factor for the proportion of shell to kernel in whole nuts and oilseeds. This proportion is used to ascertain the amount of kernel in the aggregate sample taken through the sample preparation and method of analysis.

Approximately 100 whole nuts/oilseeds shall be taken at random separately from the lot or shall be put aside from each aggregate sample. The ratio may, for each laboratory sample, be obtained by weighing the whole nuts and oilseeds, shelling and re-weighing the shell and kernel portions.

However, the proportion of shell to kernel may be established by the laboratory from a number of samples and so can be assumed for future analytical work. But if a particular laboratory sample is found to be in contravention of any maximum level, the proportion shall be determined for that sample using the approximately 100 nuts/oilseeds that have been set aside.

2. TREATMENT OF THE SAMPLE AS RECEIVED IN THE LABORATORY

Each laboratory sample shall be mixed thoroughly using a process, including fine grinding if needed, that has been demonstrated to achieve complete homogenisation with the exception of samples for the control of the presence of ergot sclerotia.

In case the laboratory sample has to be analysed for the control of the presence of ergot sclerotia and mycotoxins, the part of the sample used for the determination of ergot sclerotia is taken from the laboratory sample before grinding of the laboratory sample.

In case the maximum level applies to the dry matter, the dry matter content of the product shall be determined on a part of the homogenised sample, using a method that has been demonstrated to determine accurately the dry matter content.

3. REPLICATE SAMPLES

The replicate samples for enforcement, defence and reference purposes shall be taken from the homogenised aggregate sample unless such procedure conflicts with Member States' rules as regards the rights of the food business operator.

4. METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIREMENTS

4.1. **General requirements**

Confirmatory methods of analysis used for food control purposes shall comply with the provisions of points 1 and 2 of Annex III to Regulation (EU) 2017/625.

Wherever possible, the trueness of the method should be verified by analysis of a certified reference material and/or successful participation in proficiency tests on a regular basis.

4.2. **Specific requirements**

4.2.1. *Specific requirements for confirmatory methods*

4.2.1.1. Performance criteria

For confirmatory methods the following performance criteria apply:

Recovery: the average recovery should be between 70 and 120 %.

The average recovery is the average value from replicates obtained during validation when determining the precision parameters RSDr and $RSDw_R$. The criterion applies to all concentrations and all individual toxins, with the exception of ergot alkaloids.

For ergot alkaloids the criterion applies to the sum of each epimer-pair.

In exceptional cases, average recoveries outside the above range can be acceptable but shall lie within 50-130 %, and only when the precision criteria for RSDr and $RSDw_R$ are met.

Precision

RSDr	shall be ≤ 20 %.
$RSDw_R$	shall be ≤ 20 %.
RSD_R	should be ≤ 25 %.

These criteria apply to all concentrations.

In case a laboratory provides the evidence that the $RSDw_R$ criterion is complied with, there is no need to provide that evidence for the RSDr criterion as compliance with the $RSDw_R$ guarantees compliance with the RSDr criterion.

In case the maximum level applies to a sum of toxins, then the criteria for precision apply to both the sum and the individual toxins. For ergot alkaloids, the criteria for individual toxins apply to the sum of each epimer pair.

Limit of quantification

When a specific requirement for the LOQ of a mycotoxin has been set in the Table 1 below, the method shall have an LOQ at or below this value.

Table 1

LOQ requirements for certain mycotoxins

Mycotoxin	Food	LOQ requirement (µg/kg)
Aflatoxins		
Aflatoxin B1	Baby food and processed cereal-based foods for infants and young children, and food for special medical purposes intended for infants and young children	≤ 0,1

Aflatoxin B1, B2, G1, G2, each of the aflatoxins	All other foods	≤ 1
Ochratoxin A	Liquorice confectionary containing < 97 % liquorice extract on dry basis	≤ 10,0
	Cocoa powder	≤ 3,0
Ergot alkaloids (each of 12 epimers included in sum definition of ML)	Cereals and cereal-based foods	≤ 4
	Processed cereal-based food for infants and young children	≤ 2

In all other cases, the following applies:

LOQ: hall be ≤ 0,5*ML and should preferably be lower (≤ 0,2*ML).

In case the maximum level applies to a sum of toxins, then the LOQ of the individual toxins shall be ≤ 0,5*ML/n, with n being the number of toxins included in the ML definition.

Identification

For identification, the criteria as laid down in the Guidance document on identification of mycotoxins and plant toxins in food and feed ([1]) shall be applied.

4.2.1.2. Extension of the scope of the method

4.2.1.2.1. *Extension of scope to other mycotoxins:*

When additional analytes are added to the scope of an existing confirmatory method, a full validation is required to demonstrate the suitability of the method.

4.2.1.2.2. *Extension to other commodities:*

If the confirmatory method is known or expected to be applicable to other commodities, the validity to these other commodities shall be verified. As long as the new commodity belongs to a commodity group (see Table 2 in this Annex) for which an initial validation has already been performed, a limited additional validation is sufficient.

4.2.2. *Specific requirements for semi-quantitative screening methods*

4.2.2.1. Scope

This section applies to bioanalytical methods based on immuno-recognition or receptor binding (such as ELISA, dip-sticks, lateral flow devices, immuno-sensors) and physicochemical methods based on chromatography or direct detection by mass spectrometry (e.g. ambient MS). Other methods (e.g. thin layer chromatography) are not excluded provided the signals generated relate directly to the mycotoxins of interest and allow that the principle described hereunder is applicable.

The specific requirements apply to methods of which the result of the measurement is a numerical value, for example a (relative) response from a dip-stick reader, a signal from LC-MS, etc., and that normal statistics apply.

The requirements do not apply to methods that do not give numerical values (e.g. only a line that is present or absent), which require different validation approaches. Specific requirements for these methods are provided in point 4.2.3.

([1]) available at: https://food.ec.europa.eu/document/download/f16cac78-9318-4f1f-b2fa-efb25d2f1880_en

This document describes procedures for the validation of screening methods by means of an inter-laboratory validation, the verification of the performance of a method validated by means of an inter-laboratory exercise and the single-laboratory validation of a screening method.

4.2.2.2. Validation procedure

The aim of the validation is to demonstrate the fitness of purpose of the screening method. This is done by determination of the cut-off value and determination of the false negative and false suspect rate. In these two parameters performance characteristics such as detection capability, selectivity, and precision are embedded.

Screening methods may be validated by inter-laboratory or by single laboratory validation. If inter-laboratory validation data is already available for a certain mycotoxin/matrix/STC combination, a verification of method performance is sufficient in a laboratory implementing the method.

4.2.2.2.1. *Initial validation by single laboratory validation*

Mycotoxins

The validation shall be performed for every individual mycotoxin in the scope. In case of bio-analytical methods that give a combined response for a certain mycotoxin group (e.g. aflatoxins B_1, B_2, G_1 & G_2; fumonisins B_1 & B_2), applicability shall be demonstrated and limitations of the test mentioned in the scope of the method. Undesired cross-reactivity (e.g. DON-3-glycoside, 3- or 15-acetyl-DON for immuno-based methods for DON) is not considered to increase the false negative rate of the target mycotoxins, but may increase the false suspect rate. This unwanted increasing shall be diminished by confirmatory analysis for unambiguous identification and quantification of the mycotoxins.

Matrices

An initial validation shall be performed for each commodity, or, when the method is known to be applicable to multiple commodities, for each commodity group. In the latter case, one representative and relevant commodity shall be selected from that group (see Table 2).

Sample set

The minimum number of different samples required for validation is 20 homogeneous negative control samples and 20 homogeneous positive control samples that contain the mycotoxin at the STC, analysed under intermediate precision (RSD_{Ri}) conditions spread over 5 different days. Additional sets of 20 samples containing the mycotoxin at other levels may be added to the validation set to gain insight as to what extent the method can distinguish between different mycotoxin concentrations.

Concentration

For each STC to be used in routine application, a validation shall be performed.

4.2.2.2.2. *Initial validation through collaborative trials*

Validation through collaborative trials shall be done in accordance with ISO 5725:1994 or the IUPAC International Harmonised Protocol or other internationally recognised protocol on collaborative trials which requires inclusion of valid data from at least eight different laboratories. The only other difference compared to single laboratory validations shall be that the ≥ 20 samples per commodity/level may be evenly divided over the participating laboratories, with a minimum of two samples per laboratory.

4.2.2.3. Determination of cut-off value and rate of false suspected results of blank samples

The (relative) responses for the negative control and positive control samples shall be taken as basis for the calculation of the required parameters.

Screening methods with a response proportional with the mycotoxin concentration

For screening methods with a response proportional with the mycotoxin concentration the following applies:

$$Cut\text{-}off\ value = R_{STC} - t\text{-}value_{0,05} * SD_{STC}$$

R_{STC} = mean response of the positive control samples (at STC)

t-value: = one tailed t-value for a rate of false negative results of 5 % (see Table 3)

SD_{STC} = standard deviation

Screening methods with a response inversely proportional with the mycotoxin concentration

Similarly, for screening methods with a response inversely proportional with the mycotoxin concentration, the cut-off value is determined as:

$$Cut\text{-}off\ value = R_{STC} + t\text{-}value_{0,05} * SD_{STC}$$

By using this specific t-value for determining the cut-off value, the rate of false negative results is by default set at 5 %.

Fitness for purpose assessment

Results from the negative control samples are used to estimate the corresponding rate of false suspect results. The t-value is calculated corresponding to the event that a result of a negative control sample is above the cut-off value, thus erroneously classified as suspect.

t-value = (cut-off value – $mean_{blank}$)/SD_{blank}

for screening methods with a response proportional with the mycotoxin concentration

or

t-value = ($mean_{blank}$ – cut-off value)/SD_{blank}

for screening methods with a response inversely proportional with the mycotoxin concentration.

From the obtained t-value, based on the degrees of freedom calculated from the number of experiments, the probability of false suspect samples for a one tailed distribution can either be calculated (e.g. spread sheet function 'TDIST') or taken from a table for t-distribution (see Table 3).

The corresponding value of the one tailed t-distribution specifies the rate of false suspect results.

This concept is described in detail with an example in Analytical and Bioanalytical Chemistry DOI 10.1007/s00216 -013-6922-1.

4.2.2.4. Extension of the scope of the method

4.2.2.4.1. *Extension of scope to other mycotoxins:*

When additional analytes are added to the scope of an existing screening method, a full validation shall be required to demonstrate the suitability of the method.

4.2.2.4.2. *Extension to other commodities:*

If the screening method is known or expected to be applicable to other commodities, the validity to these other commodities shall be verified. As long as the new commodity belongs to a commodity group (see Table 2 in this Annex) for which an initial validation has already been performed, a limited additional validation is sufficient. For this, a minimum of 10 homogeneous negative control and 10 homogeneous positive control (at STC) samples shall be analysed under intermediate precision conditions. The positive control samples shall all be above the cut-off value. In case this criterion is not met, a full validation is required.

4.2.2.5. Verification of methods already validated through collaborative trials

For screening methods that have already been successfully validated through a collaborative laboratory trial, the method performance shall be verified. For this a minimum of 6 negative control and 6 positive control (at STC) samples shall be analysed. The positive control samples shall all be above the cut-off value. In case this criterion is not met, the laboratory has to perform a root-cause analysis to identify why it cannot meet the specification as obtained in the collaborative trial. Only after taking corrective action, it shall re-verify the method performance in its laboratory. In case the laboratory is not capable to verify the results from the collaborative trial, it will need to determine its own cut-off value in a complete single laboratory validation.

4.2.2.6. Continuous method verification/on-going method validation

After initial validation, additional validation data are acquired by including at least two positive control samples in each batch of samples screened. One positive control sample shall be a known sample (e.g. one used during initial validation), the other shall be a different commodity from the same commodity group (in case only one commodity is analysed, a different sample of that commodity is used instead). Inclusion of a negative control sample is optional. The results obtained for the two positive control samples are added to the existing validation set.

At least once a year the cut-off value is re-determined and the validity of the method is re-assessed (re-evaluation of the available QA/QC data obtained in the last year). The continuous method verification serves several purposes, including:

— quality control for the batch of samples screened;

— providing information on robustness of the method at conditions in the laboratory that applies the method;

— justification of applicability of the method to different commodities;

— allowing to adjust cut-off values in case of gradual drifts over time.

4.2.2.7. Validation report

The validation report shall contain:

— a statement on the STC;

— a statement on the determined cut-off value;

Note: The cut-off value shall have the same number of significant figures as the STC. Numerical values used to calculate the cut-off value need at least one more significant figure than the STC.

— a statement on calculated false suspected rate;

— a statement on how the false suspected rate was generated.

Note: The statement on the calculated false suspected rate indicates if the method is fit-for-purpose as it indicates the number of blank (or low level contamination) samples that will be subject to verification.

Table 2

Commodity groups for the validation of confirmatory and screening methods

Commodity groups	Commodity categories	Typical representative commodities included in the category
High water content	Fruit Juices Alcoholic beverages Root and tuber vegetables Cereal or fruit based purees	Apple juice, grape juice Wine, beer, cider Fresh ginger, herbal infusions (liquid) Purees intended for infants and small children
High oil content	Tree nuts Oil seeds and products thereof Oily fruits and products thereof	Walnuts, hazelnuts, chestnuts rapeseed, sunflower, cottonseeds, soybeans, peanuts, sesame seeds etc. Oils and pastes (e.g. peanut butter, tahina)
High starch and/or protein content and low water and fat content	Cereal grain and products thereof Dietary products	Wheat, rye, barley, maize, rice, oats Wholemeal bread, white bread, crackers, breakfast cereals, pasta Dried powders for the preparation of food for infants and small children
High acid content and high water content (*)	Citrus products	
'Difficult or unique commodities' (**)		Cocoa beans and products thereof, copra and products thereof, coffee, tea (dried product) Spices, liquorice root, herbal infusions (dried product), food supplements, pollen, and pollen products
High sugar low water content	Dried fruits	Figs, raisins, currants, sultanas
Milk and milk products	Milk Cheese Dairy products (e.g. milk powder)	Cow, goat and buffalo milk Cow, goat cheese Yogurt, cream
Meat (tissue)	Edible offals Muscle, processed meat products	Kidney, liver ham

(*) If a buffer is used to stabilise the pH changes in the extraction step, then this commodity group can be merged into one commodity group 'High water content'.

(**) 'Difficult or unique commodities' needs only to be fully validated if they are frequently analysed. If they are only analysed occasionally, validation may be reduced to just checking the reporting levels using spiked blank extracts.

Table 3

One tailed t-value for a false negative rate of 5 %

Degrees of Freedom	Number of replicates	t-value (5 %)
10	11	1,812
11	12	1,796
12	13	1,782
13	14	1,771
14	15	1,761
15	16	1,753
16	17	1,746
17	18	1,74
18	19	1,734
19	20	1,729
20	21	1,725
21	22	1,721
22	23	1,717
23	24	1,714
24	25	1,711
25	26	1,708
26	27	1,706
27	28	1,703
28	29	1,701
29	30	1,699
30	31	1,697
40	41	1,684
60	61	1,671
120	121	1,658
∞	∞	1,645

4.2.3. *Requirements for qualitative screening methods (methods that do not give numerical values)*

The development of validation guidelines for binary test methods is currently carried out by various standardisation bodies (e.g. AOAC, ISO). AOAC has drafted a guideline on the validation of binary test methods. This document can be regarded as the current state of the art in the field of validation of binary test methods. Therefore, methods that give binary results (e.g. visual inspection of dip-stick tests) should be validated according to AOAC International Guidelines for Validation of Qualitative Binary Chemistry Methods ([2]).

([2]) Available at: https://academic.oup.com/jaoac/article-pdf/97/5/1492/32425003/jaoac1492.pdf

However, other recognised validation guidelines can be used such as the approach provided for in ISO/TS 23758:2021 | IDF/RM 251 Guidelines for the validation of qualitative screening methods for the detection of residues of veterinary drugs in milk and milk products.

4.2.4. *Quantitative determination of ergot sclerotia*

Ergot sclerotia in cereals shall be determined by visual (macroscopic/microscopic) identification of the ergot sclerotia and ergot sclerotia fragments. Quantification shall be done by weighing the amount of identified ergot sclerotia and ergot sclerotia fragments with a particle size > 0,5 mm.

4.3. **Estimation of measurement uncertainty, recovery calculation and reporting of results** ([3])

4.3.1. *Confirmatory methods*

The analytical result shall be reported as follows:

(a) Corrected for recovery, where appropriate and relevant, and when corrected it shall be stated. The recovery rate is to be quoted unless intrinsic correction for bias is part of the procedure. The correction for recovery is not necessary in case the recovery rate is between 90-110 %.

(b) As x +/– U whereby x is the analytical result and U is the expanded analytical measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

As a possibility a default expanded measurement uncertainty of 50 % may be reported, provided that the laboratory meets all precision requirements specified in point 4.2. An individual laboratory can demonstrate that by achieving the criteria for the repeatability (RSDr) and the within-laboratory reproducibility ($RSDw_R$), supplemented by successful participation in proficiency testing programs (unless no suitable proficiency testing program is available), as a mean z-score of $|z| \leq 2$ demonstrates that the required reproducibility (RSD_R) is met (based on a target standard deviation of 25 %).

In case the maximum level has been set for the sum of toxins (e.g. aflatoxins, T-2/HT-2-toxin, fumonisins, ergot alkaloids), the analytical results of all individual toxins shall be reported. For ergot alkaloids, it is also allowed to report the sum of each of the six epimer pairs instead of the 12 individual epimers.

Recovery correction, if applicable, shall be done for each of the individual toxins before summation of the concentrations. For ergot alkaloids, the correction can also be done based on the recovery obtained for each of the epimer pairs.

For compliance verification with the sum-ML, a lower-bound approach shall be applied which means that results for individual toxins that are <LOQ shall be replaced by zero for the calculation of the sum.

The present interpretation rules of the analytical result in view of acceptance or rejection of the lot apply to the analytical result obtained on the sample for official control. In case of analysis for defense or referee purposes, the national rules apply. In particular, if

the analytical result of the official control sample indicates a non-compliance beyond reasonable doubt, taking into account the expanded measurement uncertainty and

the analytical result of the defense sample indicates a non-compliance but not beyond reasonable doubt with a larger expanded measurement uncertainty than the one of the official control,

then the analytical result of the defense sample cannot supersede the non-compliance established for the official control sample.

([3]) More details on procedures for the estimation of measurement uncertainty and on procedures for assessing recovery can be found in the report 'Report on the relationship between analytical results, measurement uncertainty, recovery factors and the provisions of EU food and feed legislation' https://food.ec.europa.eu/system/files/2016-10/cs_contaminants_sampling_analysis-report_2004_en.pdf

4.3.2. *Screening methods*

The result of the screening shall be expressed as compliant or suspected to be non-compliant.

'Suspected to be non-compliant' means the sample exceeds the cut-off value and may contain the mycotoxin at a level higher than the STC. Any suspect result triggers a confirmatory analysis for unambiguous identification and quantification of the mycotoxin.

'Compliant' means that the mycotoxin content in the sample is < STC with a level of confidence of 95 % (i.e. there is a 5 % chance that samples will be incorrectly reported as negative). The analytical result is reported as '< level of STC' with the level of STC specified.

4.4. **Laboratory quality standards**

A laboratory shall comply with the provisions of Article 37(4) and (5) of Regulation (EU) 2017/625.