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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [1], in particular Article 11(4),

Whereas:

(1) Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs [2] provides for maximum limits for certain mycotoxins in certain foodstuffs.

(2) Sampling plays a crucial part in the precision of the determination of the levels of mycotoxins, which are very heterogeneously distributed in a lot. It is therefore necessary to fix general criteria which the sampling method should comply with.

(3) It is also necessary to fix general criteria which the method of analysis should comply with in order to ensure that control laboratories use methods of analysis with comparable levels of performance.

(4) Commission Directive 98/53/EC of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of the levels for certain contaminants in foodstuffs [3] establishes sampling methods and performance criteria for the methods of analysis to be used for the official control of levels of aflatoxins in foodstuffs.

(5) Commission Directive 2002/26/EC of 13 March 2002 laying down the sampling methods and the methods of analysis for the official control of the levels of ochratoxin A in foodstuffs [4], Commission Directive 2003/78/EC of 11 August 2003 laying down the sampling methods and the methods of analysis for the official control of the levels of patulin in foodstuffs [5] and Commission Directive 2005/38/EC of 6 June 2005 laying down the sampling methods and the methods of analysis for the official control of the levels of *Fusarium*-toxins in foodstuffs [6] similarly establish sampling methods and performance criteria for ochratoxin A, patulin and *Fusarium*-toxins respectively.

(6) It is appropriate to apply whenever possible the same sampling method to the same product for the control of mycotoxins. Therefore, the sampling methods and performance criteria for the methods of analysis to be used for the official control of all mycotoxins should be brought together in a single legal act in order to make them easier to apply.

(7) Aflatoxins are very heterogeneously distributed in a lot, in particular in a lot of food products with a large particle size such as dried figs or groundnuts. In order to obtain the same representativeness, for batches with food products with large particle size, the weight of the aggregate sample should be larger than in case of batches with food products with a smaller particle size. Since the distribution of mycotoxins in processed products is generally less heterogeneous than in the unprocessed cereal products, it is appropriate to provide for simpler sampling provisions for processed products.

(8) Directives 98/53/EC, 2002/26/EC, 2003/78/EC and 2005/38/EC should therefore be repealed.

(9) It is appropriate that the date of application of this Regulation coincides with the date of application of Commission Regulation (EC) No 856/2005 of 6 June 2005 amending Regulation (EC) No 466/2001 as regards Fusarium toxins [7].

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee for the Food Chain and Animal Health,

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[1] OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1.
[2] OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 199/2006 (OJ L 32, 4.2.2006, p. 34).
[3] OJ L 201, 17.7.1998, p. 93. Directive as last amended by Directive 2004/43/EC (OJ L 113, 20.4.2004, p. 14).
[4] OJ L 75, 16.3.2002, p. 38. Directive as last amended by Directive 2005/5/EC (OJ L 27, 29.1.2005, p. 38).
[5] OJ L 203, 12.8.2003, p. 40.
[6] OJ L 143, 7.6.2005, p. 18.
[7] OJ L 143, 7.6.2005, p. 3.

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

Article 3

Directives 98/53/EC, 2002/26/EC, 2003/78/EC and 2005/38/EC are repealed.

References to the repealed Directives shall be construed as references to this Regulation.

Article 4

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 July 2006.

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

Done at Brussels, 23 February 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I [1]

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF MYCOTOXINS IN FOODSTUFFS

A. GENERAL PROVISIONS

Official controls shall be performed in accordance with the provisions of Regulation (EC) No 882/2004. The following general provisions shall apply without prejudice to the provisions in Regulation (EC) No 882/2004.

A.1. **Purpose and scope**

Samples intended for official control of the levels of mycotoxins content in foodstuffs shall be taken according to the methods set out in this Annex. Aggregate samples thus obtained shall be considered as representative of the lots. Compliance with maximum limits laid down in Regulation (EC) No 466/2001 shall be established on the basis of the levels determined in the laboratory samples.

A.2. **Definitions**

For the purpose of this Annex, the following definitions shall apply:

A.2.1. 'lot' means an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings;

A.2.2. 'sublot' means a designated part of a large lot in order to apply the sampling method on that designated part; each sublot must be physically separate and identifiable;

A.2.3. 'incremental sample' means a quantity of material taken from a single place in the lot or sublot;

A.2.4. 'aggregate sample' means the combined total of all the incremental samples taken from the lot or sublot;

A.2.5. 'laboratory sample' means a sample intended for the laboratory.

A.3. **General provisions**

A.3.1. *Personnel*

Sampling shall be performed by an authorised person as designated by the Member State.

A.3.2. *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.3.3. *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;

— 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.3.4. *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 A.3.8. of this Annex I.

[1] A guidance document for competent authorities for the control of compliance with EU legislation on aflatoxins is available at http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/aflatoxin_guidance_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.3.5. *Preparation of the aggregate sample*

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

A.3.6. *Replicate samples*

The replicate samples for enforcement, trade (defence) and reference (referee) 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.3.7. *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.3.8. *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.

A record shall be kept of each sampling, 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.4. **Different types of lots**

Food commodities may be traded in bulk, containers, or individual packings, such as sacks, bags, retail packings. The method of sampling may be applied to all the different forms in which the commodities are put on the market.

Without prejudice to the specific provisions set out in other parts of this Annex, the following formula may be used as a guide for the sampling of lots traded in individual packs, such as sacks, bags, retail packings.

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

— weight: in kg

— sampling frequency (SF): every n^{th} sack or bag from which an incremental sample must be taken (decimal figures should be rounded to the nearest whole number).

B. METHOD OF SAMPLING FOR CEREALS AND CEREAL PRODUCTS

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1, total aflatoxins, ochratoxin A and *Fusarium*-toxins in cereals and cereal products.

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

The weight of the incremental sample shall be about 100 grams, unless otherwise defined in this part B of Annex I.

In the case of lots in retail packings, the weight of the incremental sample shall depend on the weight of the retail pack.

In the case of retail packs of more than 100 grams, this will result in aggregate samples weighing more than 10 kg. If the weight of a single retail pack is much more than 100 grams, then 100 grams shall be taken from each individual retail pack 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 packs of 500 grams 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 Tables 1 and 2.

Where the retail pack is less than 100 grams and if the difference is not very large, one retail pack is to be considered as one incremental sample, resulting in an aggregate sample of less than 10 kg. If the weight of the retail pack is much less than 100 grams, one incremental sample consists of two or more retail packs, whereby the 100 grams are approximated as closely as possible.

B.2. **General survey of the method of sampling for cereals and cereal products**

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)
Cereals and cereal products	≥ 1 500	500 tonnes	100	10
	> 300 and < 1 500	3 sublots	100	10
	≥ 50 and ≤ 300	100 tonnes	100	10
	< 50	—	3-100 (*)	1-10

(*) Depending on the lot weight — see Table 2.

B.3. **Method of sampling for cereals and cereal products for lots ≥ 50 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 %. In case the lot is not or cannot be physically separated into sublots, a minimum of 100 incremental samples is taken from the lot.

— 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 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 e.g. the case where large lots of cereals are stored in warehouses or where cereals are stored in silos ([1]).

B.4. **Method of sampling for cereals and cereal products for lots < 50 tonnes**

For lots of cereals and cereal 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. 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 be also in that case at least 1 kg.

The figures in Table 2 may 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 and cereal products

Lot weight (tonnes)	Number of incremental samples	Aggregate sample weight (kg)
≤ 0,05	3	1
> 0,05-≤ 0,5	5	1
> 0,5-≤ 1	10	1
> 1-≤ 3	20	2
> 3-≤ 10	40	4
> 10-≤ 20	60	6
> 20-≤ 50	100	10

([1]) Guidance for sampling such lots will be provided in a guidance document available from 1 July 2006 onwards on following website: http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/index_en.htm

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

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

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 [1].

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

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

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

C. METHOD OF SAMPLING FOR DRIED FRUIT, INCLUDING DRIED VINE FRUIT AND DERIVED PRODUCTS BUT WITH THE EXCEPTION OF DRIED FIGS

This method of sampling is of application for the official control of the maximum levels established for:

— aflatoxin B1 and total aflatoxins in dried fruit but with the exception of dried figs and

— ochratoxin A in dried vine fruit (currants, raisins and sultanas).

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

The weight of the incremental sample shall be about 100 grams, unless otherwise defined in this part C of Annex I.

In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

In the case of retail packs of more than 100 grams, this will result in aggregate samples weighing more than 10 kg. If the weight of a single retail pack is much more than 100 grams, then 100 grams shall be taken from each individual retail pack 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 packs of 500 grams 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 pack is less than 100 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 10 kg. If the weight of the retail pack is much less than 100 grams, one incremental sample shall consist of two or more retail packs, whereby the 100 grams are approximated as closely as possible.

C.2. **General survey of the method of sampling dried fruit, 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	≥ 15	15-30 tonnes	100	10
	< 15	—	10-100 (*)	1-10

(*) Depending on the lot weight — see Table 2 of this part of this Annex.

[1] 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.

C.3. **Method of sampling for dried fruit (lots ≥ 15 tonnes), with the exception of figs**

— 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 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.

C.4. **Method of sampling for dried fruit (lots < 15 tonnes), with the exception of 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

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

C.5. **Sampling at retail stage**

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

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 ([1]).

C.6. **Specific sampling provisions for dried fruit with the exception of dried figs traded in vacuum packs**

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).

([1]) 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.

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

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

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

D. METHOD OF SAMPLING FOR DRIED FIGS, GROUNDNUTS AND NUTS

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1 and total aflatoxins in dried figs, groundnuts and nuts.

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

The weight of the incremental sample shall be about 300 grams, unless otherwise defined in part D of Annex I.

In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

In the case of retail packs of more than 300 grams, this will result in aggregate samples weighing more than 30 kg. If the weight of a single retail pack is much more than 300 grams, then 300 grams shall be taken from each individual retail pack 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 packs of 500 grams 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 pack is less than 300 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 30 kg. If the weight of the retail pack is much less than 300 grams, one incremental sample shall consist of two or more retail packs, whereby the 300 grams are approximated as closely as possible.

D.2. **General survey of the method of sampling for dried figs, groundnuts and nuts**

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 figs	≥ 15	15-30 tonnes	100	30
	< 15	—	10-100 (*)	≤ 30
Groundnuts, pistachios, brazil nuts and other nuts	≥ 500	100 tonnes	100	30
	> 125 and < 500	5 sublots	100	30
	≥ 15 and ≤ 125	25 tonnes	100	30
	< 15	—	10-100 (*)	≤ 30

(*) Depending on the lot weight — see Table 2 of this part of this Annex.

D.3. **Method of sampling for dried figs, groundnuts and nuts (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 = 30 kg which shall be mixed and to be divided into three equal laboratory samples of 10 kg before grinding (this division into three laboratory samples is not necessary in case of groundnuts and nuts subjected to further sorting or other physical treatment and of the 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 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 dried figs, groundnuts and nuts (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)	Number of incremental samples	Aggregate sample Weight (kg) (in case of retail packings, weight of aggregate sample can diverge — see point D.1)	Number 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, groundnuts and nuts subjected to further sorting or other physical treatment and of the 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 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 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 products and compound foods**

D.5.1. *Derived products with very small particle weight, i.e. flour, peanut butter (homogeneous distribution of aflatoxin contamination)*

— Number of incremental samples: 100; for lots of under 50 tonnes 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)	Number 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 grams. In the case of lots in retail packing, the weight of the incremental sample depends on the weight of the retail packing.

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

D.5.2. *Other derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination)*

Method of sampling and acceptance as for dried figs, groundnuts and nuts ((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 provisions set out in this part of Annex I.

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 [1].

D.7. **Specific method of sampling for groundnuts, nuts, dried figs and derived products traded in vacuum packs**

D.7.1. *Pistachios, groundnuts, Brazil nuts and 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).

D.7.2. *Nuts other than pistachios and Brazil nuts*

For lots equal to or more than 15 tonnes at least 25 incremental samples resulting in a 30 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 is equal to the weight of the sampled lot (see Table 2).

[1] 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.

D.7.3. *Products derived from nuts, figs and groundnuts 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).

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

— For dried figs, groundnuts and 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 limit, 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 limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

— For dried figs, groundnuts and nuts intended for direct human consumption:

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

— rejection if one or more of the laboratory samples exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

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

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

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

E. METHOD OF SAMPLING FOR SPICES

This method of sampling is of application for the official control of the maximum levels established for aflatoxin B1 and total aflatoxins in spices.

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

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

In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

In the case of retail packs of >100 grams, this will result in aggregate samples weighing more than 10 kg. If the weight of a single retail pack is >> 100 grams, then 100 grams shall be taken from each individual retail pack 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 packs of 500 grams 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 pack is less than 100 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 10 kg. If the weight of the retail pack is much less than 100 grams, one incremental sample shall consist of two or more retail packs, whereby the 100 grams are approximated as closely as possible.

E.2. **General survey of the method of sampling for 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)
Spices	≥ 15	25 tonnes	100	10
	< 15	—	5-100 (*)	0,5-10

(*) Depending on the lot weight — see Table 2 of this part of this Annex.

E.3. **Method of sampling for 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 spices (lots < 15 tonnes)**

For lots of 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 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 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 of Annex 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. In any case, the aggregate sample shall be at least 0,5 kg [1].

E.6. **Specific method of sampling for spices traded in vacuum packs**

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 limit, taking into account the correction for recovery and measurement uncertainty;

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

F. METHOD OF SAMPLING FOR MILK AND MILK PRODUCTS; INFANT FORMULAE AND FOLLOW-ON FORMULAE, INCLUDING INFANT MILK AND FOLLOW-ON MILK

This method of sampling is of application for the official control of the maximum levels established for aflatoxin M1 in milk and milk products and infant formulae and follow-on formulae, including infant milk and follow-on milk and dietary foods (milk and milk products) for special medical purposes intended specifically for infants.

F.1. **Method of sampling for milk, milk products, infant formulae and follow-on formulae, including infant milk and follow-on milk.**

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.

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 aflatoxin M1 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 grams, 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 A.3.8 of Annex I.

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 provisions set out in this part of Annex I.

[1] 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.

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 ([1]).

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

— acceptance if the laboratory sample conforms to the maximum limit, taking into account the correction for recovery and measurement uncertainty (or decision limit — see Annex II, point 4.4.),

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty (or decision limit — see Annex II, point 4.4.).

G. METHOD FOR SAMPLING COFFEE AND COFFEE PRODUCTS

This method of sampling is of application for the official control of the maximum levels established for ochratoxin A in roasted coffee beans, ground roasted coffee and soluble coffee.

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

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

In the case of lots in retail packings, the weight of the incremental sample shall depend on the weight of the retail packing.

In the case of retail packs of more than 100 grams, this will result in aggregate samples weighing more than 10 kg. If the weight of a single retail pack is much more than 100 grams, then 100 grams shall be taken from each individual retail pack 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 packs of 500 grams 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 pack is less than 100 grams and if the difference is not very large, one retail pack shall be considered as one incremental sample, resulting in an aggregate sample of less than 10 kg. If the weight of the retail pack is much less than 100 grams, one incremental sample shall consist of two or more retail packs, whereby the 100 grams are approximated as closely as possible.

G.2. **General survey of the method of sampling for roasted coffee**

Table 1

Subdivision of lots into sublots depending on product and lot weight

Commodity	Lot weight (tones)	Weight or number of sublots	Number of incremental samples	Aggregate sample Weight (kg)
Roasted coffee beans, ground roasted coffee and soluble coffee	≥ 15	15-30 tonnes	100	10
	< 15	—	10-100 (*)	1-10

(*) Depending on the lot weight — see Table 2 of this Annex.

G.3. **Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee (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.

([1]) 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.

— 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 roasted coffee beans, ground roasted coffee, soluble coffee (lots < 15 tonnes)**

For roasted coffee beans, ground roasted coffee, soluble coffee 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 roasted coffee beans, ground roasted coffee, soluble coffee

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

G.5. **Method of sampling for roasted coffee beans, ground roasted coffee, soluble coffee traded in vacuum packs**

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 of Annex 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. In any case, the aggregate sample shall be at least 1 kg [1].

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

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

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

[1] 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 FRUIT JUICES INCLUDING GRAPE JUICE, GRAPE MUST, CIDER AND WINE

This method of sampling is of application for the official control of the maximum levels established for

— ochratoxin A in wine, grape juice and grape must and

— patulin in fruit juices, fruit nectar, spirit drinks, cider and other fermented drinks derived from apples or containing apple juice.

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 ochratoxin A and patulin 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 weight. The weight of an incremental sample shall be at least 100 grams, 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 A.3.8 of Annex I.

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 (fruit juice, spirit drinks, cider, wine)	—	3	1
Bottles/packages (fruit juice, spirit drinks, cider)	≤ 50	3	1
Bottles/packages (fruit juice, spirit drinks, cider)	50 to 500	5	1
Bottles/packages (fruit juice, spirit drinks, cider)	> 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 provisions set out in this part of Annex I ([1]).

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.

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

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

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

([1]) 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.

I. METHOD OF SAMPLING FOR SOLID APPLE PRODUCTS AND APPLE JUICE AND SOLID APPLE PRODUCTS FOR INFANTS AND YOUNG CHILDREN

This method of sampling is of application for the official control of the maximum levels established for patulin in solid apple products and apple juice and solid apple 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. In the case of liquid products the lot shall be thoroughly mixed insofar as possible by either manual or mechanical means immediately prior to sampling. In this case, a homogeneous distribution of patulin 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 shall be of similar weight. The weight of an incremental sample shall be at least 100 grams, resulting in an aggregate sample of at least 1 kg. Departure from this method shall be recorded in the record provided for under part A.3.8 of Annex I.

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 of the Annex.

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 [1].

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

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

[1] 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 limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery.

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 maximum levels established:

— for aflatoxins, ochratoxin A and *Fusarium*-toxins in baby foods and processed cereal-based foods for infants and young children,

— for aflatoxins and ochratoxin A in dietary foods for special medical purposes (other than milk and milk products) intended specifically for infants and

— for patulin in baby foods other than processed cereal based foods for infants and young children. For the control of the maximum levels established for patulin in apple juice and solid apple products for infants and young children the method of sampling as described under part I of Annex I shall apply.

J.1. **Method of sampling**

— The method of sampling for cereals and cereal products as set out in point B.4 of Annex I 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 B.4 of Annex I. 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 grams. In the case of lots in retail packing, the weight of the incremental sample shall depend on the weight of the retail packing 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 A.3.8.

— weight of aggregate sampling = 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 provisions set out in this part of Annex 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 ([1]).

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

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

— rejection if the laboratory sample exceeds the maximum limit beyond reasonable doubt taking into account the correction for recovery and measurement uncertainty.

([1]) 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.

ANNEX II

CRITERIA FOR SAMPLE PREPARATION AND FOR METHODS OF ANALYSIS USED FOR THE OFFICIAL CONTROL OF THE LEVELS OF MYCOTOXINS IN FOODSTUFFS

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 homogenized, in case the homogenisation is performed by the laboratory.

For the analysis of aflatoxins, daylight should 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**

The limits fixed for aflatoxins in Regulation (EC) No 466/2001 apply to the edible part. The level of aflatoxins in the edible part can be determined by:

— samples of nuts 'in shell' can be shelled and the level of aflatoxins is determined in the edible part.

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

Approximately 100 whole nuts 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, 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 limit, the proportion shall be determined for that sample using the approximately 100 nuts that have been set aside.

2. TREATMENT OF THE SAMPLE AS RECEIVED IN THE LABORATORY

Each laboratory sample shall be finely grinded and mixed thoroughly using a process that has been demonstrated to achieve complete homogenisation.

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, trade (defence) and reference (referee) purposes shall be taken from the homogenised material 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. **Definitions**

A number of the most commonly used definitions that the laboratory shall be required to use are the following:

r = Repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions, namely same sample, same operator, same apparatus, same laboratory, and short interval of time may be expected to lie within a specific probability (typically 95 %) and hence $r = 2{,}8 \times s_r$.

s_r = Standard deviation, calculated from results generated under repeatability conditions.

RSD_r = Relative standard deviation, calculated from results generated under repeatability conditions $[(s_r / \bar{x}) \times 100]$.

R = Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions, namely on identical material obtained by operators in different laboratories, using the standardised test method may be expected to lie within a certain probability (typically 95 %); $R = 2{,}8 \times s_R$.

s_R = Standard deviation, calculated from results under reproducibility conditions.

RSD_R = Relative standard deviation calculated from results generated under reproducibility conditions $[(s_R / \bar{x}) \times 100]$.

4.2. **General requirements**

Methods of analysis used for food control purposes shall comply with the provisions of items 1 and 2 of Annex III to Regulation (EC) No 882/2004.

4.3. **Specific requirements**

4.3.1. *Performance criteria*

Where no specific methods for the determination of mycotoxin levels in foodstuffs are required by Community legislation, laboratories may select any method provided the selected method meets the following criteria:

(a) Performance criteria for aflatoxins

Criterion	Concentration Range	Recommended Value	Maximum permitted Value
Blanks	All	Negligible	—
Recovery — Aflatoxin M1	0,01-0,05 µg/kg	60 to 120 %	
	> 0,05 µg/kg	70 to 110 %	
Recovery — Aflatoxins B_1, B_2, G_1, G_2	< 1,0 µg/kg	50 to 120 %	
	1-10 µg/kg	70 to 110 %	
	> 10 µg/kg	80 to 110 %	
Precision RSD_R	All	As derived from Horwitz Equation	2 × value derived from Horwitz Equation
Precision RSD_r may be calculated as 0,66 times Precision RSD_R at the concentration of interest.			

Note:

— Values to apply to both B_1 and sum of $B_1 + B_2 + G_1 + G_2$.
— If sum of individual aflatoxins $B_1 + B_2 + G_1 + G_2$ are to be reported, then response of each to the analytical system must be either known or equivalent.

(b) Performance criteria for ochratoxin A

Level µg/kg	Ochratoxin A		
	RSD_r %	RSD_R %	Recovery %
< 1	≤ 40	≤ 60	50 to 120
1-10	≤ 20	≤ 30	70 to 110

(c) Performance criteria for patulin

Level µg/kg	Patulin		
	RSD_r %	RSD_R %	Recovery %
< 20	≤ 30	≤ 40	50 to 120
20-50	≤ 20	≤ 30	70 to 105
> 50	≤ 15	≤ 25	75 to 105

(d) Performance criteria for deoxynivalenol

Level µg/kg	Deoxynivalenol		
	RSD_r %	RSD_R %	Recovery %
> 100-≤ 500	≤ 20	≤ 40	60 to 110
> 500	≤ 20	≤ 40	70 to 120

(e) Performance criteria for zearalenone

Level µg/kg	Zearalenone		
	RSD_r %	RSD_R %	Recovery %
≤ 50	≤ 40	≤ 50	60 to 120
> 50	≤ 25	≤ 40	70 to 120

(f) Performance criteria for Fumonisin B_1 and B_2

Level µg/kg	Fumonisin B_1 or B_2		
	RSD_r %	RSD_R %	Recovery %
≤ 500	≤ 30	≤ 60	60 to 120
> 500	≤ 20	≤ 30	70 to 110

(g) Performance criteria for T-2 and HT-2 toxin

Level µg/kg	T-2 toxin		
	RSD_r %	RSD_R %	Recovery %
50-250	≤ 40	≤ 60	60 to 130
> 250	≤ 30	≤ 50	60 to 130

Level µg/kg	HT-2 toxin		
	RSD_r %	RSD_R %	Recovery %
100-200	≤ 40	≤ 60	60 to 130
> 200	≤ 30	≤ 50	60 to 130

(h) Notes to the performance criteria for the mycotoxins

— The detection limits of the methods used are not stated as the precision values are given at the concentrations of interest

— The precision values are calculated from the Horwitz equation, i.e.:

$$RSD_R = 2^{(1-0,5\log C)}$$

where:

— RSD_R is the relative standard deviation calculated from results generated under reproducibility conditions $[(s_R/\overline{x}) \times 100]$

— C is the concentration ratio (i.e. 1 = 100g/100g, 0,001 = 1 000 mg/kg)

This is a generalised precision equation which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

4.3.2. *'Fitness-for-purpose' approach*

In the case where there are a limited number of fully validated methods of analysis, alternatively, a 'fitness-for-purpose' approach, defining a single parameter, a fitness function, to evaluate the acceptability of methods of analysis may be used. A fitness function is an uncertainty function that specifies maximum levels of uncertainty regarded as fit for purpose.

Given the limited number of methods of analysis, fully validated by a collaborative trial, especially for the determination of T-2 and HT-2 toxin, the uncertainty function approach, specifying the maximum acceptable uncertainty, may also be used to assess the suitability (the 'fitness-for-purpose') of the method of analysis to be used by the laboratory. The laboratory may use a method which produces results within the maximum standard uncertainty. The maximum standard uncertainty may be calculated using the following formula:

$$Uf = \sqrt{(\mathrm{LOD}/2)^2 + (\alpha \times \mathrm{C})^2}$$

where:

— *Uf* is the maximum standard uncertainty (µg/kg)

— LOD is the limit of detection of the method (µg/kg)

— α is a constant, numeric factor to be used depending on the value of C. The values to be used are set out in the table hereafter

— C is the concentration of interest (μg/kg).

If the analytical method provides results with uncertainty measurements less than the maximum standard uncertainty the method shall be considered being equally suitable to one which meets the performance criteria given in point 4.3.1.

Table

Numeric values to be used for α as constant in formula set out in this point, depending on the concentration of interest

C (μg/kg)	α
≤ 50	0,2
51-500	0,18
501-1 000	0,15
1 001-10 000	0,12
> 10 000	0,1

4.4. **Estimation of measurement uncertainty, recovery calculation and reporting of results** [1]

The analytical result must be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported. The analytical result corrected for recovery shall be used for controlling compliance.

The analytical result must be reported as x +/– U whereby x is the analytical result and U is the expanded measurement uncertainty.

U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

For food of animal origin, the taking into account of the measurement uncertainty can also be done by establishing the decision limit (CCα) in accordance with Commission Decision 2002/657/EC [2] (point 3.1.2.5. of the Annex — the case of substances with established permitted limit).

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 defence or referee purposes, the national rules apply.

4.5. **Laboratory quality standards**

Laboratory must comply with the provisions of Article 12 of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [3].

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[1] 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' — http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

[2] OJ L 221, 17.8.2002, p. 8. Decision as last amended by Decision 2004/25/EC (OJ L 6, 10.1.2004, p. 38).

[3] See also the transitional arrangements provided for in article 18 of Commission Regulation (EC) No 2076/2005 of 5 December 2005 laying down transitional arrangements for the implementation of Regulation (EC) No 853/2004, 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and 854/2004 (OJ L 338, 22.12.2005, p. 83).