Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EC) No 401/2006. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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)

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.

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(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,

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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EC) No 401/2006. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I[8]

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.

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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.

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.

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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

[*F1 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 and cereal products	> 300 and < 1 500	3 sublots	100	10
	≥ 50 and ≤ 300	100 tonnes	100	10
	< 50	—	3-100[a]	1-10

a Depending on the lot weight — see Table 2.**]**

Textual Amendments

F1 Substituted by Commission Regulation (EU) No 519/2014 of 16 May 2014 amending Regulation (EC) No 401/2006 as regards methods of sampling of large lots, spices and food supplements, performance criteria for T-2, HT-2 toxin and citrinin and screening methods of analysis (Text with EEA relevance).

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. **[**[F2]For lots > 500 tonnes, the number of incremental samples is provided for in part L.2 of Annex I.**]**

— Each sublot shall be sampled separately.

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