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

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food [1], and in particular Article 2 thereof,

Having regard to Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption [2], and in particular Article 1 thereof,

Whereas:

(1) Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs [3], as last amended by Regulation (EC) No 472/2002 [4], fixes maximum limits for ochratoxin A in certain foodstuffs.

(2) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs [5] introduces a system of quality standards for laboratories entrusted by the Member States with the official control of foodstuffs.

(3) Sampling plays a crucial part in the precision of the determination of the levels of ochratoxin A, which are very heterogeneously distributed in a lot.

(4) It seems necessary to fix general criteria, which the method of analysis has to comply with in order to ensure that laboratories, in charge of the control, use methods of analysis with comparable levels of performance.

(5) The provisions for the sampling and methods of analysis have been drawn up on the basis of present knowledge and they may be adapted to take account of advances in scientific and technological knowledge.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Member States shall take all measures necessary to ensure that the sampling for the official control of the levels of ochratoxin A in foodstuffs is carried out in accordance with the methods described in Annex I to this Directive.

Article 2

The Member States shall take all measures necessary to ensure that sample preparation and methods of analyses used for the official control of the levels of ochratoxin A in foodstuffs comply with the criteria described in Annex II to this Directive.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 28 February 2003 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 13 March 2002.

For the Commission

David BYRNE

Member of the Commission

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[1] OJ L 37, 13.2.1993, p. 1.
[2] OJ L 372, 31.12.1985, p. 50.
[3] OJ L 77, 16.3.2001, p. 1.
[4] See page 18 of this Official Journal.
[5] OJ L 290, 24.11.1993, p. 14.

ANNEX I

METHODS OF SAMPLING FOR OFFICIAL CONTROL OF THE LEVELS OF OCHRATOXIN A IN CERTAIN FOODSTUFFS

1. Purpose and scope

Samples intended for official checking of the levels of ochratoxin A content in foodstuffs shall be taken according to the methods described below. 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.

2. Definitions

Lot:	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
Sublot:	designated part of a lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable
Incremental sample:	a quantity of material taken from a single place in the lot or sublot
Aggregate sample:	the combined total of all the incremental samples taken from the lot or sublot.

3. General provisions

3.1. *Personnel*

Sampling shall be performed by an authorised person as specified by the Member States.

3.2. *Material to be sampled*

Each lot which is to be examined must be sampled separately. In accordance with the specific provisions of this Annex, large lots should be subdivided into sublots to be sampled separately.

3.3. *Precautions to be taken*

In the course of sampling and preparation of the samples precautions must be taken to avoid any changes which would affect the ochratoxin A content, adversely affect the analytical determination or make the aggregate samples unrepresentative.

3.4. *Incremental samples*

As far as possible incremental samples should be taken at various places distributed throughout the lot or sublot. Departure from this procedure must be recorded in the record.

3.5. *Preparation of the aggregate sample*

The aggregate sample is made up by uniting the incremental samples.

3.6. *Replicate samples*

The replicate samples for enforcement, trade (defence) and referee purposes are to be taken from the homogenised sample, unless this conflicts with Member States' rules on sampling.

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.

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 Member State's regulations.

A record must 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.

4. **Specific provisions**

4.1. *Different types of lots*

Food commodities may be traded in bulk, containers, or individual packings (sacks, bags, retail packings, etc.). The sampling procedure can be applied to all the different forms in which the commodities are put on the market.

Without prejudice to the specific provisions as laid down in points 4.3, 4.4 and 4.5 of this Annex, the following formula can be used as a guide for the sampling of lots traded in individual packings (sacks, bags, retail packings, etc.):

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

— Weight: in kg

— Sampling Frequency (SF): every nth sack or bag from which an incremental sample must be taken (decimal figures should be rounded to the nearest whole number).

4.2. *Weight of the aggregate sample*

The weight of the incremental sample should be about 100 grams, unless otherwise defined in this Annex. In the case of lots in retail packings, the weight of the incremental sample depends on the weight of the retail packing.

4.3. *General survey of the sampling procedure for cereals and dried vine fruit*

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	—	10-100 (1)	1-10
Dried vine fruit (currants, raisins and sultanas)	≥ 15	15-30 tonnes	100	10
	< 15	—	10-100 (2)	1-10

(1) Depending on the lot weight — see Table 2 of this Annex.
(2) Depending on the lot weight — see Table 3 of this Annex.

4.4. *Sampling procedure for cereals and cereal products (lots ≥ 50 tonnes) and dried vine fruit (lots ≥ 15 tonnes)*

— On condition that the sublot can be separated physically, each lot must 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 must be sampled separately.

— Number of incremental samples: 100. In the case of lots of cereals under 50 tonnes and lots of dried vine fruit under 15 tonnes, see point 4.5. 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.

4.5. *Sampling provisions for cereals and cereal products (lots < 50 tonnes) and for dried vine fruit (lots < 15 tonnes)*

For cereal lots under 50 tonnes and for dried vine fruit lots under 15 tonnes, the sampling plan has to 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 cereals

Lot weight (tonnes)	Number of incremental samples
≤ 1	10
> 1 - ≤ 3	20
> 3 - ≤ 10	40
> 10 - ≤ 20	60
> 20 - ≤ 50	100

Table 3: Number of incremental samples to be taken depending on the weight of the lot of dried vine fruit

Lot weight (tonnes)	Number of incremental samples
≤ 0,1	10
> 0,1 - ≤ 0,2	15
> 0,2 - ≤ 0,5	20
> 0,5 - ≤ 1,0	30
> 1,0 - ≤ 2,0	40
> 2,0 - ≤ 5,0	60
> 5,0 - ≤ 10,0	80
> 10,0 - ≤ 15,0	100

4.6. *Sampling at retail stage*

Sampling of foodstuffs at the retail stage should be done where possible in accordance with the above sampling provisions. Where this is not possible, other effective sampling procedures at retail stage can be used provided that they ensure sufficient representativeness for the sampled lot.

5. **Acceptance of a lot or sublot**

— Acceptance if the aggregate sample conforms to the maximum limit.
— Rejection if the aggregate sample exceeds the maximum limit.

ANNEX II

SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICIAL CHECKING OF THE LEVELS OF OCHRATOXIN A IN CERTAIN FOODSTUFFS

1. **Precautions**

As the distribution of ochratoxin A is non-homogeneous, samples should be prepared — and especially homogenised — with extreme care.

All the material received by the laboratory is to be used for the preparation of test material.

2. **Treatment of the sample as received in the laboratory**

Finely grind and mix thoroughly the complete aggregate sample using a process that has been demonstrated to achieve complete homogenisation.

3. **Subdivision of samples for enforcement and defence purposes**

The replicate samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised material unless this conflicts with Member States' rules on sampling.

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 will be required to use are given below:

The most commonly quoted precision parameters are repeatability and reproducibility.

r= Repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i.e. 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 $r = 2{,}8 \times s_r$

$s_r = 1$ Standard deviation, calculated from results generated under repeatability conditions

RSD_r = Relative standard deviation, calculated from results generated under repeatability conditions $[(s_r/\bar{x}) \times 100]$ where $\bar{x}$ is the average of results over all laboratories and samples

R = Reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i.e. 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 must comply with the provisions of items 1 and 2 of the Annex to Directive 85/591/EEC concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption.

4.3. *Specific requirements*

Where no specific methods for the determination of ochratoxin A levels in foodstuffs are prescribed at Community level, laboratories may select any method provided the selected method meets the following criteria:

Performance characteristics 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

— 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:

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

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 = 100 g/100 g, 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.

4.4. *Recovery calculation*

The analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported.

4.5. *Laboratory quality standards*

Laboratories must comply with Directive 93/99/EEC on the subject of additional measures concerning the official control of foodstuffs.