COMMISSION DIRECTIVE 2004/43/EC

of 13 April 2004

amending Directive 98/53/EC and Directive 2002/26/EC as regards sampling methods and methods of analysis for the official control of the levels of aflatoxin and ochratoxin A in food for infants and young children

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 [1], 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 [2] fixes maximum limits for aflatoxin B1, aflatoxin M1 and ochratoxin A in food for infants and young children.

(2) Sampling plays a crucial part in the precision of the determination of the levels of aflatoxins and ochratoxin A. 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 of certain contaminants in foodstuffs [3] and Commission Directive 2002/26/EC of 13 March 2002 laying down the sampling methods and methods of analysis for the official control of the levels of ochratoxin A in foodstuffs [4] should be amended to include provisions related to food for infants and young children.

(3) It is of major importance that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach across the European Union. These interpretation rules are of application for the analytical result obtained on the sample for official control. In case of analysis for defence or referee purposes, the national rules apply.

(4) Directives 98/53/EC and 2002/26/EC should therefore be amended accordingly.

(5) 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

Annexes I and II to Directive 98/53/EC are amended as set out in Annex I to this Directive.

Article 2

Annexes I and II to Directive 2002/26/EC are amended as set out in Annex II to this Directive.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive 12 months after its entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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.

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 4

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

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[1] OJ L 372, 31.12.1985, p. 50. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
[2] OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 455/2004 (OJ L 74, 12.3.2004, p. 11).
[3] OJ L 201, 17.7.1998, p. 93. Directive as last amended by Directive 2003/121/EC (OJ L 332, 19.12.2003, p. 38).
[4] OJ L 75, 16.3.2002, p. 38.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 13 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

Annexes I and II to Directive 98/53/EC are amended as follows:

1. In Annex I to Directive 98/53/EC the following point 5.7 is inserted after point 5.6:

'5.7. *Foods intended for infants and young children*

5.7.1. Sampling procedure

The sampling procedure as mentioned for milk and derived products as well as for compound food in points 5.4, 5.5 and 5.6 applies.

5.7.2. Acceptance of a lot

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

— Rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt, taking into account the measurement uncertainty and correction for recovery.'

2. In Annex II, point 2 shall read as follows

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

Finely grind and thoroughly mix each laboratory sample 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 shall be determined on a part of the homogenised sample, using a procedure that has been demonstrated to determine accurately the dry matter content.'

ANNEX II

Annexes I and II to Directive 2002/26/EC are amended as follows:

1. Annex I is amended as follows:

(a) point 4.6 shall read as follows:

'4.6. *Sampling procedure for foods intended for infants and young children*

The sampling procedure as mentioned for cereals and cereal products in point 4.5 of this Annex applies. This means that 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, in accordance with Table 2 at point 4.5.

— The weight of the incremental sample should be about 100 grams. In case of lots in retail packing, the weight of the incremental sample depends on the weight of the retail packing.

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

(b) the following point 4.7 is inserted:

'4.7. *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.'

(c) point 5 shall read as follows:

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

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

— Rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt, taking into account the measurement uncertainty and correction for recovery.'

2. Annex II is amended as follows:

(a) point 2 shall read as follows

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

Finely grind and thoroughly mix each laboratory sample 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 shall be determined on a part of the homogenised sample, using a procedure that has been demonstrated to determine accurately the dry matter content.'

(b) point 4.4 shall read as follows:

'4.4. *Recovery calculation and reporting of results*

The analytical result is to 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 checking compliance (see Annex I, point 5)

The analytical result has to be reported as x +/- U, whereby x is the analytical result and U is the expanded measurement uncertainty.

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