

COMMISSION DIRECTIVE 2003/121/EC
of 15 December 2003
amending Directive 98/53/EC laying down the sampling methods and the methods of analysis for
the official control of the levels for certain contaminants 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 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⁾, as last amended by Regulation (EC) No 1425/2003 ⁽³⁾, fixes specific maximum limits for maize to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs.
- (2) Sampling plays a crucial part in the precision of the determination of the levels of aflatoxins, which are very heterogeneously distributed in a lot. Commission Directive 98/53/EC ⁽⁴⁾, as amended by Directive 2002/27/EC ⁽⁵⁾, should be amended to include specific provisions for maize to be subjected to sorting, or other physical treatment, before human consumption or use as an ingredient in foodstuffs.
- (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 Union. These interpretation rules should be 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) Directive 98/53/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

Annex I to Directive 98/53/EC is amended as set out in Annex I to this Directive.

Annex II to Directive 98/53/EC is amended as set out in Annex II to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 October 2004 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 governed by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 15 December 2003.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 372, 31.12.1985, p. 50.

⁽²⁾ OJ L 77, 16.3.2001, p. 1.

⁽³⁾ OJ L 203, 12.8.2003, p. 1.

⁽⁴⁾ OJ L 201, 17.7.1998, p. 93.

⁽⁵⁾ OJ L 75, 16.3.2002, p. 44.

ANNEX I

Annex I to Directive 98/53/EC is amended as follows:

1. in point 5.2.1, the fourth indent is replaced by the following:

— weight of the aggregate sample = 30 kg which has to be mixed and to be divided into three equal subsamples of 10 kg before grinding (this division into three subsamples is not necessary in the case of groundnuts, nuts, dried fruit and maize intended for further sorting or other physical treatment, however, this will depend upon the availability of equipment which is able to homogenise a 30 kg sample). In cases where the aggregate sample weights are under 10 kg, the aggregate sample must not be divided into three subsamples. In the case of spices the aggregate sample weighs not more than 10 kg and therefore no division in subsamples is necessary.;

2. point 5.2.2 is replaced by the following:

‘5.2.2. Acceptance of a lot or subplot

- For groundnuts, nuts, dried fruit and maize subjected to a sorting or other physical treatment and spices:
 - acceptance if the aggregate sample or the average of the subsamples conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,
 - rejection if the aggregate sample or the average of the subsamples exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery.
- For groundnuts, nuts, dried fruit and cereals intended for direct human consumption and cereals, with the exception of maize, to be subjected to a sorting or other physical treatment:
 - acceptance if none of the subsamples exceeds the maximum limit, taking into account the measurement uncertainty and correction for recovery,
 - rejection if one or more of the subsamples exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery,
 - where the aggregate sample is under 10 kg:
 - 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 analytical uncertainty and correction for recovery.;

3. point 5.4.2 is replaced by the following:

‘5.4.2. Acceptance of a lot or subplot

- 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.;

4. point 5.5.1.2 is replaced by the following:

‘5.5.1.2. Acceptance of a lot or subplot

- 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.;

5. point 5.5.2.3 is replaced by the following:

‘5.5.2.3. Acceptance of a lot or subplot

- 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.’
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ANNEX II

In Annex II to Directive 98/53/EC, point 4.4 is replaced by the following:

'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 is used for checking compliance (see Annex I, points 5.2.2, 5.3.2, 5.4.2, 5.5.1.2 and 5.5.2.3).

The analytical result has to be reported as $x \pm U$ whereby x is the analytical result and U is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.'
