COMMISSION DIRECTIVE 2005/4/EC

of 19 January 2005

amending Directive 2001/22/EC laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD 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 Directive 2001/22/EC of 8 March 2001 lays down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs [2].

(2) It is necessary to include updated standard information for contaminants in food, in particular to take into account the measurement uncertainty for analysis.

(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.

(4) Directive 2001/22/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 2001/22/EC is amended as set out in Annex I to this Directive.

Annex II to Directive 2001/22/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 the provisions of this Directive within twelve months after 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 shall 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 main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

This Directive is addressed to the Member States.

Done at Brussels, 19 January 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

[1] OJ L 372, 31.12.1985, p. 50.
[2] OJ L 77, 16.3.2001, p. 14.

ANNEX I

In Annex I to Directive 2001/22/EC, point 5 is replaced by the following:

'5. COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION

The control laboratory shall analyse the laboratory sample for enforcement at least in two independent analyses, and calculate the mean of the results.

The lot is accepted if the mean does not exceed the respective maximum level as laid down in Regulation (EC) No 466/2001, taking into account the expanded measurement uncertainty and correction for recovery (1).

The lot is rejected if the mean exceeds the respective maximum level beyond reasonable doubt, taking into account the expanded measurement uncertainty and correction for recovery.

The present 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.'

ANNEX II

Annex II to Directive 2001/22/EC is amended as follows:

1. In point 3. 'Method of analysis to be used by the laboratory and laboratory control requirements', the following point 3.3.3. is inserted after Table 4:

'3.3.3. *Performance Criteria — Uncertainty Function Approach*

However, an uncertainty approach may also be used to assess the suitability of the method of analysis to be used by the laboratory. The laboratory may use a method which will produce results within a maximum standard uncertainty. The maximum standard uncertainty can be calculated using the following formula:

$$Uf = \sqrt{\left[\left(LOD/2\right)^2 + \left(\alpha C\right)^2\right]}$$

where:

Uf is the maximum standard uncertainty

LOD is the limit of detection of the method

C is the concentration of interest

α is a numeric factor to be used depending on the value of C. The values to be used are given in the table below:

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

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

If an analytical method provides results with uncertainty measurements less than the maximum standard uncertainty the method will be equally suitable to one which meets the performance characteristics given above.'

2. Point 3.4. is replaced by the following:

'3.4. **Estimation of the analytical trueness, recovery calculations and reporting of results**

Wherever possible the trueness of analysis shall be estimated by including suitable certified reference materials in the analysis.

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 analyst should note the "European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation"(1).

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

REFERENCES

(1) European Commission Report on the relationship between analytical results, the measurement of uncertainty, recovery factors and the provisions in EU food legislation, 2004

(http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/sampling_en.htm).'