

**COMMISSION DIRECTIVE 2005/31/EC****of 29 April 2005****amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with 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 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC <sup>(1)</sup>, and in particular Article 5(2) thereof,

Whereas:

- (1) Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs <sup>(2)</sup> is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004. It concerns the possible migration of lead and cadmium from ceramic articles which, in their finished state, are intended to come into contact with foodstuffs, or which are in contact with foodstuffs, and are intended for that purpose.
- (2) Article 16 of Regulation (EC) No 1935/2004 provides that the specific measures are to require that materials and articles covered by those measures are accompanied by a written declaration stating that they comply with the rules applicable to them.
- (3) That requirement has not yet been set out in Directive 84/500/EEC. There is a need to lay down that obligation for all ceramic articles which are not yet in contact with foodstuffs to clearly distinguish them from decorative articles.
- (4) The national competent authorities should have access to documents demonstrating that the ceramic articles comply with the migration limits for lead and cadmium. Therefore, the manufacturer or importer into the Community should make information concerning analysis carried out available to them on request.
- (5) Directive 84/500/EEC lays down a method for the analysis of lead and cadmium. Technological progress has been made in that area and the analytical method set out in that Directive is only one amongst several

possible methods. This Directive should take technological progress into account and establish a set of performance criteria that the analytical method must comply with having regard to Commission Directive 2001/22/EC of 8 March 2001 laying down the sampling methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs <sup>(3)</sup>.

- (6) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of ceramic articles intended to come into contact with foodstuffs to lay down rules for a correct enforcement of Directive 84/500/EEC. This Directive does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.
- (7) Directive 84/500/EEC should therefore be amended accordingly.
- (8) 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*

Directive 84/500/EEC is amended as follows:

1. The following Article 2a is inserted:

*'Article 2a*

1. At the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council (\*).

That declaration shall be issued by the manufacturer or by a seller established within the Community and shall contain the information laid down in Annex III to this Directive.

<sup>(1)</sup> OJ L 338, 13.11.2004, p. 4.

<sup>(2)</sup> OJ L 277, 20.10.1984, p. 12.

<sup>(3)</sup> OJ L 77, 16.3.2001, p. 14. Directive as last amended by Directive 2005/4/EC (OJ L 19, 21.1.2005, p. 50).

2. Appropriate documentation to demonstrate that the ceramic articles comply with the migration limits for lead and cadmium set out in Article 2 shall be made available by the manufacturer or the importer into the Community to the national competent authorities on request. That documentation shall contain the results of the analysis carried out, the test conditions and the name and the address of the laboratory that performed the testing.

(\*) OJ L 338, 13.11.2004, p. 4.'

2. Annex II is replaced by the text in Annex I to this Directive.
3. A new Annex III, the text of which is set out in Annex II to this Directive, is added.

#### *Article 2*

1. Member States shall adopt and publish, by 20 May 2006 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions in such a way as to:

- (a) permit the trade in and use of ceramic articles complying with this Directive, from 20 May 2006;

- (b) prohibit the manufacture and importation into the Community of ceramic articles which do not comply with this Directive, from 20 May 2007.

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 text 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 its publication in the *Official Journal of the European Union*.

#### *Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 29 April 2005.

*For the Commission*  
Markos KYPRIANOU  
*Member of the Commission*

## ANNEX I

## ANNEX II

**METHODS OF ANALYSIS FOR DETERMINATION OF THE MIGRATION OF LEAD AND CADMIUM****1. Object and field of application**

The method allows the specific migration of lead and/or cadmium to be determined.

**2. Principle**

The determination of the specific migration of lead and/or cadmium is carried out by an instrumental method of analysis that fulfils the performance criteria of point 4.

**3. Reagents**

— All reagents must be of analytical quality, unless otherwise specified.

— Where reference is made to water, it shall always mean distilled water or water of equivalent quality.

**3.1. 4 % (v/v) acetic acid, in aqueous solution**

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

**3.2. Stock solutions**

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution, as referred to in point 3.1.

**4. Performance criteria of the instrumental method of analysis**

4.1. The detection limit for lead and cadmium must be equal to or lower than:

— 0,1 mg/litre for lead,

— 0,01 mg/litre for cadmium.

The detection limit is defined as the concentration of the element in the 4 % acetic acid solution, as referred to in point 3.1, which gives a signal equal to twice the background noise of the instrument.

4.2. The limit of quantification for lead and cadmium must be equal to or lower than:

— 0,2 mg/litre for lead,

— 0,02 mg/litre for cadmium.

4.3. *Recovery.* The recovery of lead and cadmium added to the 4 % acetic acid solution, as referred to in point 3.1, must lie within 80-120 % of the added amount.

4.4. *Specificity.* The instrumental method of analysis used must be free from matrix and spectral interferences.

**5. Method****5.1. Preparation of the sample**

The sample must be clean and free from grease or other matter likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tap-water and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested is not to be handled after it has been cleaned.

5.2. *Determination of lead and/or cadmium*

- The sample thus prepared is tested under the conditions laid down in Annex I.
- Before taking the test solution for determining lead and/or cadmium, homogenise the content of the sample by an appropriate method, which avoids any loss of solution or abrasion of the surface being tested.
- Carry out a blank test on the reagent used for each series of determinations.
- Carry out determinations for lead and/or cadmium under appropriate conditions.'

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ANNEX II

'ANNEX III

**DECLARATION OF COMPLIANCE**

The written declaration referred to in Article 2a(1) shall contain the following information:

1. the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the Community;
2. the identity of the ceramic article;
3. the date of the declaration;
4. the confirmation that the ceramic article meets relevant requirements in this Directive and Regulation (EC) No 1935/2004.

The written declaration shall permit an easy identification of the goods for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration of lead and cadmium.'

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