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COUNCIL DIRECTIVE

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

(84/500/EEC)

(OJ L 277, 20.10.1984, p. 12)

Amended by:

	Official Journal		
	No	page	date
► <u>M1</u> Commission Directive 2005/31/EC of 29 April 2005	L 110	36	30.4.2005



COUNCIL DIRECTIVE
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**

(84/500/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs ⁽¹⁾, and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽²⁾,

Having regard to the opinion of the Economic and Social Committee ⁽³⁾,

Whereas Article 2 of Directive 76/893/EEC provides that materials and articles must not transfer their constituents to foodstuffs in quantities which could endanger human health;

Whereas Article 3 of the same Directive provides that the Council, under the procedure provided for in Article 100 of the Treaty, shall adopt by means of Directives special provisions applicable to certain groups of materials and articles (specific Directives);

Whereas in most of the Member States ceramic articles intended to come into contact with foodstuffs are subject to mandatory provisions for protecting human health which lay down limits for the extractable quantities of lead and cadmium;

Whereas these provisions vary from one Member State to another, thus creating obstacles to the establishment and functioning of the common market;

Whereas these obstacles may be eliminated if the placing of ceramic articles on the Community market is made subject to uniform rules; whereas it is therefore necessary to harmonize the limit values and the test and analysis methods for such articles;

Whereas the appropriate instrument for attaining this objective is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC the general provisions of which also become applicable in this particular case;

Whereas the adaptation to technical progress of certain checking and analysis measures provided for in the Directive is an implementing measure the adoption of which should be entrusted to the Commission in order to simplify and expedite the procedure;

Whereas, in all cases where the Council grants the Commission powers to implement provisions concerning materials and articles intended to come into contact with foodstuffs, a procedure should be established to ensure close cooperation between the Member States and the Commission in the Standing Committee for Foodstuffs set up by the Council Decision of 13 November 1969,

⁽¹⁾ OJ No L 340, 9. 12. 1976, p. 19.

⁽²⁾ OJ No C 95, 28. 4. 1975, p. 41.

⁽³⁾ OJ No C 263, 17. 11. 1975, p. 66.



HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive is a specific Directive within the meaning of Article 3 of Directive 76/893/EEC.
2. This Directive 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.
3. 'Ceramic articles' means articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.

Article 2

1. The quantities of lead and cadmium transferred from ceramic articles shall not exceed the limits laid down below.
2. The quantities of lead and cadmium transferred from ceramic articles shall be determined by means of a test, the conditions of which are specified in Annex I, using the method of analysis described in Annex II.
3. Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead and/or cadmium limit which may not be exceeded (mg/dm² or mg/litre) shall be that which applies to the vessel alone.

The vessel alone and the inner surface of the lid shall be tested separately and under the same conditions.

The sum of the two lead and/or cadmium extraction levels thus obtained shall be related as appropriate to the surface area or the volume of the vessel alone.
4. A ceramic article shall be recognized as satisfying the requirements of this Directive if the quantities of lead and/or cadmium extracted during the test carried out under the conditions laid down in Annexes I and II do not exceed the following limits:

	<i>Pb</i>	<i>Cd</i>
— Category 1: Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm	0,8 mg/dm ²	0,07 mg/dm ²
— Category 2: All other articles which can be filled	4,0 mg/l	0,3 mg/l
— Category 3: Cooking ware; packaging and storage vessels having a capacity of more than three litres	1,5 mg/l	0,1 mg/l

5. However, where a ceramic article does not exceed the above quantities by more than 50 %, that article shall nevertheless be recognized as satisfying the requirements of this Directive if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in Annexes I and II and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50 %.

▼ **M1***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 ⁽¹⁾.

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.

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.

▼ **B***Article 3*

The amendments to be made to the Annexes in the light of developments in scientific and technical knowledge, with the exception of sections 1 and 2 of Annex I, shall be adopted in accordance with the procedure laid down in Article 10 of Directive 76/893/EEC.

Article 4

1. Within three years of notification ⁽²⁾ of this Directive, the Council shall determine in accordance with the procedure laid down in Article 100 of the Treaty:

- (a) the limitations to be imposed on those areas of ceramic articles with which the mouth is intended to come into contact;
- (b) the methods for checking that the limitations provided for in (a) are complied with.

2. Within the same period, the Commission shall, on the basis of toxicological and technological data, re-examine the limits laid down in Article 2, with a view to reducing them, and the lighting conditions for the test specified in Annex I, and shall, if appropriate, submit to the Council proposals for amendments to the Directive.

Article 5

1. The Member States shall, if necessary, amend their national laws to comply with this Directive so that:

- three years after the notification of this Directive, trade in ceramic articles which comply with its provisions is permitted,
- five years after the notification of this Directive, the plating on the market of ceramic articles which do not comply with its provisions is prohibited.

They shall forthwith inform the Commission of any such amendment.

2. Without prejudice to paragraph 1, Member States may prohibit or continue to prohibit the manufacture of ceramic articles which do not comply with this Directive.

Article 6

This Directive is addressed to the Member States.

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.

⁽²⁾ This Directive was notified to the Member States on 17 October 1984.



ANNEX I

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM**1. Test liquid ('simulant')**

4 % (v/v) acetic acid, in a freshly prepared aqueous solution.

2. Test conditions

- 2.1. Carry out the test at a temperature of 22 ± 2 °C for a duration of $24 \pm 0,5$ hours.
- 2.2. When the migration of lead is to be determined, cover the sample by an appropriate means of protection and expose it to the usual lighting conditions in a laboratory.

When the migration of cadmium or of lead and cadmium is to be determined, cover the sample so as to ensure that the surface to be tested is kept in total darkness.

3. Filling**3.1. Samples which can be filled**

Fill the article with a 4 % (v/v) acetic acid solution to a level no more than 1 mm from the overflow point; the distance is measured from the upper rim of the sample.

Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6 mm measured along the sloping rim.

3.2. Samples which cannot be filled

The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4 % (v/v) acetic acid solution. The sample is then immersed in a recipient containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with foodstuffs is completely covered by the test liquid.

4. Determination of the surface area

The surface area of the articles in category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in section 3 above.

▼ **M1***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.

▼ M1

- 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.

▼M1*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.