

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with food (limitation of extractable quantities of lead and cadmium)

(Submitted to the Council by the Commission on 31 December 1974)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament;

Having regard to the Opinion of the Economic and Social Committee;

Whereas the Council Directive of ... on the approximation of the laws of the Member States relating to substances intended to come into contact with food provides, in its Article 4, that specific Directives will state the special provisions applicable to certain groups of substances and articles;

Whereas in most of the Member States, ceramic articles intended to come into contact with food are subject to mandatory provisions, aimed at protecting human health, relating to the limitation of the extractable quantities of lead and cadmium;

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

Whereas these obstacles may be eliminated if the placing of ceramic articles on the market on a Community-wide basis is made subject to uniform rules; whereas it is therefore necessary to harmonize the limit values, the test and analysis methods and the wording shown on the labels and markings or the documents which accompany ceramic articles when they are marketed;

Whereas the recent demonstration of the effect of luminescent radiation on the extraction of cadmium requires the development of a specific test method and it will consequently be necessary to provide, at a later stage, for revision of both the proposed method and the limits in order to take account of the results of the studies in progress;

Whereas the same applies to the effect of temperature in the case of vessels for baking;

Whereas, irrespective of the number of articles selected when official tests are carried out in the Member States, the limit values adopted are maximum values with which any article taken individually must comply;

Whereas technical progress requires frequent adaptation of the technical specifications laid down in the Annexes to the Directive and whereas it is advisable in order to facilitate the implementation of the measures required for this purpose, to lay down a

procedure establishing close cooperation between the Member States and the Commission within the Committee for Adaptation to Technical Progress and in the sector of ceramic articles;

Whereas it could happen that a ceramic article which is intended to come into contact with food, although conforming to the provisions of this Directive, endangers public health; whereas it is, therefore, advisable to provide a procedure intended to remove this danger,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The requirements of this Directive shall apply to ceramic articles which are made according to the general principles laid down in Annex I and are intended to come into contact with food; such articles comprise:

- tableware and kitchenware,
- plates specially designed for very young children,
- cooking ware,
- packaging and storage vessels,

or any other article which may be employed for these purposes except if a direction to the contrary is duly stated on the article itself in a clear and perfectly visible fashion. These articles are hereinafter called 'ceramic articles used for food'.

Article 2

1. Member States shall take all appropriate measures to ensure that ceramic articles used for food are not marketed unless they satisfy the requirements of this Directive and its Annexes.

2. They shall also take all appropriate measures to ensure that ceramic articles which have the appearance of the articles listed in Article 1, but which are not ceramic articles as meant in this Directive, are not marketed unless they bear appropriate markings.

Article 3

1. At any marketing stage, any ceramic article tested in the manner laid down in Annex II shall be such that the quantities of lead and cadmium do not exceed, according to the case, the following limit values:

(a) Tableware and kitchenware:

— flatware:

lead	$1 \pm 0.05 \text{ mg/dm}^2$,
cadmium	$0.1 \pm 0.005 \text{ mg/dm}^2$;

— hollow ware articles with a capacity of up to five litres:

lead	$5 \pm 0.25 \text{ mg/l}$,
cadmium	$0.5 \pm 0.025 \text{ mg/l}$.

(b) Plates specially designed for very young children:

lead	$2.5 \pm 0.25 \text{ mg/l}$,
cadmium	$0.25 \pm 0.025 \text{ mg/l}$.

(c) Cooking ware:

— flatware:

lead	$0.5 \pm 0.025 \text{ mg/dm}^2$,
cadmium	$0.05 \pm 0.0025 \text{ mg/dm}^2$;

— hollow ware articles:

lead	$2.5 \pm 0.25 \text{ mg/l}$,
cadmium	$0.25 \pm 0.025 \text{ mg/l}$.

(d) Packaging and storage vessels:

lead	$2.5 \pm 0.25 \text{ mg/l}$,
cadmium	$0.25 \pm 0.025 \text{ mg/l}$.

2. Ceramic articles used for food with a capacity of over five litres which normally come within the category 'tableware and kitchenware' shall, for the purposes of this Directive, be deemed to be storage vessels.

3. When a ceramic article used for food consists of a vessel fitted with a lid, the inner surface of the lid shall be tested under the same conditions as the vessel itself.

In this case the level of extraction of lead and/or cadmium shall be calculated by relating the total extraction obtained to the vessel alone, adding the

extraction obtained for the lid to the extraction obtained for the vessel alone.

4. A ceramic article used for food shall be recognized as satisfying the requirements of this Directive as regards limits if, after a single test, the quantities of lead and cadmium extracted in the manner laid down in Annex II are equal to or lower than the corresponding limit values stated in paragraph 1.

5. The method of analysis described in Annex III is the reference method for the quantitative determination of lead and/or cadmium extracted by the leaching solution during the test.

Article 4

1. When marketed, ceramic articles within the meaning of this Directive shall be labelled or marked. Such labelling or marking may be replaced or supplemented by accompanying commercial literature when these products are not offered for sale to the final consumer.

2. The labelling or marking shall contain the following information in readily legible and clearly visible characters:

- (a) the name or trade name and the address or, where appropriate, the registered trade mark of the producer or the importer of the person responsible for placing the article on the market;
- (b) where appropriate, the words 'for children';
- (c) where appropriate, the words 'for cooking';
- (d) where appropriate, in the case of packaging sold empty to the final consumer and with a capacity of up to five litres, the word 'packaging'.

3. Member States may require that at the time of offer and sale to the final consumer in their territories, the labelling or marking specified in this Article shall also be expressed in their national languages.

In this case this requirement shall apply only to the labels and packaging of ceramic articles.

Article 5

For reasons concerning the extraction limits for lead and/or cadmium and the labelling or marking

requirements, Member States shall not prohibit or impede the placing of ceramic articles on the market if these articles satisfy the provisions of this Directive and its Annexes.

Article 6

1. If a Member State finds that a ceramic article which is intended to come into contact with food, although complying with the requirements of the Directive, constitutes a danger to health, that State may provisionally forbid the placing of the product on the market in its territory. It shall forthwith inform the Commission and the other Member States thereof and state the reasons for its decision.

2. The Commission shall, within six weeks, consult the Member States concerned and then, without delay, express its opinion and take the appropriate measures.

3. Where the Commission is of the opinion that technical adaptations to the Directive prove necessary, such adaptations shall be adopted by either the Commission, or by the Council under the procedure laid down in Article 8. In this event, the Member State having adopted safeguard measures may maintain them until such adaptations enter into force.

Article 7

1. A committee (hereinafter called the 'committee'), is hereby set up to adapt to technical progress Directives which concern the elimination of technical barriers to trade in the sector of ceramic articles. It shall consist of representatives of the Member States with a representative of the Commission as chairman.

2. The committee shall adopt its own rules of procedure.

3. Amendments needed technically to adapt the provisions of this Directive and its Annexes shall be adopted in accordance with the procedure laid down in Article 8.

Article 8

1. Where the procedure laid down in this Article is followed, matters shall be referred to the Committee by the Chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the committee a draft of the measures to be adopted. The committee shall deliver its Opinion of the draft within a time limit set by the chairman, having regard to the urgency of the matter. Opinions shall be adopted by a majority of 41 votes, the votes of Member States being weighted as provided in Article 148 (2) of the Treaty.

The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the Opinion of the committee.

(b) If no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted.

The Council shall act by a qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 9

1. Member States shall adopt and publish before 1 January 1977 the provisions needed to comply with this Directive and shall forthwith inform the Commission thereof.

They shall implement these provisions as from 1 July 1977.

2. As soon as this Directive is notified, the Member States shall also take care to inform the Commission, in time to enable it to make its observations, of any proposed provisions, to be laid down by law, regulation or administrative action, which they propose adopting in the field governed by the Directive.

Article 10

This Directive is addressed to the Member States.

ANNEX I

MANUFACTURE OF CERAMIC ARTICLES

General principles

The ceramic articles listed in Article 1 are manufactured from a mixture of inorganic substances normally comprising a high proportion of argillaceous or siliceous minerals. A small quantity of organic substance may be added to this mixture in certain cases.

These articles are first of all shaped and the shape thus obtained is permanently fixed by firing. Thereafter, they may or may not be coated with coloured or uncoloured glazes and/or decorations.

Ceramic articles manufactured in this way are often described by the following terms:

faience — pottery — porcelain — bone china — whiteware — earthenware — stoneware — etc.

ANNEX II

TEST METHOD

1. Simulating solvent

(a) *Nature:*

The simulating solvent to be used in the extraction of lead and cadmium from ceramic articles used as food containers is a 4 % by volume acetic acid solution.

(b) *Preparation of the solution:*

The 4 % by volume acetic acid solution is obtained by adding 40 ml of glacial acetic acid to 960 ml of distilled water or water of equivalent quality.

2. Preparation of the samples

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

The sample is accordingly washed at a temperature of about 40° C with a solution obtained from a liquid detergent.

The sample thus washed is first of all rinsed in tapwater and then in distilled water or water of equivalent quality.

It is then drained and dried either in a drying oven or by means of a new filter paper so as to avoid any stain.

After being cleansed in this way, the sample must be so handled that the surface to be tested does not come into contact with the hands of the person carrying out the test.

3. Filling

To avoid loss of liquid due to accidental spillage, which could distort the test results, and also in order that the sample may be covered with a suitable means of protection, the level of the liquid must be not more than 1 mm from the overflow point. For articles with a flat rim, the distance between the surface of the liquid and the overflow point must not be more than 6 mm.

4. Flatware

(a) *Definition:*

Ceramic articles to be classified as flatware are those of which the internal depth, as measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm.

(b) *Determination of the surface area:*

In the case of ceramic flatware, the extraction limit for lead and/or cadmium is related to the surface of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in Section 3 above.

5. Lighting

After being prepared in the manner described in Section 2, the sample is placed on a flat horizontal surface, filled as laid down in Section 4 with a 4 % by volume acetic acid solution prepared as described in Section 1 (b).

The lighting conditions during the test shall be as follows:

(a) *Lead extraction:*

When only the extractability of lead is tested, the article shall be covered with an appropriate means of protection and exposed to the usual conditions of illumination in a laboratory.

(b) *Lead and/or cadmium extraction:*

When the extractability of lead and/or cadmium is tested, the article shall be covered with a watch glass of a quality normally employed in chemical analysis laboratories and exposed to the following conditions of illumination:

- for a unit period of 24 hours the room in which the test is carried out shall be illuminated for five hours, kept in darkness for 14 hours and then illuminated for the remaining five hours;
- during the two, five-hour periods of illumination, the room shall be illuminated solely with fluorescent lamps of the Philips 'Daylight MCFE.33' type or tubes with equivalent characteristics. These lamps will have to be placed at a height of some 1.5 m above the bench so as to give uniform illumination of approximately $1\,000 \pm 10\%$ lux.

6. **Temperature**

An ambient temperature of $22 \pm 2^\circ \text{C}$ shall be maintained in the place where the test is being carried out.

7. **Duration**

The duration of the test will be 24 hours, in the conditions set out in Section 5 (a) or (b), according to the type of test carried out.

ANNEX III

METHOD OF ANALYSIS

1. **Sampling of the test solution for analysis**

Prior to sampling of the test solution to determine the lead and/or cadmium concentration, the contents of the ceramic article to be tested are homogenized by an appropriate method for obviating any loss of solution and any abrasion of the surface of the article to be tested.

2. **Method of analysis**

The quantity of the lead and/or cadmium extracted by the solvent during the test is determined by the atomic absorption method with the aid of a flame spectrophotometer, the instrument having a sensitivity of at least one-tenth of the lowest limit fixed for the elements to be determined. This sensitivity is defined as the concentration of elements which gives rise to an absorption of 1 %.

The determinations must be carried out in correspondence with the linear part of the instrument's calibration curve plotted by means of reference solutions. In the case of the concentrations of lead and/or cadmium in the test solution which lie outside the linear part of the calibration curve, prior dilution with 4 % by volume acetic acid will have to be carried out in order to work with a concentration corresponding to the linear part of the calibration curve.

In order to plot the calibration curve, the reference solutions to be employed will have to be prepared prior to each calibration using concentrated stock solutions (at least 1 000 ppm for lead and 100 ppm for cadmium) which are diluted with freshly prepared 4 % by volume acetic acid.

Prior to any calibration or analysis, a blank determination is carried out on a sample of 4 % by volume freshly prepared acetic acid in order to take into consideration any quantities of lead and/or cadmium present in the glacial acetic acid and/or the water employed.