

COMMISSION OF THE EUROPEAN COMMUNITIES

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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)

Explanatory memorandum

I. INTRODUCTION

The problem of reducing contamination caused by contact with household utensils and articles used for the preparation, storage and consumption of food and drink for human use has for a long time been dealt with in the national laws and regulations of many countries.

In the case of contamination from the lead content of glazing and decoration on ceramic household articles, one of the oldest regulations could be the German law of 25 June 1887 stipulating that: "Containers for food, drink and cooking, and those used for the measurement of liquids, shall not be coated with an enamel or glaze releasing lead after 30 minutes' boiling in vinegar containing 4% acetic acid".

Like the German regulation, the other national measures dating from times long past contain the same, or an equivalent, requirement to the effect that "ceramic articles shall not release lead".

Taking into account, on the one hand, the increasingly sophisticated analysis methods afforded to laboratories by technical progress and, on the other hand, the intensification of public health protection, interpretation of the outmoded requirements has become very difficult, if not impossible.

For this reason, efforts have for some years been directed throughout the world, and especially in the Member States, to up-dating the provisions in question.

Unfortunately, the manner in which this up-dating process is being carried out is far from methodical, and national laws are seen to be developing unevenly. These disparities have already involved obstacles to trade, whereas harmonization of production techniques in Europe has reached an advanced stage.

In July 1972, therefore, the European Federation of the Industries of Earthenware and China Tableware and Ornamental Ware (FEPPF) brought this question to the attention of the Commission. This step was accompanied by a proposal from the European industry for the harmonization of laws on lead migration.

Without waiting for the adoption of the Council Resolution of 21 May 1973, supplementing the Resolution of 28 May 1969 laying down a programme for the elimination of technical barriers to trade in industrial products, the Commission set up a Working Party.

The task of the Working Party, which was formed in March 1973, was to study the problems involved in the harmonization at European level of provisions relating to the extraction of lead and of cadmium for ceramic articles intended to come into contact with foodstuffs, and concerning in particular:

- extraction limits,
- test methods,
- analysis methods,
- conditions governing the placing on the market.

Metallic elements other than lead and cadmium are also present in glazes and decorations on ceramic articles and may be extracted. In practice, however, it is observed that they are only extracted to a significant degree when the object is clearly disintegrating following the acetic acid test. This disintegration is accompanied by the extraction of lead or cadmium to an extent which is sufficient in itself for the object to be declared unfit for use by the consumer.

By way of guidance, the following table summarises the regulations already in force or in preparation in the Member States.

Country	State of legislation	Situation in practice				
		Solvent acetic acid	Temperature	Duration of test	Limits	Remarks
West Germany	Draft standard in preparation	4% (w/v)	ambient	24 h	Pb 1.5 mg/dm ²	
Belgium	- Royal decree of 12 September 1972 - Implementing provisions concerning ceramic objects pending					
Denmark	Statutory Order N. 450 of 11 October 1972	4% (w/v)	boiling	3 tests, each of 30 mins.	Total from 3 tests Pb 3 mg/l cd 1 mg/l	Extraction related to useful capacity. Special provisions for the edges of objects coming into contact with the lips. (depth 2 cm) Pb 2.5 mg/dm ² cd 0.2 mg/dm ²
France	- Decree N. 73.138 of 12 January 1973 - Implementing provisions concerning ceramic objects pending					
Ireland	Irish Standard specification IS. 188.1973	4% v/v)	16 - 23o C	24 h	Pb 7 mg/l cd 0.5 mg/l	Similar to U.S. regulations
Italy	- Law No 283 of 30 April 1962 - Circular No 198 of 17 November 1964 from the Ministry of Health (Reference analysis method) - Decree of 21 March 1973 implementing provisions concerning objects pending	1%	ambient	24 h	Pb 0.5 mg/dm ²	Proposed : Acetic acid : 3% Temperature : 40o C Duration : 24 h Number of tests : 3 First tests : Pb 10 ppm; cd 0.5 ppm Third test : Pb 3 ppm (0.5 mg/dm ²) cd 0.2 ppm
Luxembourg	Legislation of a general nature					
Netherlands	Draft Royal Decree					Proposed legislation : Acetic acid : 3% Temperature : 40o C Duration : 2 h Number of tests : 3 Third test : Pb 0.3 mg/dm ² ; cd 0.02 mg/dm ²
United Kingdom	- National standard BS 4880 Part 1 : 1972 "tableware" Part 2 : 1972 "cooking ware" - Statutory Instrument 1972 No 1967 The cooking utensils (Safety) Regulation 1972 : promulgated 1 April 1973	4%(v/v)	19-21o C	24 h	Tableware Flatware Pb 20mg/l; cd 2 mg/l Holloware 1.1 l; Pb 7mg/l cd 0.7 mg/l 1.11 Pb 2mg/l; cd 0.2 mg/l	The cooking utensils (Safety) regulation 1972 limits the lead content of enamels to 2000 ppm
					Cooking ware Pb 7 mg/l; cd 0.7mg/l	

II. NOTES ON THE PROPOSAL FOR A DIRECTIVE, ARTICLE BY ARTICLE

Article 1

This Article defines the scope of the Directive.

Ceramic articles intended to come into contact with foodstuffs have been classified in four categories:

-- Tableware and kitchenware

This is the largest and most varied category. It includes all articles for use at the table or in the cold or low-temperature preparation of food. The use of these articles accords as a general rule with brief and repeated contact with the food.

-- Plates specially designed for very young children

This category consists of articles used daily by particularly sensitive consumers, who therefore require greater protection.

-- Cooking ware

This category relates to those articles which when in use come into direct contact with a high-temperature heat source or are placed in an oven. Their contact with food can therefore be regarded, generally speaking, as brief and repeated.

-- Packaging and storage containers

Articles in this category are characterized by prolonged contact with the food they contain.

In the case of ceramic packaging a distinction can be made between those containers which are sold empty to the final consumer and those which contain a particular product at the time of sale. In view of their intrinsic qualities of durability, these articles are often used again, after the consumption of the initial contents, to preserve products generally of a different nature from the original product.

Storage containers may have a capacity of several tens of litres, and in certain countries (e.g. Italy) are used by private individuals to preserve pickles (olives), for example, or oil.

Generally speaking, ceramic articles by their nature present no difficulty, as regards establishing the use for which they are intended. In some cases, however, articles of a purely artistic or decorative nature can be designed in shapes identical to those of domestic articles. In order to cope with this very peculiar situation which is typical of ceramic goods, and bearing in mind the possibilities of derogations provided in the proposal of the outline directive relating to materials and articles intended to come into contact with foodstuffs, positive labelling has not been chosen. To remove any possible danger, however, the Directive provides all such articles, unless they bear a declaration to the contrary, must satisfy the requirements of the Directive as laid down in several national regulations (Belgium, Denmark and France). It must be pointed out, however, that the Directive specifies neither the kind of article which has to bear this "negative marking" nor the form which such marking should take.

Article 2

This Article lays down the kind of harmonization provided for by the Directive in the field of ceramic articles.

Since the limitation of extractable quantities of lead and cadmium is a measure aimed at the protection of human health, and the degree of such protection should be the same for all the inhabitants of the member countries of the European Community, the type of harmonization adopted is total harmonization.

Article 3

This Article lays down the extraction limits for lead and cadmium in the various cases under consideration.

The choice of these limits has proved one of the most difficult tasks of the Working Party and it should be pointed out that the proposed values do not meet with the complete satisfaction of all the experts. Some consider them too high, others consider them too low. These experts have felt it necessary to express reservations.

Expression of the limits

The limited values are expressed

- for flat articles - in milligrammes per square decimetre (mg/dm^2)
- for curved objects - in milligrammes per litre (mg/l).

Although at first sight this system may appear inconsistent, it becomes perfectly clear and logical when one considers the many shapes that ceramic articles can assume, even within the same service with the same decoration.

Although, in the case of hollow articles, the surface area/volume ratio varies relatively little, in the case of flat articles this ratio, which is intrinsically very high (order of magnitude 1:10), may in addition vary widely (from 1:x to 1:2x) for a relatively small variation in surface area. In the case of flat articles, the inconsistency would therefore lie in the expression of the limit value as a concentration (mg/l), as this would amount, for example, in the case of articles belonging to the same service, to treating the same surface much more severely when it belongs to a flat article than when it belongs to a hollow article, even though flat articles are generally in contact with solid foods and the risk of possible contamination is therefore relatively low.

Nature of the limits

The limit values adopted in the Directive are maximum values. This has the advantage of simplifying the sampling method, while ensuring a high degree of protection for the consumer, as every article tested individually must comply with the appropriate limit value.

This means that, in order to take into account the considerable variations which occur from article to article, even when such articles are deemed to be identical, the manufacturer will have to aim, for his overall production, at a level of extraction approximately half the level permitted. This should spare him the risk of putting on the market more than, say, one article per 100,000, which exceeds the permitted limit, as is shown by a study carried out by the British Ceramic Research Association¹.

To test the ceramic articles at the level of sale to the final consumer, therefore, the sampling of a single article should in principle be sufficient. The article must fall within the appropriate limit after a single trial.

Level of the limits

In some countries (Denmark, Italy) the recommended limits are laid down on the basis of weekly permitted levels recommended by the FAO/WHO in 1972, i.e., 3 mg for lead and 0.5 mg for cadmium.

¹ Some Statistical Aspects of Metal Release Regulations, by F. MOORE, The British Ceramic Research Association, Technical Note No 210 - November 1973.

As these weekly levels are total levels, including contributions from all possible sources to establish a limit for ceramic articles, it is necessary to perform a large number of hypotheses and estimates which are difficult to verify.

Experience has proved that ceramic articles which meet the limits laid down in the Directive, or values of the same order of magnitude, can be used in complete safety by the consumer.

It should be remembered that these values accord with the use of a simulating solvent, 4% by volume acetic acid, which is considerably more aggressive than the actual foodstuffs, as is shown by the available results of experiments.

The adoption of these limits would permit rapid removal from the market of articles which, in the absence of effective regulations, are at present sold to the consumer in spite of the fact that they are liable to release quantities of lead and cadmium several tens of times as high as the proposed limits.

Having regard to the test method proposed in Annex II, and in order to take into account the kind of use to which the different categories of article will be put, the limits for plates specially designed for very young children, and for baking ware and storage vessels have been fixed as half the limits adopted for tableware and kitchenware.

These limits have been adjusted to the potential of modern technology, and recent progress in this field makes it possible to foreshadow even better results in the near future and therefore to consider revision of the suggested limits then.

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On the other hand, the nominal values of these limits have been affected by a tolerance margin corresponding to the efficiency of the reference method proposed for carrying out the analysis: i.e., atomic absorption with the aid of a flame spectrophotometer (see Annex III).

Article 4

This Article concerns conditions governing placing on the market.

As ceramic articles are classified in four categories corresponding to different limit values, it is necessary to lay down a marking system by which they can be identified.

In order to reduce to a minimum the markings required, each article would bear the following markings:

- in the case of plates specially designed for very young children: "for children",
- in the case of ~~cooking water~~ "for cooking",
- in the case of packaging sold empty to the final consumer and with a capacity of five litres or less: "storage".

Other articles "tableware and kitchenware" or vessels with a capacity of more than five litres which can easily be identified by elimination, need not carry a distinguishing mark.

Article 5

This Article establishes freedom of movement on the Community market of ceramic articles intended to come into contact with food and which satisfy the requirements of this directive.

Article 6

This Article constitutes the safeguard clause customarily included in a Directive, the requirements of which relate to human health protection.

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The text of this Article has already been approved by the Council in respect of other Directives.

Articles 7 and 8

The purpose behind these Articles is to control adaptation to technical progress of the Annexes to Directives issued on the subject of ceramic articles and they lay down in particular the operating procedure for the Committee for Adaptation to Technical Progress. The texts of these Articles have already been approved by the Council in respect of other Directives. However, bearing in mind the use for which ceramic goods are made, in the case where the Council would adopt the proposal of the outline directive relating to materials and articles intended to come into contact with foodstuffs before adopting the present directive, the content of these two articles should be modified accordingly. Especially, it should then be referred to the "Standing Committee on foodstuffs" instead of the usual Committee for Adaptation to Technical Progress mentioned in the directives concerning industrial products.

Articles 9 and 10

These Articles concern final provisions which appear in other Directives already approved by the Council.

III. NOTES ON TECHNICAL ANNEXES

Annex I

Annex I, entitled:

Manufacture of ceramic articles,
General principles,

sets out briefly the general principles which form the basis for the manufacture of ceramic articles coming within the scope of the Directive.

The last paragraph gives, by way of example, a number of words used to designate the products obtained.

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Annex II

Annex II, entitled:

Testing Method,

outlines the operations to be carried out and the conditions to be fulfilled by the laboratories responsible for checking the quantities of lead and cadmium which can be extracted from ceramic articles.

One body of national law lays down a special test for the edges of articles which come into contact with the lips (cups, bowls, etc.). Within the Working Party, the majority of the experts felt that this point was worth considering but that a more detailed study should be carried out before it would be possible to consider a solution.

1. Simulating solvent

Acetic acid, 4% by volume, was selected as a simulating solvent or test solution. This kind of solution is the most widely used throughout the world.

It should be noted, however, that some experts (Italy, Netherlands) were inclined to favour a solution of 3% by volume. The main reason for this was that at this concentration the water-acetic acid mixture is an azeotropic mixture. The tests performed showed that this was not the case in the conditions of use envisaged.

In any case, experience confirms that a slight variation in the concentration of the test solution does not influence the test results.

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2. Preparation of samples

This concerns recommendations of a general nature.

3. Filling

Idem.

4. Flat-ware

a) Definition

The fact that the limits are expressed differently according to whether the article in question is flat or hollow makes it necessary to lay down exactly how the distinction between the two kinds of articles is to be made.

By reason of the use for which they are intended, flat-ware generally comes into contact with solid foodstuffs and, therefore, constitutes less of a risk.

Since plates specially designed for very young children form a separate category, and in order to take into account technical contingencies flat-ware means those articles of which the depth is 25 mm or less.

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b) Determination of the surface area

With this simple method of determination the surface area of the article is underestimated, which has the effect of making the limit extraction levels more stringent.

5. Lighting

The effect of luminous radiation on the extraction of cadmium from some decorations or glazings is a phenomenon which has only recently been studied². For this reason, as simple a test as possible has been provisionally adopted so as to permit this factor to be taken into account.

Research work on developing a standard method is in progress. This work formed the subject matter of the first contract between the Commission and the Institute for Industrial Research and Standards, Dublin.

Some experts are inclined to favour a test carried out in darkness, entailing, where appropriate, the reduction of the limit for cadmium so as to take into account the effect of the light. This approach to the problem is inconsistent with the scientific data currently available.

6. Temperature

In every case, whatever the type of ceramic article, the test is carried out at a temperature of $22 \pm 2^{\circ}\text{C}$.

For tableware and kitchen ware, the Italian and Netherlands experts consider that this temperature should be 40°C . Experience shows that the fact of increasing the temperature from 22°C to 40°C has practically no effect on the

² Report on the Light Sensitivity of Cadmium Release from Glazed Ceramic Tableware -- by D. M. CARROL and M. K. HALPIN
J.I.R.S. Report No AC/MI - 11/73, 26 November 1973.

results, and actually makes the test much more complicated (use of a thermostatically controlled chamber) and, therefore, more expensive. The Danish experts prefer a boiling temperature test.

The same considerations regarding temperature apply to plates specially designed for very young children and packaging and storage vessels.

In the case of cooking ware, several experts, anxious to reproduce the conditions of use as closely as possible, are in favour of a temperature boiling test. This kind of test is particularly difficult to carry out as a routine test, boiling being a phenomenon which generally gives results that are difficult to reproduce, particularly in view of the variations due to evaporation.

This test is, in any case, impossible to perform on flat-ware.

Moreover, although these regulations are intended for the checking of articles sold retail to the final consumer, it should be remembered that they must also be easily applicable at the industrial level to allow manufacturers to test the quality of their products.

However, since the test will be carried out at ambient temperature, the limit values for cooking ware have been fixed provisionally at half the levels adopted for tableware and kitchen ware. At the same time, the chemistry department of the Joint Research Centre has started on a programme of research into the relationship between cold and hot tests.

In the case of plates specially designed for very young children the limits have also been taken as being half the levels adopted for tableware and kitchen utensils in the case of hollow ware.

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7. Duration

As has already been mentioned, a single test of 24 hours is required in all cases. Because contact with the food is of long duration in the case of packaging and storage vessels the relevant limits have been fixed at half the maximum values adopted for tableware and kitchenware. This proportion is confirmed by the results of experimental work carried out in particular by the Group of European Specialists for Ceramic Colours, Enamels and Glazes.

Some experts (Italy, Netherlands) favour three consecutive tests of 24 hours each, the result of the third test being the one taken into consideration.

In view of the low level at which the relevant limit values have been set, this would involve making the testing method for ceramic articles cumbersome to an unjustified extent.

Generally speaking, a comparison of the results obtained by applying the various test methods used throughout the world shows that on the whole these methods are largely equivalent and such a comparison therefore lends weight to the argument for the adoption of the simplest method possible³.

Annex III

This Annex sets out the general principles of the method of analysis using atomic absorption and gives the basic characteristics of the reference flame spectrophotometer, on the basis of which the tolerance margins adopted for the limits were determined.

³ Enquête analytique expérimentale sur la migration des matériaux céramiques destinés à entrer au contact des aliments, par Sampaolo A., Rossi L., Esposito E., Gramiccioni L., Di Marzio S. (Istituto Superiore di Sanità, Laboratori di Chimica, Roma) - Piccinini M., Bonciani S. (Laboratorio Provinciale Igiene e Profilassi, Sezione Chimica, Firenze).

IV. CONSULTATION WITH BODIES CONCERNED

During the drafting of the Directive, there were frequent contacts with the various bodies concerned.

The representatives of these bodies took part in the work of the Working Party set up by the Commission.

This enabled them to observe the lines followed in drafting the Directive and at the same time to put forward any suggestions or observations for possible improvements to the text of the Directive.

V. CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

Under Paragraph 2 of Article 100 of the Treaty of Rome, these two bodies must be consulted. The implementation of the requirements laid down calls for amendment of the laws of the Member States.

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)

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 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 and 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 that 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 co-operation 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, endanger 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 5 litres:

Lead 5 ± 0.25 mg/l
Cadmium 0.5 ± 0.025 mg/l

b) Plates specially designed for very young children

Lead 2.5 ± 0.25 mg/l
Cadmium 0.25 ± 0.025 mg/l

c) cooking ware

flatware:

Lead 0.5 ± 0.025 mg/dm²
Cadmium 0.05 ± 0.00 mg/dm²

d) hollow ware articles

Lead 2.5 ± 0.25 mg/l
Cadmium 0.25 ± 0.025 mg/l

2. Ceramic articles used for food with a capacity of over 5 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 5 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 forty-one 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, or, 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.
b) 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 :

faïence - 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.

Annex II.

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 1000 ± 10 % lux.

Annex II.

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 5 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 $\frac{1}{10}$ 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.

Annex III.

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.
