

UDENRIGSMINISTERIET

EU 375

Medlemmerne af Folketingets Europaudvalg
og deres stedfortrædere

Asiatisk Plads 2
DK-1448 København K
Tel. +45 33 92 00 00
Fax +45 32 54 05 33
E-mail: um@um.dk
Telex 31292 ETR DK
Telegr. adr. Etrangeres
Girokonto 300-1806



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KOMITÉSAG

Til underretning for Folketingets Europaudvalg vedlægges Fødevareministeriets notater om forslag til ændring af Rådets direktiv 84/500/EØF om indbyrdes tilnærmelse af medlemsstaternes lovgivning om keramiske genstande bestemt til at komme i berøring med levnedsmidler, dokument SAN-CO/2002/10107.

Forslaget forventes sat til afstemning på et kommende møde i Den Stående Komité for Fødevarekæden og Dyresundhed.

P. H. Olsen

Ministeriet for Fødevarer, Landbrug og Fiskeri

Fødevaredirektoratet

J.nr.: 2002-20-221-00247

Den 8. december 2003

DLI/BFA/TAJ

FVM 143

NOTAT TIL FOLKETINGETS EUROPAUDVALG

om forslag til ændring af Rådets direktiv 84/500/EØF om indbyrdes tilnærmelse af medlemsstaternes lovgivning om keramiske genstande bestemt til at komme i berøring med levnedsmidler

SANCO/2002/10107

Forslaget forventes sat til afstemning på et kommende møde i Den Stående Komité for Fødevarekæden og Dyresundhed.

Forslaget skal behandles i en procedure III i komitéen. Hvis der er kvalificeret flertal, udsteder Kommissionen direktivet. Opnås der ikke kvalificeret flertal, forelægger Kommissionen sagen for Rådet og underretter samtidig Europa-Parlamentet. Rådet kan med kvalificeret flertal vedtage forslaget uændret eller udtale sig mod det. Hvis der er kvalificeret flertal imod forslaget, skal Kommissionen behandle sagen på ny. Handler Rådet ikke inden en frist på højst tre måneder, kan Kommissionen udstede direktivet.

Forslaget har til formål at udvide reglerne for mærkning og markedsføring af keramik, således at kravene bliver de samme for keramik som for plastmaterialer.

Vedtagelse af forslaget vurderes at indebære et øget beskyttelsesniveau, da det med kravet om mærkning vil være mere gennemskueligt for forbrugerne, hvilke produkter der er egnet til kontakt med fødevarer.

Regeringen agter på den baggrund at tilslutte sig forslaget.

Ministeriet for Fødevarer, Landbrug og Fiskeri

Fødevaredirektoratet

J.nr.: 2002-20-221-00247

Den 8. december 2003

DLI/BFA/TAJ

FVM 143

AKTUELT NOTAT TIL FOLKETINGETS EUROPAUDVALG

om forslag til ændring af Rådets direktiv 84/500/EØF om indbyrdes tilnærmelse af medlemsstaternes lovgivning om keramiske genstande bestemt til at komme i berøring med levnedsmidler

SANCO/2002/10107

Baggrund

Kommissionen har ved dokument SANCO/2002/10107 fremsendt forslag om udvidelse af reglerne for keramik til kontakt med fødevarer med hensyn til mærkning og certifikater.

Forslaget er fremsat med hjemmel i artikel 3 i Rådets direktiv 89/109/EØF af 21. december 1988 om indbyrdes tilnærmelse af medlemsstaternes lovgivning om materialer og genstande, bestemt til at komme i berøring med levnedsmidler.

Forslaget skal behandles i en procedure III i Den Stående Komité for Fødevarekæden og Dyresundhed. Hvis der er kvalificeret flertal, udsteder Kommissionen direktivet. Opnås der ikke kvalificeret flertal, forelægger Kommissionen sagen for Rådet og underretter samtidig Europa-Parlamentet. Rådet kan med kvalificeret flertal vedtage forslaget uændret eller udtale sig mod det. Hvis der er kvalificeret flertal imod forslaget, skal Kommissionen behandle sagen på ny. Handler Rådet ikke inden en frist på højst tre måneder, kan Kommissionen udstede direktivet.

Forslaget forventes sat til afstemning på et kommende møde i komitéen.

Nærheds- og proportionalitetsprincippet

Forslaget er en ændring af en gennemførelsesretsakt til Rådets direktiv 89/109 om indbyrdes tilnærmelse af medlemsstaternes lovgivning om materialer og genstande bestemt til at komme i berøring med levnedsmidler. Kommissionens begrundelse for at fremsætte forslaget er ønsket om harmonisering af regler om mærkning og certifikater til keramiske genstande til kontakt med fødevarer af hensyn til samhandelen, kontrollen og forbrugerne. Forslaget vurderes derfor at være i overensstemmelse med nærheds- og proportionalitetsprincippet.

Formål og indhold

Forslaget har til formål at udvide reglerne for mærkning og markedsføring af keramik, således at kravene bliver de samme for keramik som for plastmaterialer.

Forslaget indeholder bestemmelser om:

- At keramiske genstande til fødevarekontakt skal mærkes med et handelsnavn eller navnet på producenten. Da keramik typisk sælges uden emballage skal selve keramikgenstanden være mærket med et bestandigt mærke, hvilket er en skærpelse i forhold til de generelle bestemmelser for materialer og genstande.
- Keramik skal fra produktion til detailniveau være ledsaget af et certifikat med information om oprindelse (fx producent, importør etc.), reference til EU-regler samt bekræftelse på, at produktet overholder relevante EU-regler og eventuelle nationale regler.
- Analysemetoden til analyse af bly og cadmium ændres fra at være en specifik angivet analysemetode til, at der i stedet er stillet krav til analysemetodens kvalitet. Dette betyder, at mere moderne analyseudstyr vil kunne anvendes.
- Keramiske genstande som produceres eller importeres skal opfylde direktivets krav 2 år efter vedtagelse.

Udtalelser

Europa-Parlamentet skal ikke udtale sig om forslaget.

Gældende dansk ret

Bekendtgørelse nr. 111 af 20. februar 2003 om materialer og genstande bestemt til kontakt med fødevarer indeholder implementering af det eksisterende direktiv 84/500/EØF. Revision af bekendtgørelsen vil være påkrævet.

Konsekvenser

Vedtagelse af forslaget vurderes at indebære et øget beskyttelsesniveau, da det med kravet om mærkning vil være mere gennemskueligt for forbrugerne, hvilke produkter der er egnet til kontakt med fødevarer. Forslaget vurderes ikke at få statsfinansielle eller samfundsøkonomiske konsekvenser.

Høring

Forslaget har i medfør af fødevarerlovens § 6, stk. 1 været sendt i høring til en bred kreds af organisationer og myndigheder. Høringskredsen indbefatter de organisationer, der er med i Det Rådgivende Fødevarerudvalg og § 2-udvalget.

Landbrugsraadet og Danske Slagterier finder, at der bør gives hensigtsmæssige overgangsordninger, idet den angivne periode på 2 år er for kort for mærkning af al keramik.

Den Danske Dyrlægeforening, Forbrugerrådet, SiD, Mejeriforeningen og KVL har meddelt, at man ikke har bemærkninger til forslaget.

Tidligere forelæggelse for Folketingets Europaudvalg

Sagen har ikke tidligere været forelagt Folketingets Europaudvalg.

EN

SANCO/2002/10107



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02 October 2003
SANCO/2002/10107

EMB 901/Rev1d

**WORKING DOCUMENT: IT DOES
NOT NECESSARILY REPRESENT
THE VIEWS OF THE COMMIS-
SION**

COMMUNICATION FROM THE COMMISSION

EXPLANATORY NOTE

Draft

COMMISSION DIRECTIVE/EC

of [...]

**amending Council Directive 84/500/EEC relating to ceramic articles intended to come
into contact with foodstuffs**

(version updated to 02 October 2003)

(EN)

(Text with EEA relevance)

COMMUNICATION FROM THE COMMISSION

EXPLANATORY NOTE ON THE DRAFT OF 1st AMENDMENT OF DIRECTIVE 84/500/EEC ON CERAMIC ARTICLES

1. This version should be considered as first attempt to prepare in future an amendment to the Ceramic Directive. This draft was prepared taking into account the discussions held during 2002 and 2003 with Member States and representatives of Ceramic industry. At this stage, the draft should be considered a preliminary draft which does not yet represent the point of view of the Commission services because the document should be subject to an official consultation of the stakeholders (Member States and professional and consumer organisations). Therefore the draft may subject to relevant changes.
2. The European professional organisation of ceramic (Cerame-Unie) requested in a meeting with Commission representatives to amend the Directive 84/500/EEC in order to:
 - a) introduce the obligation under which imported ceramic articles shall be accompanied by a written declaration attesting their compliance with the rules of the Directive in accordance with the provision of Article 6(5) of the Framework Directive 89/109/EEC. They requested also for imported ceramic articles the availability of a declaration containing the results of the migration testing. Furthermore, they asked for the labelling rules of Article 6 to be applied more strictly for ceramic materials and articles by having a mandatory backstamp, which is identifying the manufacturer or seller in the Community or the country of origin. This will ensure the traceability of the articles even when they are sold without packaging.
 - b) change the limits of lead (Pb) and cadmium (Cd) established in 1984 to be in line with the new limits fixed by ISO norms 6486-1 and 6486-2 in 1999.
3. Cerame-Unie's request under 1(a) was motivated by the need to avoid the manufacture and the importation of articles not in compliance with the requirements of the Directive. The obligation for the manufacturer outside the Community or the importer to deliver a declaration of compliance and the results of the analysis makes them more aware of their legal constraints. The current draft of a Commission Directive is in line with the industrial request but will be applied to all ceramic articles on the European market and thus increases the protection of the consumer.
4. The request under 1(b) needs the consultation of EFSA and an enquiry in order to (a) verify whether or not the limits fixed by ISO are always more restrictive and (b) to take into account the requests of the Member States to extend the Directive to other materials having similar problems (crystal glass, enamels) and to other metals (barium, chromium etc). Because the consultation of EFSA, the enquiry and the reaching an agreement on the new values will require time, the Commission services decided to proceed step by step. The first step will be to satisfy the request under 1(a).

5. The Ceramic Directive provides a method for the extraction of lead and cadmium from the controlled ceramic objects. Technological progress has been made in the area of instrumental detection methods. Criteria for methods of analysis used in official control of the levels of lead and cadmium in foodstuff are laid down in Directive 2001/22/EC. Consequently, this Directive takes into account the analytical progress and defines a set of quality assurance criteria (Annex II) that the instrumental method of analysis must fulfil and leaves the choice of instrumentation to the analyst.

Draft

COMMISSION DIRECTIVE ../.../EC

of [...]

amending Council Directive 84/500/EEC relating to ceramic articles intended to come into contact with foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs¹, and in particular Article 3 thereof,

Whereas:

- (1) Directive 89/109/EEC provides in Article 6(5) that the specific Directives shall require that materials and articles not already in contact with foodstuffs must, when placed on the market, be accompanied by a written declaration attesting that they comply with the rules applicable to them.
- (2) Directive 84/500/EEC of 15 October 1984 relating to ceramic articles intended to come into contact with foodstuffs² has not yet introduced this requirement. There is a need to provide this obligation for all ceramic articles intended to come in contact with foodstuffs or brought into contact with foodstuffs with a view to making the manufacturers and sellers more aware of their responsibility and then to obtaining a better enforcement of the rules applicable to these articles.
- (3) For the enforcement authorities it shall be comprehensible how the manufacturer came to the conclusion that the ceramic articles comply with the migration limits for lead and cadmium. Therefore, information concerning the analysis carried out shall be made available to them on request.
- (4) Directive 89/109/EEC provides in Article 6 (1) (c) for the labelling of materials and articles not already in contact with food with the name and address of the manufacturer or seller. Article 6 (2) gives several possibilities for providing this information. As ceramic articles are often sold without packaging or are repacked, correct information throughout the distribution chain up to the consumer can often only be ensured by marking the name of the responsible in the Community on the article itself.
- (5) Directive 89/109/EEC provides in Article 6 (1) (a) for the labelling of materials and articles not already in contact with food an indication that the item is suitable for food

¹ OJ L 40, 11.2.1989, p. 38

² OJ L 277, 20.10.1984, p.12

use. Article 6 (3) exempts from this compulsory labelling materials and articles, which by their nature are clearly intended to come into contact with foodstuffs. For ceramic articles it is often not obvious if the article is suitable for food contact or if it is a decorative item, which does not respect lead and cadmium limits for ceramics in contact with food. Therefore, a mandatory marking on the article itself is necessary to inform the consumer on its suitability for food contact use.

- (6) Directive 84/500/EEC provides a method for the analysis of lead and cadmium. Technological progress has been made in this area and the instrumental method mentioned in the Directive is only one amongst several possible instrumental methods. Directive 2001/22/EC³ is laying down amongst others criteria for methods of analysis used in official control of the levels of lead and cadmium in foodstuff. This Directive takes this into account and establishes a set of quality assurance criteria that the instrumental method used must comply with.
- (7) 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 the Directive 84/500/EEC. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (8) Directive 84/500/EEC should therefore be amended accordingly.
- (9) 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

The following Article 2a is inserted:

“Article 2a

1. By derogation of Art.6 paragraph 2 of Directive 89/109/EEC ceramic articles, which are placed on the market in the Community, shall be marked on the article itself with the name, or trade name, or a registered trade mark of the manufacturer, or of a seller established within the Community. Furthermore, they shall be marked with the symbol for food use laid down in Directive 80/590/EEC⁴. The marking must be conspicuous, clearly legible and indelible.
2. At the marketing stages up to and including the retail stage, the ceramic articles, which are intended to be placed in contact with foodstuffs shall be accompanied by a written declaration in accordance with Article 6 (5) of Directive 89/109/EEC. This written declaration shall be issued by the manufacturer or a seller established within the Community and shall contain the information set down in Annex III. Appropriate documentation able to demonstrate that the articles comply with the limits of Article 2 shall be made available to the national competent authorities on request.

³ OJ L 77, 13.03.2001, p.14

⁴ OJ L 151, 19.6.1980, p.21

3. Annex I to this Directive is added as Annex III.
4. Annex II to this Directive replaces Annex II.

Article 2

1. Member States shall adopt and publish, by [one year after the date of the adoption of the Directive by the Commission] at the latest, 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 intended to come into contact with foodstuffs and complying with this Directive, 1 year after the date of adoption of the Directive by the Commission ;
- (b) prohibit the manufacture and importation into the Community of ceramic articles intended to come into contact with foodstuffs and which do not comply with this Directive, from 2 years after the date of adoption of the Directive by the Commission

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 4

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 5

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission

Member of the Commission

ANNEX I

The written declaration, shall contain the following information:

1. Identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the European Union
2. Identity of the article
3. Date of the declaration
4. References to Community legislation applicable
5. The confirmation that the ceramic article meets relevant requirements in this Directive and Directive 89/109/EC.

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.

The appropriate documentation able to demonstrate that the articles comply with the limits of Article 2 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.

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 paragraph 4.

3. Reagents

- All reagents must be of analytical quality, unless otherwise specified.
- Where reference is made to water, this always means 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 (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.

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.

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

4.3 Recovery. The recovery of lead and cadmium added to the 4 % acetic acid 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 tapwater and then in distilled water or water of equivalent quality. Drain and dry so as to avoid any stain. The surface to be tested should not 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.