

2006 No. 1179

FOOD

**The Ceramic Articles in Contact with Food (England)
Regulations 2006**

<i>Made</i>	- - - -	<i>24th April 2006</i>
<i>Laid before Parliament</i>		<i>27th April 2006</i>
<i>Coming into force</i>		
	<i>(except for regulations 3(3)(a) and (b) and 4)</i>	<i>20th May 2006</i>
	<i>Regulations 3(3)(a) and (b) and 4</i>	<i>20th May 2007</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by sections 16(2), 17(1), 26(1)(a), (2)(a) and (3), and 48(1) of the Food Safety Act 1990^(a) and section 11 of the Consumer Protection Act 1987^(b);

In accordance with section 48(4A)(c) of the Food Safety Act 1990 he has had regard to relevant advice given by the Food Standards Agency and consulted as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety^(d);

In accordance with section 11(5) of the Consumer Protection Act 1987 he has consulted such organisations as appear to him to be representative of interests substantially affected by the proposal to revoke the Ceramic Ware (Safety) Regulations 1988^(e), such other persons as he considered appropriate and the Health and Safety Commission.

Citation, Commencement, Extent and Revocation

1.—(1) These Regulations may be cited as the Ceramic Articles in Contact with Food (England) Regulations 2006 and shall come into force on 20th May 2006 except for regulations 3(3)(a) and (b) and 4 which shall come into force on 20th May 2007.

(2) The Ceramic Ware (Safety) Regulations 1988 (which extend to the United Kingdom) are revoked except in their application to Scotland.

(3) These Regulations, except for paragraphs (1) and (2), extend only to England.

(a) 1990 c.16.

(b) 1987 c.43.

(c) Subsection (4A) was inserted by paragraph 21 of Schedule 5 to the Food Standards Act 1999 (c.28).

(d) O.J. No. L. 31, 1/2/2002, p.1.

(e) S.I. 1988/1647.

(4) In the Official Feed and Food Controls (England) Regulations 2006^(a) sub-paragraph (b) of Schedule 3 (Definition of relevant food law) is amended by the omission of the words “except in so far as it involves the regulation of food contact materials under the Ceramic Ware (Safety) Regulations 1988”.

Interpretation

2. In these Regulations—

“ceramic article” means an article—

- (a) 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. Such an article is first shaped and the shape thus obtained is permanently fixed by firing. It may be glazed, enamelled and/or decorated;
- (b) which, in its finished state, is intended to come into contact with foodstuffs, or which is in contact with foodstuffs, and is intended for that purpose;

but does not include an article which is supplied as an antique;

“the Community” means the member States and Norway, Iceland and Liechtenstein;

“enforcement authority” means an authority mentioned in regulation 5;

“import” means the release into the UK for free circulation in the Community;

“place on the market” means the holding of ceramic articles for sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves.

Limits on the transfer of lead and cadmium

3.—(1) The quantities of lead and cadmium transferred from a ceramic article shall not exceed the limits laid down in Schedule 1.

(2) Compliance with paragraph (1) shall be determined by testing and analysis in accordance with Schedule 2 unless it is demonstrated that the materials used to make the ceramic article did not contain lead or cadmium.

(3) No person may—

- (a) manufacture,
- (b) import, or
- (c) place on the market,

a ceramic article which does not comply with the requirements of paragraph (1).

Declaration of Compliance

4.—(1) A manufacturer or seller of a ceramic article which is not yet in contact with food shall provide a written declaration in accordance with Schedule 3 to accompany the article at the marketing stages up to and including the retail stage.

(2) The declaration shall be issued by the manufacturer or by a seller established within the Community.

(3) A manufacturer or importer of a ceramic article into the Community shall on request make available to an enforcement authority appropriate documentation to demonstrate compliance with the requirements of regulation 3(1) including—

- (a) the results of analysis carried out,
- (b) the test conditions, and

(a) S.I. 2006/15.

- (c) the name and the address of the laboratory that performed the testing, or
 - (d) evidence that the materials used to make the ceramic article did not contain lead or cadmium.
- (4) This regulation does not apply to a ceramic article which is second-hand.

Enforcement

5. The following authorities shall execute and enforce these Regulations—
- (a) each food authority in its area;
 - (b) each port health authority in its district.

Offences and penalties

6.—(1) A person who contravenes a provision of regulation 3(3) or 4(1) or (3) is guilty of an offence.

- (2) A person guilty of an offence under paragraph (1) is liable—
- (a) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both; or
 - (b) on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both.

(3) In proceedings for an offence in respect of failure to comply with regulation 4 it shall be a defence to prove that the ceramic article to which the offence relates was first placed on the market in the Community before 20th May 2007.

Application of the Food Safety Act 1990

7. The following provisions of the Food Safety Act 1990 apply for the purposes of these Regulations, with reference in those provisions to the Act or a Part of it being construed as a reference to these Regulations—

- (a) section 20 (offences due to fault of another person);
- (b) section 21(1), (5) and (6) (defence of due diligence);
- (c) section 33 (obstruction etc of officers);
- (d) section 34 (time limit for prosecutions) applies to offences under regulation 6 as it applies to offences punishable under section 35(2);
- (e) section 35(1)(a), (2) and (3)(b) (punishment of offences) in so far as it relates to offences under section 33 as applied by this regulation;
- (f) section 36 (offences by bodies corporate);
- (g) section 36A(b) (offences by Scottish partnerships);
- (h) section 44 (protection of officers acting in good faith).

Gerry Sutcliffe
Parliamentary Under Secretary of State
for Employment Relations and Consumer Affairs
Department of Trade and Industry

24th April 2006

(a) Section 35(1) is amended by paragraph 42 of Schedule 26 to the Criminal Justice Act 2003 (c.44) from a date to be appointed.
(b) Section 36A was inserted by paragraph 16 of Schedule 5 to the Food Standards Act 1990.

SCHEDULE 1

Regulation 3(1)

Maximum quantities of lead and cadmium which may be transferred from a ceramic article (migration limits)

The quantity of lead and/or cadmium extracted during the test carried out under the conditions laid down in Schedule 2 shall not exceed the following limits—

	<i>Lead</i>	<i>Cadmium</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

Where a ceramic article does not exceed the above quantities by more than 50%, that article shall nevertheless be recognised as satisfying the requirements of these Regulations 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 Schedule 2 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%.

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 obtained shall be related as appropriate to the surface area or the volume of the vessel alone.

PART 1

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND
CADMIUM**Test liquid (“simulant”)**

1. 4% (v/v) acetic acid, in a freshly prepared aqueous solution.

Test conditions

- 2.—(1) Carry out the test at a temperature of $22^{\circ} \pm 2^{\circ}$ C for a duration of 24 ± 0.5 hours.
(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.
(3) 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.

Filling

- 3.—(1) Samples which can be filled—
 - (a) 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.
 - (b) 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.
- (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 receptacle containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with the foodstuffs is completely covered by the test liquid.

Determination of the surface area

4. 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 paragraph 3.

PART 2

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

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

Principle

2. 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.

Reagents

3.—(1) All reagents must be of analytical quality, unless otherwise specified.

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

(3) 4 % (v/v) acetic acid, in aqueous solution: add 40 ml of glacial acetic acid to water and make up to 1000 ml.

(4) 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 sub-paragraph (3).

Performance criteria of the instrumental method of analysis

4.—(1) The detection limit for lead and cadmium must be equal to or lower than—

(a) 0.1 mg/litre for lead;

(b) 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 paragraph 3(3), which gives a signal equal to twice the background noise of the instrument.

(2) The limit of quantification for lead and cadmium must be equal to or lower than—

(a) 0.2 mg/litre for lead;

(b) 0.02 mg/litre for cadmium.

(3) Recovery: the recovery of lead and cadmium added to the 4% acetic acid solution, as referred to in paragraph 3(3), must lie within 80-120% of the added amount.

(4) Specificity: the instrumental method of analysis used must be free from matrix and spectral interferences.

Method

5.—(1) Preparation of the sample—

(a) the sample must be clean and free from grease or other matter likely to affect the test;

(b) 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.

(2) Determination of lead and/or cadmium—

(a) the sample thus prepared is tested under the conditions laid down in Schedule 1;

(b) 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;

(c) carry out a blank test on the reagent used for each series of determinations;

(d) carry out determinations for lead and/or cadmium under appropriate conditions.

DECLARATION OF COMPLIANCE

1.—(1) The written declaration referred to in regulation 4(1) shall contain the following information—

(2) the identity and address of the company which manufactured the finished ceramic article or articles and (if applicable) of the importer who imports it or them into the Community;

(3) the identity of the ceramic article or articles;

(4) the date of the declaration;

(5) confirmation that the ceramic article or articles meet the relevant requirements in—

(a) these Regulations; or

(b) Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs^(a) as amended by Commission Directive 2005/31/EC of 29 April 2005^(b); and

(c) Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC^(c).

2. The written declaration shall permit an easy identification of the article or articles 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.

(a) O.J. L.,277 of 20.10.84 p.12.

(b) O.J. L. 110 of 30.4.05 p.36.

(c) O.J. L. 338, 13/11/2004 p.4-14.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations apply to ceramic articles which are intended to come into contact with food. They set limits on the amount of lead and cadmium which may be transferred from such articles together with requirements for testing for such transfer (migration) and require ceramic articles to be accompanied at the marketing stages by certificates of compliance.

These Regulations implement Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs (O.J. L.277 of 20.10.84 p.12) as amended by Commission Directive 2005/31/EC regarding a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs (O.J. L.110 of 30.4.05 p.36). The former Directive was previously implemented by the Ceramic Ware (Safety) Regulations 1988 (S.I. 1988/1647) which these Regulations revoke in respect of England, Wales and Northern Ireland.

The 1988 Regulations applied to the United Kingdom. These Regulations apply to England. Corresponding Regulations are being made for Northern Ireland, Scotland and Wales.

Regulation 2 defines “ceramic article”. Regulation 3 and Schedule 1 limit the quantities of lead and cadmium which may be transferred by a ceramic article and Schedule 2 sets out how tests for such transfer (migration) are to be carried out. Regulation 4 requires a written declaration of compliance to accompany a ceramic article or articles not yet in contact with food at all marketing stages up to the retail stage. The details of the declaration are set out in Schedule 3. The regulation also requires a manufacturer, or importer into the Community, to keep appropriate documentation to show that the article or articles comply with the requirements of Schedule 1.

Regulation 5 provides that the Regulations are to be enforced by food authorities and port health authorities in their respective areas or districts. Regulation 6 sets out the penalties for failure to comply with the Regulations and the defences that are available. Regulation 7 sets out the provisions of the Food Safety Act 1990 which are applied for the purposes of the Regulations.

A full regulatory impact assessment of the effect that this instrument will have on costs to business is available from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London, SW1H 0ET. Copies of a transposition note relating to these Regulations have been placed in the libraries of both Houses of Parliament. Copies are also available to the public from the Consumer and Competition Policy Directorate of the Department of Trade and Industry, 1 Victoria Street, London, SW1H 0ET.

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