

**2006 No. 230**

**FOOD**

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

*Made* - - - - - *28th April 2006*

*Laid before Parliament* *28th April 2006*

*Coming into force in accordance with regulation 1(2)*

The Scottish Ministers, in exercise of the powers conferred by sections 6(4), 16(2), 17(1), 26(1)(a), 2(a) and (3), 31 and 48(1) of the Food Safety Act 1990(a), section 11 of the Consumer Protection Act 1987(b) and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)(c) of the Food Safety Act 1990 to relevant advice given by the Food Standards Agency and after consultation as required by section 11(5) of the Consumer Protection Act 1987 and by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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), hereby make the following Regulations:

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Ceramic Articles in Contact with Food (Scotland) Regulations 2006.

(2) These Regulations 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.

(3) These Regulations extend to Scotland only.

**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

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(a) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; section 17(1) and (2) was amended by the Food Standards Act 1999 (c.28) (“the 1999 Act”), section 40(1) and Schedule 5, paragraphs 8 and 12(a); section 26(3) was amended by the 1999 Act, section 40(4) and Schedule 6; sections 31 and 48(1) were amended by the 1999 Act, section 40(1) and Schedule 5, paragraph 8; amendments made by the 1999 Act, Schedule 5 shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (“the 1998 Act”) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(b) 1987 c.43.

(c) Section 48(4A) was inserted by the 1999 Act, section 40(1) and Schedule 5, paragraph 21.

(d) O.J. No. L 31, 1.2.02, p.1, as last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (O.J. No. L 245, 29.9.03, p.4).

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; and

- (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, Norway, Iceland and Liechtenstein;

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

“place on the market” means the holding of ceramic articles for the purpose of 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 authority specified in regulation 5 appropriate documentation to demonstrate compliance with the requirements of regulation 3(1), including:

- (a) evidence that the materials used to make the ceramic article did not contain lead or cadmium; or
- (b) the results of analysis carried out;
- (c) the test conditions; and
- (d) the name and the address of the laboratory that performed the testing.

(4) This regulation does not apply to a ceramic article which is second-hand.

### **Enforcement**

5. Each food authority shall execute and enforce these Regulations within its area.

### **Offences and penalties**

6.—(1) A person who contravenes or fails to comply with the provisions of regulations 3(3) or 4(1) or (3) is guilty of an offence.

(2) A person found guilty of an offence under paragraph (1) is liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both; or
- (b) on conviction on indictment, to a fine or to a term of imprisonment not exceeding two years 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), with the modification that—
  - (i) the time limit referred to in section 34(b) shall be 1 year from the date on which evidence sufficient in the opinion of the prosecutor to warrant proceedings came to the knowledge of the prosecutor; and
  - (ii) the reference to section 35(2) shall be construed as a reference to regulation 6 of these Regulations;
- (e) section 35(1) to (3) (punishment of offences), in so far as it relates to offences under section 33 as applied by sub-paragraph (c);
- (f) section 36 (offences by bodies corporate);
- (g) section 36A(a) (offences by Scottish partnerships); and
- (h) section 44 (protection of officers acting in good faith).

### **Revocations**

8.—(1) The Ceramic Ware (Safety) Regulations 1988(b), in so far as they extend to Scotland, are hereby revoked.

(2) In the Official Feed and Food Controls (Scotland) Regulations 2006(c), Schedule 3 (definition of relevant food law), sub-paragraph (b), omit “except in so far as it involves the regulation of food contact materials under the Ceramic Ware (Safety) Regulations 1988”.

*LEWIS MACDONALD*

Authorised to sign by the Scottish Ministers

St Andrew's House,  
Edinburgh  
28th April 2006

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(a) Section 36A was inserted by the 1999 Act, section 40(1) and Sch. 5, para. 16.  
(b) S.I. 1988/1647.  
(c) S.S.I. 2005/616.

## 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 <sup>2</sup>	0.07 mg/dm <sup>2</sup>
Category 2: All other articles which can be filled	4.0 mg/l	0.3mg/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/dm<sup>2</sup> 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.

## TESTING OF CERAMIC ARTICLES

## PART I

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  $24 \pm 0.5$  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 1mm 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 6mm 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 above.

## PART II

### 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 1000 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; and
  - (b) 0.01 mg/litre for cadmium,where 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; and
  - (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:

- (a) the identity and address of the company which manufactured the finished ceramic article and (if applicable) of the importer who imports it into the Community;
- (b) the identity of the ceramic article;
- (c) the date of the declaration;
- (d) confirmation that the ceramic article meets the relevant requirements in—
  - (i) these Regulations; or
  - (ii) 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<sup>(a)</sup>, as last amended by Commission Directive 2005/31/EC amending Council Directive 84/500/EC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs<sup>(b)</sup>; and
  - (iii) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27th October on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC<sup>(c)</sup>.

(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.

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

(b) O.J. L 110, 30.9.05, p.36.

(c) O.J. L 338, 13.11.04, p.4.

## 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 migrate from such articles, lay down requirements for testing ceramic articles and require them to be accompanied at the marketing stages (including the retail stage) 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 so far as they extend to Scotland at regulation 8.

The 1988 Regulations applied to the United Kingdom. These Regulations extend to Scotland. Corresponding Regulations are being made for Northern Ireland, England 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 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 the manufacturer or importer into the Community to keep appropriate documentation to show that the article complies with the requirements of Schedule 1.

Regulation 5 provides that the Regulations are to be enforced by food authorities in their respective areas. 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, which includes a compliance cost assessment of the effect which these Regulations will have on business costs, has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency (Scotland), 6th Floor, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ.





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