#### WELSH STATUTORY INSTRUMENTS

## 2006 No. 1704 (W.166) FOOD, WALES

# The Ceramic Articles in Contact with Food (Wales) Regulations 2006

 Made
 27 June 2006

 Coming into force
 30 June 2006

The National Assembly for Wales makes the following Regulations in exercise of the powers conferred on it by sections 16(2), 17(1), 26(1)(a), 26(2)(a) and (3), and 48(1) of the Food Safety Act 1990(1);

In accordance with section 48(4A)(2) of the Food Safety Act it 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 (3).

#### Title, Commencement, Extent and Revocation

- 1.—(1) The title of these Regulations is the Ceramic Articles in Contact with Food (Wales) Regulations 2006, which come into force on 30 June 2006 except for regulation 3(3)(a) and (b) and 4 which come into force on 30 June 2007.
  - (2) These Regulations apply to Wales.
- (3) In the Official Feed and Food Controls (Wales) Regulations 2006(4) sub-paragraph (b) of Schedule 3 (Definition of relevant food law) is omitted.

#### Interpretation

2. In these Regulations—

"ceramic article" ("eitem geramig") 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.

**<sup>1)</sup>** 1990 c. 16.

<sup>(2)</sup> Subsection (4A) was inserted by para. 21 of Sch. 5 to the Food Standards Act 1999 (c. 28).

<sup>(3)</sup> O.J. No L 31, 1/2/2002, p.1.

<sup>(4)</sup> S.I. 2006 No.590(W.66).

- 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" ("y Gymuned") means the member States and Norway, Iceland and Liechtenstein;

"enforcement authority" ("awdurdod gorfodi") means an authority mentioned in regulation 5;

"import" ("mewnforio") means the release into the UK for free circulation in the Community;

"place on the market" ("rhoi ar y farchnad") 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 must not exceed the limits laid down in Schedule 1.
- (2) Compliance with paragraph (1) is to be determined by testing and analysis in accordance with Schedule 2 unless it is demonstrated that the materials used to make the ceramic articles 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 in paragraph (1).

#### **Declaration of Compliance**

- **4.**—(1) A manufacturer or seller of a ceramic article which is not yet in contact with food must 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 must be issued by the manufacturer or by a seller established within the Community.
- (3) The manufacturer or importer of a ceramic article into the Community must 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
  - (c) the name and address of the laboratory that performed the testing, or
  - (d) evidence that the materials used to make the ceramic article did not contact lead or cadmium
  - (4) This regulation does not apply to a ceramic article which is second-hand.

#### **Enforcement**

- 5. The following authorities are to 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 regulations 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 is a defence to prove that the ceramic article to which the offence relates was first placed on the market in the Community before 20 May 2007.

#### **Application of the Food Safety Act 1990**

- 7.—(1) The following provisions of the Food Safety Act 1990(5) 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 of the Food Safety Act 1990 (time limit for prosecutions) applies to offences under regulations 6 as it applies to offences punishable under section 35(2).
  - (e) section 35(1)(6), (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(7) (offences by Scottish partnerships);
  - (h) section 44 (protection of officers acting in good faith).

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(8).

27 June 2006

D. Elis-Thomas
The Presiding Officer of the National Assembly

**<sup>5</sup>**) 1990 c. 16

<sup>(6)</sup> Section 35(1) is amended by Sch. 26 para. 42 of the Criminal Justice Act 2003 (c. 44) from a date to be appointed.

<sup>(7)</sup> Section 36A was inserted by Sch. 5 para. 16 of the Food Standards Act 1990.

<sup>(8) 1998</sup> c. 38.

#### 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 must not exceed the following limits:

	Lead	Cadmium
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 will 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) will be that which applies to the vessel alone. The vessel alone and the inner surface of the lid must be tested separately and under the same conditions; the sum of the two lead and/or cadmium extraction levels obtained must be related as appropriate to the surface area or the volume of the vessel alone.

SCHEDULE 2

Regulation 3(2)

#### 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  $22 \pm 2^{\circ}$  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.

#### 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 will 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 1 000 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 I;
  - (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.

#### SCHEDULE 3

Regulation 4

#### DECLARATION OF COMPLIANCE

- 1.—(1) The written declaration referred to in regulation 4(1) must contain the following information—
- (2) the identity and address of the company which manufactured the finished ceramic article and (if applicable) of the importer who imports it or them into the Community;
  - (3) the identity of the ceramic article(s);
  - (4) the date of the declaration;
  - (5) confirmation that the ceramic article(s) meets 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(9) as amended by Commission Directive 2005/31/EC of 29 April 2005(10); and
- (c) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC(11).
- 2. The written declaration will permit an easy identification of the article(s) for which it is issued and must be renewed when substantial changes in the production bring about changes in the migration of lead and cadmium.

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

- 1. 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 such transfer (migration) and require ceramic articles to be accompanied at the marketing stages by certificates of compliance.
- **2.** 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 the Ceramic Articles in Contact with Food (England) Regulations 2006 (S.I. 2006/1179) revoke.
- **3.** The 1988 Regulations applied to the United Kingdom. These Regulations apply to Wales. Corresponding Regulations are being made for England, Northern Ireland and Scotland.
- **4.** 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, Schedule 2 sets out how an article is to be tested. 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 article or articles comply with the requirements of Schedule 1..
- **5.** Regulation 5 provides that the Regulations are to be enforced by food authorities and port health authorities in their respective areas of 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 provision of the Food Safety Act which are applied for the purposes of the Regulations.
- **6.** A full regulatory appraisal has been prepared for these Regulations and has been placed in the Library of the National Assembly for Wales along with a copy of the transposition note relating to

<sup>(9)</sup> O.J. L.277 of 20.10.84 p.12.

<sup>(10)</sup> O.J. L.110 of 30.4.05 p.36.

<sup>(11)</sup> O.J. L338, 13/11/2004 p.4—14.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

these Regulations. Copies are also available from the Food Standards Agency, 11th Floor, Southgate House, Cardiff CF10 1EW.