
W E L S H S T A T U T O R Y
I N S T R U M E N T S

2019 No. 425 (W. 99)

**EXITING THE EUROPEAN
UNION, WALES**

AGRICULTURE, WALES

FOOD, WALES

**The Food and Feed Regulated
Products (Miscellaneous
Amendments) (Wales) (EU Exit)
Regulations 2019**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, other than regulation 3(6), are made in exercise of the powers conferred on the Welsh Ministers by paragraph 1(1) of Schedule 2 to the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

Regulation 3(6) is made under section 16 of the Food Safety Act 1990 (c. 16) to amend the Materials and Articles in Contact with Food (Wales) Regulations 2012 to set the criteria applicable to the method for determining the level of vinyl chloride in materials and articles in contact with food and of determining the level of vinyl chloride released by those materials and articles.

These Regulations make amendments to subordinate legislation applying in Wales in the field of genetically modified food and feed, materials and articles in contact with food, and food additives, flavourings, enzymes and extraction solvents.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a

regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

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Sift requirements satisfied 11 February 2019

Made 4 March 2019

Laid before the National Assembly for Wales
5 March 2019

*Coming into force in accordance with
regulation 1(3)*

The Welsh Ministers make these Regulations in exercise of the powers conferred by paragraph 1(1) of Schedule 2 to the European Union (Withdrawal) Act 2018(1) and by section 16(2)(a) of the Food Safety Act 1990(2).

The requirements of paragraph 4(2) of Schedule 7 to the European Union (Withdrawal) Act (relating to the appropriate National Assembly for Wales scrutiny procedure for these Regulations) have been satisfied.

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- (1) 2018 c.16.
(2) 1990 c. 16. Section 16(2) was amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”). Functions formerly exercisable by “the Ministers” so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).

As required 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⁽¹⁾ there has been open and transparent public consultation during the preparation of these Regulations.

Title, application and commencement

1.—(1) The title of these Regulations is the Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019.

(2) These Regulations apply in relation to Wales.

(3) These Regulations come into force on exit day.

The Genetically Modified Food (Wales) Regulations 2004

2. In the Schedule to the Genetically Modified Food (Wales) Regulations 2004⁽²⁾, in Part 2, in the table, omit the entry for Article 8.6.

The Materials and Articles in Contact with Food (Wales) Regulations 2012

3.—(1) The Materials and Articles in Contact with Food (Wales) Regulations 2012⁽³⁾ are amended as follows.

(2) In regulation 2(1), omit the definition of “Directive 84/500/EEC”.

(3) In regulation 9, omit paragraph (b).

(4) For regulation 10 substitute—

“**10.**—(1) The quantities of lead and cadmium transferred from a ceramic article must not exceed the limits set out in paragraph (5) as read with paragraphs (4) and (6).

(2) Unless it is demonstrated that the materials used to make the ceramic article did not contain lead or cadmium, the quantities of lead and cadmium transferred from a ceramic article must be determined by means of a test, the conditions of which are specified in Schedule 3, using the method of analysis described in Schedule 4.

(3) No person may place on the market a ceramic article that does not comply with the

(1) OJ No. L 31, 1.2.2002, p. 1, to which there are amendments not relevant to these Regulations.

(2) S.I. 2004/3220 (W. 276), to which there are amendments not relevant to these Regulations.

(3) S.I. 2012/2705 (W. 291), to which there are amendments not relevant to these Regulations.

requirements of paragraph (1) as read with paragraph (2).

(4) Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead or cadmium limits (or both) which may not be exceeded (mg/dm² or mg/litre) must 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 or cadmium extraction levels obtained by this method must be related as appropriate to the surface area or the volume of the vessel alone.

(5) A ceramic article is to be recognised as satisfying the requirements of these Regulations relating to such articles if the quantities of lead and/or cadmium extracted during the test carried out under the conditions laid down in Schedule 3 and Schedule 4 do not exceed the following limits—

	<i>Lead (Pb)</i>	<i>Cadmium (Cd)</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

(6) However, where a ceramic article does not exceed the above quantities by more than 50%, that article is nevertheless to be recognised as satisfying the requirements of these Regulations relating to such articles 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 3 and Schedule 4 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%.”

(5) After regulation 10 insert—

“**10A.**—(1) A person who places on the market a ceramic article which is not yet in contact with foodstuffs must provide a written declaration in accordance with Article 16 of Regulation 1935/2004 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 in the United Kingdom and must contain the information laid down in Schedule 5.

(3) A person who manufactures or, in the course of a business, imports into the United Kingdom a ceramic article must on request make available to an authorised officer appropriate documentation to demonstrate that the ceramic article complies with the migration limits for lead and cadmium set out in regulation 10 including—

- (a) the results of the analysis carried out;
- (b) the test conditions;
- (c) the name and the address of the laboratory that performed the testing.

(4) Paragraphs (1), (2) and (3) do not apply in relation to a ceramic article which is second-hand.

(5) The documentation specified in paragraph (3)(a), (b) and (c) is not required where documentary evidence is provided to show that the materials used to make the ceramic article did not contain lead or cadmium.”

(6) In regulation 18, after paragraph (2) insert—

“(3) The method of analysis used for checking compliance with paragraph (1) must comply with the criteria set out in paragraphs (4), (5) and (6).

(4) The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the ‘headspace’ method.

(5) For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit is 0.01 milligrams of vinyl chloride per kilogram of food.

(6) Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in

certain foodstuffs is shown to be impossible for technical reasons, a food authority may permit determination by simulants for these particular foodstuffs.”

(7) After Schedule 2, insert the new Schedules 3 to 5 set out in the Schedule to these Regulations.

The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013

4. In regulation 10(b) of the Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013⁽¹⁾, for “European Union” substitute “United Kingdom”.

Vaughan Gething

Minister for Health and Social Services, one of the
Welsh Ministers

4 March 2019

(1) S.I. 2013/2591 (W. 255), to which there are amendments not relevant to these Regulations.

SCHEDULE Regulation 3(7)

“SCHEDULE 3 Regulation 10

**BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND
CADMIUM**

1. Test liquid

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

2. Test conditions

- (a) Carry out the test at a temperature of 22 ± 2 °C for a duration of $24 \pm 0,5$ hours.
- (b) 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. 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.

3. Filling

- (a) Samples which can be filled—

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. 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.

- (b) 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 recipient containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with foodstuffs is completely covered by the test liquid.

4. Determination of the surface area

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.

SCHEDULE 4

Regulation 10

**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, it means distilled water or water of equivalent quality.

- (a) 4 % (v/v) acetic acid, in aqueous solution

Add 40 ml of glacial acetic acid to water and make up to 1 000 ml.

- (b) 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 (a).

4. Performance criteria of the instrumental method of analysis

- (a) 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.

The detection limit is defined as the concentration of the element in the 4 % acetic acid solution, as referred to in paragraph 3(a), which gives a signal equal to twice the background noise of the instrument.

- (b) 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.
- (c) Recovery. The recovery of lead and cadmium added to the 4 % acetic acid solution, as referred to in paragraph 3(a), must lie within 80-120 % of the added amount.
- (d) Specificity. The instrumental method of analysis used must be free from matrix and spectral interferences.

5. Method

- (a) 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 tap water and then in distilled water or water of equivalent quality. Drain and dry the sample so as to avoid any stain. The surface to be tested is not to be handled after it has been cleaned.

- (b) Determination of lead and/or cadmium

The sample thus prepared is tested under the conditions laid down in Schedule 3.

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.

SCHEDULE 5

Regulation 10A

DECLARATION OF COMPLIANCE

- 1.** The written declaration referred to in regulation 10A must contain the following information—
 - (a) the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the United Kingdom;
 - (b) the identity of the ceramic article;
 - (c) the date of the declaration;
 - (d) the confirmation that the ceramic article meets relevant requirements in these Regulations and Regulation 1935/2004.

- 2.** The written declaration must permit an easy identification of the goods for which it is issued and must be renewed when substantial changes in the production bring about changes in the migration of lead or cadmium or both.”