
SCOTTISH STATUTORY INSTRUMENTS

2019 No. 52

The Food and Feed Safety and Hygiene (EU Exit) (Scotland) (Amendment) Regulations 2019

Amendment of the Materials and Articles in Contact with Food (Scotland) Regulations 2012

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

(2) In regulation 4 (offences of contravening specified provisions of Regulation 1935/2004) in paragraph (3) omit “Community”.

(3) In regulation 6 (competent authorities for the purposes of Regulation 1935/2004 and Regulation 2023/2006)—

(a) in paragraph (1)(a)—

(i) for “Articles” substitute “Article”, and

(ii) omit “and 13 (competent authorities of Member States)”⁽²⁾, and

(b) in paragraph (1)(b) for “16(1)” substitute “16”.

(4) In regulation 9 (interpretation of this part) omit paragraph (b).

(5) For regulation 10 (limits for lead and cadmium and declaration of compliance) 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 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 or cadmium (or both) extracted during the test carried out under the conditions laid down in Schedule 3 and Schedule 4 do not exceed the following limits—

(1) [S.S.I. 2012/318](#), relevant amending instrument [S.S.I. 2015/100](#).

(2) Regulation 6(1)(a) was amended by [S.S.I. 2015/100](#), regulation 2.

	<i>Pb</i>	<i>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 or cadmium (or both) extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50%.”

(6) 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, and
- (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.”

(7) In regulation 20 (execution and enforcement) in paragraph (2)(a) for “16(1)” substitute “16”.

(8) After schedule 2 (revocations) insert schedules 3, 4 and 5:

“SCHEDULE 3

Regulation 10

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

1. Test liquid (‘simulant’)

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

4. The surface area of the articles in category 1 in regulation 10(5) 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

1. The method allows the specific migration of lead or cadmium (or both) to be determined.

2. Principle

2. The determination of the specific migration of lead or cadmium (or both) is carried out by an instrumental method of analysis that fulfils the performance criteria of paragraph 4.

3. Reagents

3. All reagents must be of analytical quality, unless otherwise specified.

Where reference is made to water, it shall always mean 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 paragraph 3(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 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 or cadmium (or both)
The sample prepared in accordance with paragraph 5(a) is tested under the conditions laid down in schedule 3.
Before taking the test solution for determining lead or cadmium (or both), 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 or cadmium (or both) under appropriate conditions.

SCHEDULE 5

Regulation 10

DECLARATION OF COMPLIANCE

1. The declaration referred to in regulation 10A must contain the following information—
- the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into the United Kingdom,
 - the identity of the ceramic article,
 - the date of the declaration, and

(d) the confirmation that the ceramic article meets relevant requirements in these Regulations and Regulation (EC) No 1935/2004.

2. The declaration must 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.”.