## 2019 No. 0000

# EXITING THE EUROPEAN UNION, NORTHERN IRELAND

## FOOD, NORTHERN IRELAND

The Regulated Products (Amendment) (Northern Ireland) (EU Exit) Regulations 2019

| Sift requirements satisfied- | - 2019 |
|------------------------------|--------|
| Made                         | - 2019 |
| Laid before Parliament-      | - 2019 |

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018(a).

The requirements of paragraph 3(2) of Schedule 7 to the European Union (Withdrawal) Act 2018 (relating to the appropriate Parliamentary procedure for these Regulations) have been satisfied.

There has been consultation 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(b).

### PART 1

## **PRELIMINARY**

#### Citation and commencement

**1.** These Regulations may be cited as the Regulated Products (Amendment) (Northern Ireland) (EU Exit) Regulations 2019 and come into force on exit day.

<sup>(</sup>a) 2018 c. 16.

<sup>(</sup>b) OJ No. L31, 1.2.2002, p.1, last amended by Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ No. L 117, 5.5.2017, p. 1).

#### PART 2

## Amendment of subordinate legislation

### Amendment of the Genetically Modified Food Regulations (Northern Ireland) 2004

- 2. The Genetically Modified Food Regulations (Northern Ireland 2004(a) are amended as follows.
- 3. In the Schedule, in Part II—
  - (a) omit the entries in the Table which relate to Article 8.6 of Regulation (EC) No. 1829/2003;
  - (b) in the entry in the second column of the Table which corresponds to the entry in the first column of the Table relating to Article 9.3 of Regulation (EC) No. 1829/2003, for "Commission", substitute "Food Safety Authority".

## Amendment of the Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012

- **4.** The Materials and Articles in Contact with Food Regulations (Northern Ireland) 2012(**b**) are amended as follows.
  - 5. In regulation 2(1) (Interpretation) omit the definition of "Directive 84/500/EEC".
- **6.** In regulation 4, (Offences of contravening specified provisions of Regulation 1935/2004) in paragraph (3), omit "Community".
- **7.** In regulation 6 (Competent Authorities for the purposes of Regulation 1935/2004 and Regulation 2023/2006)—
  - (a) omit paragraph (1)(a);
  - (b) in paragraph (1)(b), for "16(1)", substitute "16".
  - **8.** In regulation 9 (Interpretation of this Part) omit 9(1)(b).
  - 9. For regulation 10 (Limits for lead and cadmium and declaration of compliance), substitute—
    - "10.—(1) The quantities of lead or cadmium transferred from a ceramic article must not exceed the limits laid down in paragraph (4) of regulation 10A as read with paragraphs (3) and (5) of regulation 10A.
    - (2) Unless it is demonstrated that the materials used to make the ceramic article did not contain lead or cadmium, compliance with paragraph (1) is to be determined by testing and analysis in accordance with Schedules 3 and 4.
    - (3) A person must not place on the market a ceramic article that does not comply with the requirements of paragraph (1) as read with paragraph (2).
    - (4) A person who places on the market a ceramic article that is not yet in contact with food must provide a written declaration complying with paragraph (5) to accompany the article at the marketing stages up to and including the retail stage in accordance with Article 16 of Regulation 1935/2004.
    - (5) The declaration must be issued by the manufacturer or by a person established in the United Kingdom who placed the ceramic article on the market and must contain the information laid down in Schedule 5.
    - (6) A person who manufactures or, in the course of business, imports into the United Kingdom a ceramic article must on request make available to an authorised officer

<sup>(</sup>a) S.R. 2004 No. 385.

<sup>(</sup>**b**) S.R. 2012 No. 384.

appropriate documentation to demonstrate compliance with the requirements of paragraph (1) 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.
- (7) Paragraphs (4), (5) and (6) do not apply in relation to a ceramic article which is second-hand.
- (8) The documentation specified in paragraphs (6)(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."
- **10.** After regulation 10 (Limits for lead and cadmium and declaration of compliance) insert a new regulation 10A—

## "Limits for lead and cadmium and determining quantities transferred

- **10A.**—(1) The quantities of lead and cadmium transferred from ceramic articles must not exceed the limits laid down below.
- (2) The quantities of lead and cadmium transferred from ceramic articles 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) 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 shall be tested separately and under the same conditions. The sum of the two lead or cadmium extraction levels thus obtained shall be related as appropriate to the surface area or the volume of the vessel alone.
- (4) A ceramic article shall 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—

|  | Pb         | Cd          |
|--|------------|-------------|
| Category 1— Articles which cannot be filled and            | 0,8 mg/dm2 | 0,07 mg/dm2 |
| 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.      |            |             |
| Category 2— All other articles which can be filled.        | 4,0 mg/l   | 0,3 mg/l    |
| Category 3— Cooking ware; packaging and storage            | 1,5 mg/l   | 0,1 mg/l    |
| vessels having a capacity of more than three litres.       |            |             |

- (5) However, 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 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 %.".
- **11.** In regulation 18 (Requirements on materials and articles manufactured with vinyl chloride), after paragraph (2), insert—
  - "(3) The method of analysis for checking compliance with paragraph (1) shall 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 mg/kg.
- (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, competent authorities may permit determination by simulants for these particular foodstuffs.".
- 12. In regulation 20(2)(a) (Enforcement) for "16(1)" substitute "16".
- **13.** After Schedule 2, insert the new Schedules 3 to 5 set out in the Schedule to these Regulations.

## Amendment of the Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (Northern Ireland) 2013

- **14.** The Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations (Northern Ireland) 2013(a) are amended as follows.
  - 15. In regulation 10(b) for "European Union" substitute "United Kingdom".
  - 16. In regulation 14(1)(d) for "territory of the EU" substitute "United Kingdom".
  - **17.** Omit regulation 15.
  - **18.** In Schedule 1—
    - (a) in Table 1 in the entry for Article 26.1 in the second column for "Commission" substitute "Authority";
    - (b) in Table 2—
      - (i) in the entry for Article 21.1 (as read with Article 22) in the second column for "a language easily understandable to purchasers" substitute "English or in English and Welsh":
      - (ii) entry for Article 26.2 in the second column for "Commission" substitute "Authority".
  - **19.** In Schedule 2 in Table 1—
    - (a) in the entry for Article 10 in the second column for "Union" substitute "domestic";
    - (b) in the entry for Article 19.2 in the second column for "Commission" substitute "Authority";
    - (c) in the entry for Article 19.3 in the second column for "Commission" substitute "Authority".
- **20.** In Schedule 3 in Table 1 in the entry for Article 9.5 in the second column for "Commission" substitute "Authority".
  - 21. In Schedule 4 in Table 1—
    - (a) in the entry for Article 4 in the second column for "Union" substitute "domestic";
    - (b) in the entry for Article 14.1 in the second column for "Commission" substitute "Authority";
    - (c) in the entry for Article 14.2 in the second column for "Commission" substitute "Authority".

<sup>(</sup>a) S.R. 2013 No. 220.

#### Amendment of the Novel Foods Regulations (Northern Ireland) 2017

- 22. The Novel Foods Regulations (Northern Ireland) 2017(a) are amended as follows.
- 23. In regulation 4 (Offence and penalty) omit "Union".
- **24.** In Schedule 1, in column 2 of the Table—
  - (a) in the entry which relates to Article 6.2 as read with Article 24, omit "Union";
  - (b) in the entry which relates to Article 25, for "Commission", substitute "Food Safety Authority".

Signed by the authority of the Secretary of State for Health and Social Care.

Name

Address Date Parliamentary Under-Secretary of State, Department for Health and Social Care

## **SCHEDULE**

Regulation 13

## "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  $22 \pm 2$  °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

<sup>(</sup>a) S.R. 2017 No. 233.

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.

## 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 point (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 point 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 point 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 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 10

## **DECLARATION OF COMPLIANCE**

- **1.** The written declaration referred to in regulation 10(5) shall 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 shall 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 or cadmium or both."

### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in section 8(1) of 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.

These Regulations make amendments to subordinate legislation in the field of regulated products.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

