SCOTTISH STATUTORY INSTRUMENTS

2019 No. 52

EXITING THE EUROPEAN UNION AGRICULTURE ENVIRONMENTAL PROTECTION FOOD

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

Made - - - - 18th February 2019

Laid before the Scottish

Parliament - - - 19th February 2019

Coming into force in accordance with regulation 1

The Scottish Ministers make the following Regulations in exercise of the powers conferred on them by paragraph 1(1) and (3) of schedule 2 and paragraph 21(b) of schedule 7 of the European Union (Withdrawal) Act 2018(1) and all other powers enabling them to do so.

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.

Citation, commencement and extent

- 1.—(1) These Regulations may be cited as the Food and Feed Safety and Hygiene (EU Exit) (Scotland) (Amendment) Regulations 2019 and come into force on exit day.
 - (2) These Regulations extend to Scotland only.

Amendment of the General Food Regulations 2004

- **2.**—(1) The General Food Regulations 2004(2) are amended as follows.
- (2) In regulation 4 (requirements under Regulation (EC) No. 178/2002: offences), in paragraph (a), for "Community" substitute "United Kingdom".

^{(1) 2018} c.16. Section 20 defines "devolved authority" as the Scottish Ministers.

⁽²⁾ S.I. 2004/3279, relevant amending instruments are S.I. 2005/3254, S.S.I. 2005/616, S.I. 2005/2626, S.I. 2013/2996.

- (3) For regulation 6A (defence for exports) substitute—
 - "(6A) In any proceedings for an offence of contravening or failing to comply with food law it is a defence for the accused to prove that the item in respect of which the offence is alleged to have been committed—
 - (a) was intended for export to a third country; and
 - (b) could lawfully be exported there under Article 12 of Regulation (EC) No. 178/2002."

Amendment of the Genetically Modified Food (Scotland) Regulations 2004

- **3.**—(1) The Genetically Modified Food (Scotland) Regulations 2004(3) are amended as follows.
- (2) In regulation 2 (interpretation), in paragraph (a)—
 - (a) omit "and" at the end of the definition of "food", and
 - (b) after that definition insert—
 - ""third country" means a country other than the United Kingdom; and".
- (3) In the schedule (specified community provisions), in the table in Part II—
 - (a) omit the entry relating to Article 8.6 of Regulation (EC) No. 1829/2003, and
 - (b) in the entry relating to Article 9.3 of that Regulation, for "Commission" substitute "Food Safety Authority".

Amendment of the Genetically Modified Animal Feed (Scotland) Regulations 2004

- **4.**—(1) The Genetically Modified Animal Feed (Scotland) Regulations 2004(**4**) are amended as follows.
- (2) In the schedule (specified community provisions), in the table in Part II, omit the entry relating to Article 20.6 of Regulation (EC) No. 1829/2003.

Amendment of the Food Hygiene (Scotland) Regulations 2006

- 5.—(1) The Food Hygiene (Scotland) Regulations 2006(5) are amended as follows.
- (2) In the table in schedule 2 (specified community provisions)—
 - (a) in the entry relating to Article 6(1) of Regulation (EC) No. 852/2004, for "Community legislation or national law" substitute "retained EU law or other national law",
 - (b) in the entry relating to Article 4(1) of Regulation (EC) No. 853/2004 omit "manufactured in the Community", and
 - (c) omit the entry relating to Article 8 of Regulation (EC) No. 853/2004.
- (3) In schedule 6 (restrictions on the placing on the market of raw milk and raw cream intended for direct human consumption), in paragraph 3(a), omit—
 - (a) "or to a member state other than the United Kingdom", and
 - (b) "or to that member state".

⁽³⁾ S.S.I. 2004/432, relevantly amended by S.I. 2013/2996.

⁽⁴⁾ S.S.I. 2004/433.

⁽⁵⁾ S.S.I. 2006/3.

Amendment of the Food Irradiation (Scotland) Regulations 2009

- **6.**—(1) The Food Irradiation (Scotland) Regulations 2009(**6**) are amended as follows.
- (2) In regulation 3 (interpretation)—
 - (a) for the definition of "import" (7), substitute—
 - ""import" means to introduce from a country outside the United Kingdom;", and
 - (b) for the definition of "official reference number", substitute—
 - ""official reference number" in relation to a facility means the reference number allocated and listed for approved irradiation facilities in schedules 3 and 4;".
- (3) In regulation 5 (restrictions on importation)(8)—
 - (a) in paragraph (1), for sub-paragraph (b) substitute—
 - "(b) it has been irradiated in one of the facilities listed in the table in schedule 3 or the table in schedule 4;",
 - (b) in paragraph (2), for "another member state" substitute "an approved irradiation facility listed in schedule 3", and
 - (c) in paragraph (3), for "outside the European Union" substitute "in an approved irradiation facility listed in schedule 4".
- (4) In the heading to schedule 3 (list of approved facilities in member states), for "in member states" substitute "within the United Kingdom and European Union".
- (5) In the heading to schedule 4 (list of facilities in a country outside the European Union), insert "approved" before "facilities" and insert "United Kingdom and" before "European Union".

Amendment of the Official Feed and Food Controls (Scotland) Regulations 2009

- 7.—(1) The Official Feed and Food Controls (Scotland) Regulations 2009(9) are amended as follows.
 - (2) In regulation 4 (exchanging and providing information)(10)—
 - (a) in paragraph (1), for "member States" substitute "appropriate authorities", and
 - (b) in paragraph (4), for "EU legislation" substitute "retained EU law".
- (3) In regulation 5 (obtaining information), in paragraph (1), for "member States" substitute "appropriate authorities".
- (4) In regulation 10 (meaning of "enforcement authority" and related expressions), in paragraph (2), omit "but does not include the European Commission".
- (5) Omit regulations 14 (staff of competent authority of another member state), 15 (commission experts) and 16 (prohibition on disclosure of trade secrets).
 - (6) In regulation 17 (execution and enforcement)—
 - (a) omit paragraph (3),
 - (b) in paragraph (5), omit sub-paragraphs (a) and (b).
- (7) In regulation 19 (obstruction etc. of officers), in paragraph (1), omit "14, 15 or" in both places where it appears.

⁽⁶⁾ S.S.I. 2009/261, relevant amending instruments are S.I. 2011/1043, S.S.I. 2010/328.

⁽⁷⁾ The definition of "import" was amended by article 4(1) of part 2 of the Treaty of Lisbon (Changes in Terminology) Order 2011/1043 ("the 2011 Order").

⁽⁸⁾ Regulation 5 was amended by article 4(1) of part 2 of the 2011 Order.

⁽⁹⁾ S.S.I. 2009/446, relevant amendment S.I. 2011/1043.

⁽¹⁰⁾ Regulation 4 was amended by article 6(2)(b) of part 2 of the 2011 Order.

- (8) In regulation 20 (penalties), in paragraph (2), for ", 11 or 16" substitute "or 11".
- (9) In regulation 22 (interpretation of this part of these regulations) omit the definition of "the relevant territories".
 - (10) In regulation 28 (prohibition on introduction of certain feed and food)—
 - (a) at the end of paragraph (1)(a) insert "and",
 - (b) omit paragraph (1)(b),
 - (c) at the end of paragraph (1)(c) omit "and", and
 - (d) omit paragraph (1)(d).
- (11) Omit regulation 44 (expenses arising in respect of co-ordinated assistance and follow-up by the Commission).
- (12) In the table in schedule 4 (competent authorities for the purposes of certain provisions of Regulation 882/2004 in so far as they apply in relation to relevant feed law)—
 - (a) in the first entry, in column 2, omit the references to the following provisions of Regulation (EC) No. 882/2004—
 - (i) Article 19(3),
 - (ii) Article 34,
 - (iii) Article 35(3) and (4),
 - (iv) Article 36,
 - (v) Article 37(1),
 - (vi) Article 38,
 - (vii) Article 39,
 - (viii) Article 40(2) and (4), and
 - (ix) Article 52(1), and
 - (b) in the second entry, in column 2, omit the references to the following provisions of that Regulation—
 - (i) Article 34,
 - (ii) Article 35(3),
 - (iii) Article 36,
 - (iv) Article 37(1),
 - (v) Article 38,
 - (vi) Article 39, and
 - (vii) Article 40(2) and (4).
- (13) In the table in schedule 5 (competent authorities for the purposes of certain provisions of Regulation 882/2004 in so far as they apply in relation to relevant food law)—
 - (a) in the first entry, in column 2, omit the references to the following provisions of Regulation (EC) No. 882/2004—
 - (i) Article 19(3),
 - (ii) Article 34,
 - (iii) Article 35(3) and (4),
 - (iv) Article 36,
 - (v) Article 37(1),

- (vi) Article 38,
- (vii) Article 39,
- (viii) Article 40(2) and (4), and
- (ix) Article 52(1), and
- (b) in the second entry, in column 2, omit the references to the following provisions of that Regulation—
 - (i) Article 34,
 - (ii) Article 35(3),
 - (iii) Article 36,
 - (iv) Article 37(1),
 - (v) Article 38,
 - (vi) Article 39, and
 - (vii) Article 40(2) and (4).
- (14) In schedule 6 (specified import provisions), in the first entry in column 2 of the table, for "in the official language of the member State), although the member State may consent to common entry documents being drawn up in another official language of the European Union" substitute "in English, or in English and Welsh)."

Amendment of the Animal Feed (Scotland) Regulations 2010

- **8.**—(1) The Animal Feed (Scotland) Regulations 2010(11) are amended as follows.
- (2) In regulation 5 (competent authorities for the purpose of Regulation 767/2009)(12)—
 - (a) omit paragraph (2)(a), and
 - (b) in paragraph (2)(b) for "Commission" substitute "appropriate authority".
- (3) In the table in schedule 1, omit the entry in relation to Article 25(4) of Regulation (EC) No. 767/2009.

Amendment of the Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011

- **9.**—(1) The Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011(**13**) are amended as follows.
- (2) In regulation 3 (breach of conditions on import of plastic kitchenware from China) in paragraph (1) for "European Union" substitute "United Kingdom".
- (3) In regulation 8 (notices and actions in the case of non-compliance) in paragraph (3)(a)(i) for "European Union" substitute "United Kingdom".

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(**14**) are amended as follows.

⁽¹¹⁾ S.S.I. 2010/373, relevant amending instruments are S.S.I. 2013/340, S.S.I. 2015/100.

⁽¹²⁾ Regulation 5 was amended by S.S.I. 2015/100, article 2.

⁽¹³⁾ S.S.I. 2011/282.

⁽¹⁴⁾ S.S.I. 2012/318, relevant amending instrument S.S.I. 2015/100.

- (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)"(15), 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—

	Pb	Cd
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 ± 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) 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 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

Object and field of application

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

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.

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—
 - (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, 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."

Amendment of the Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013

- 11.—(1) The Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013(16) are amended as follows.
 - (2) In schedule 2 (qualifications of food examiners)—
 - (a) in Part 1, paragraph 7, for "another Member State", substitute "the European Union", and
 - (b) in Part 2, paragraph 2, for "of another Member State" substitute "in the European Union".
- (3) In Part 2, paragraph 4, for "of another Member State" substitute "in a Member State of the European Union".

Amendment of the Contaminants in Food (Scotland) Regulations 2013

- 12.—(1) The Contaminants in Food (Scotland) Regulations 2013(17) are amended as follows.
- (2) In regulation 5 (controls on contaminants in food) omit "EU" in each place where it appears.
- (3) In regulation 8 (application of various sections of the Food Safety Act 1990), in paragraph (2), in the text of section 9 of the Food Safety Act 1990(18) as it applies for the purposes of the Contaminants in Food (Scotland) Regulations 2013, omit "EU" in each place where it appears.

St Andrew's House, Edinburgh 18th February 2019

JOE FITZPATRICK
Authorised to sign by the Scottish Ministers

⁽¹⁷⁾ S.S.I. 2013/217.

^{(18) 1990} c.16.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by paragraph 1(1) and (3) of schedule 2 and paragraph 21(b) of schedule 7 of the European Union (Withdrawal) Act 2018 (c.16) to address failures of retained EU law to operate effectively, and other deficiencies, arising from the withdrawal of the UK from the European Union.

These Regulations make amendments to subordinate legislation in the field of Food and Feed Safety and Hygiene in relation to Scotland.

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