WELSH STATUTORY INSTRUMENTS

2012 No. 2705 (W.291) FOOD, WALES

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

Made - - - - 27 October 2012
Laid before the National
Assembly for Wales - - 30 October 2012
Coming into force - - 20 November 2012

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), (2)(a) and (3), 31 and 48(1) of the Food Safety Act 1990 ^{M1}, and now vested in them ^{M2}, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972 ^{M3}.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Welsh Ministers that it is expedient for certain references to Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food ^{M4} or to any Annex to the other EU instruments specified in regulation 2(3) to be construed as references to that Regulation or that Annex as amended from time to time.

In accordance with section 48(4A) of the 1990 Act they have had regard to relevant advice given by the Food Standards Agency.

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 ^{M5}, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Marginal Citations

M1 1990 c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c. 28), "the 1999Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c. 40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.

M2 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 (2006 c. 32).
- M3 1972 c. 68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006, c. 51) and amended by Part 1 of Schedule 1 to the European Union (Amendment) Act 2008 (2008 c. 7).
- **M4** OJ No. L384, 29.12.2006, p.75, amended by Commission Regulation (EC) No.282/2008 (OJ No. L86, 28.3.2008, p.9).
- M5 OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny Part Four (OJ No. L188, 18.7.2009, p.14).

PART 1

Preliminary

Title, application and commencement

1. The title of these Regulations is the Materials and Articles in Contact with Food (Wales) Regulations 2012, they apply in relation to Wales and come into force on 20 November 2012.

Interpretation

2.—(1) In these Regulations—

"the Act" ("y Ddeddf") means the Food Safety Act 1990;

F1...

"Directive 2007/42/EC" ("*Cyfarwyddeb 2007/42/EC*") means Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs ^{M6};

"Regulation 1935/2004" ("*Rheoliad 1935/2004*") means Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC^{M7};

"Regulation 1895/2005" ("*Rheoliad 1895/2005*") means Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food ^{M8};

"Regulation 2023/2006" ("*Rheoliad 2023/2006*") means Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food ^{M9};

"Regulation 450/2009" ("*Rheoliad* 450/2009") means Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food M10:

[F2: Regulation 10/2011" ("Rheoliad 10/2011") means Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food;]

[F3: Regulation 2018/213" ("Rheoliad 2018/213") means Commission Regulation (EU) 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials;

"authorised officer" ("swyddog awdurdodedig") means any person, whether or not an officer of the authority concerned, who is authorised in writing by an authority having responsibility for execution and enforcement under regulation 20 to act in matters arising under these Regulations;

"food authority" ("awdurdod bwyd") does not include a port health authority;

"port health authority" ("awdurdod iechyd porthladd") means, in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984 MII, a port health authority for that district constituted by order under section 2(4) of that Act;

"preparation" ("paratoi") includes manufacture and any form of treatment or process, and "prepare" ("paratoi") is to be construed accordingly.

- (2) Expressions used in these Regulations and in Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 [^{F4}, Regulation 10/2011 or Regulation 2018/213] bear the same meaning in these Regulations as they bear in those Regulations.
- (3) Any reference in these Regulations to Regulation 2023/2006 or to an Annex to Directive 2007/42/EC or Regulation 10/2011 is a reference to that Regulation or that Annex as amended from time to time.

Textual Amendments

- F1 Words in reg. 2(1) omitted (31.12.2020) by The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/425), regs. 1(3), 3(2); 2020 c. 1, Sch. 5 para. 1(1)
- Words in reg. 2(1) substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 3
- Words in reg. 2(1) inserted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 3(a)
- **F4** Words in reg. 2(2) substituted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), **3(b)**

Marginal Citations

- M6 OJ No. L172, 30.6.2007, p.71. This Directive repealed and consolidated without further amendment Commission Directive 93/10/EEC as last amended by Commission Directive 2004/14/EC.
- M7 OJ No. L338, 13.11.2004, p.4, amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.2009, p.14).
- **M8** OJ No. L302, 19.11.2005, p.28.
- **M9** OJ No. L384, 29.12.2006, p.75.
- M10 OJ No. L135, 30.5.2009, p.3.
- **M11** 1984 c. 22.

Scope

3. The provisions of these Regulations do not apply in relation to those materials and articles specified in paragraph (3) of Article 1 (purpose and subject matter) of Regulation 1935/2004.

PART 2

General Requirements for Materials and Articles

Offences of contravening specified provisions of Regulation 1935/2004

- **4.**—(1) No person may place on the market or use, in the course of a business in connection with the storage, preparation, packaging, sale or service of food any material or article that does not comply with the requirements of Article 3(1) (general requirements) or Article 4(1), (2), (3) or (4) (special requirements for active and intelligent materials and articles).
- (2) No person may place on the market any material or article that does not comply with the requirements of Article 3(2), 4(5) or (6) or 15(1), (3), (4), (7) or (8) as read with Article 15(2) (labelling).
- (3) Any person who contravenes paragraph (1) or (2) or Article 11(4) or (5) (F5... authorisation) or 17(2) (traceability) is guilty of an offence.
- (4) In this regulation a reference to a numbered Article is a reference to that Article in Regulation 1935/2004.

Textual Amendments

F5 Word in reg. 4(3) omitted (31.12.2020) by virtue of S.I. 2019/425, reg. 3(2A) (as inserted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), 2(3)(a))

Offence of contravening Article 4 of Regulation 2023/2006

5. Any person who fails to comply with the requirements of Article 4 (conformity with good manufacturing practice) of Regulation 2023/2006 is guilty of an offence.

Competent authorities for the purposes of Regulation 1935/2004 and Regulation 2023/2006

- **6.**—(1) The following bodies are designated as the competent authorities for the purposes of the provisions of Regulation 1935/2004 specified below—
 - $^{\text{F6}}(a)$
 - (b) in respect of Articles [F16] (declaration of compliance) and 17(2) (traceability), the Food Standards Agency, each food authority in its area and each port health authority in its district.
- (2) The competent authority for the purposes of Article 6(2) (quality control system) and 7(3) (documentation) of Regulation 2023/2006 is each food authority in its area.

Textual Amendments

- **F6** Reg. 6(1)(a) omitted (31.12.2020) by virtue of S.I. 2019/425, reg. 3(2B)(a) (as inserted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), **2(3)(a)**)
- F7 Word in reg. 6(1)(b) substituted (31.12.2020) by S.I. 2019/425, reg. 3(2B)(b) (as inserted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), 2(3)(a))

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

PART 3

Requirements for Active and Intelligent Materials and Articles

Offences of contravening specified provisions of Regulation 450/2009

7.—(1) Subject to the transitional provisions contained in Article 14 (entry into force and application) of Regulation 450/2009, any person who places on the market any active or intelligent material or article which does not comply with the requirements of Article 4 of that Regulation is guilty of an offence.

Textual Amendments

F8 Reg. 7(2) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 4

Competent authorities for the purposes of Regulation 450/2009

8. The competent authorities for the purposes of Article 13 of Regulation 450/2009 are the Food Standards Agency, each food authority in its area and each port health authority in its district.

PART 4

Requirements for Ceramic Articles

Interpretation of this Part

- 9. In this Part—
 - (a) "ceramic article" ("eitem geramig") means an article to which Regulation 1935/2004 applies by virtue of its Article 1(2) as read with 1(3) that—
 - (i) is 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,
 - (ii) is first shaped, with the shape thus obtained having been permanently fixed by firing, and
 - (iii) may be glazed, enamelled and/or decorated; and

^{F9} (b)																																
(1))	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

Textual Amendments

F9 Reg. 9(b) omitted (31.12.2020) by virtue of The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/425), regs. 1(3), 3(3); 2020 c. 1, Sch. 5 para. 1(1)

Limits for lead and cadmium and declaration of compliance

- [F1010.—(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 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—

	Lead (Pb)	Cadmium (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 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%.]

Textual Amendments

F10 Reg. 10 substituted (31.12.2020) by The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/425), regs. 1(3), 3(4); 2020 c. 1, Sch. 5 para. 1(1)

[F1110A.—(1) A person who places on the market a ceramic article which is not yet in contact with foodstuffs must provide a written declaration [F12 complying with paragraph (2)] to accompany the article at the marketing stages up to and including the retail stage.

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

- (2) The declaration must be issued by the manufacturer or by a seller in [F13Great Britain] and must contain the information laid down in Schedule 5.
- (3) A person who manufactures or, in the course of a business, imports into [F14Great Britain] 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.]

Textual Amendments

- F11 Reg. 10A inserted (31.12.2020) by The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/425), regs. 1(3), 3(5); 2020 c. 1, Sch. 5 para. 1(1)
- F12 Words in reg. 10A(1) substituted in earlier amending provision S.I. 2019/425, reg. 3(5) (31.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), 2(3)(b)(i)
- F13 Words in reg. 10A(2) substituted in earlier amending provision S.I. 2019/425, reg. 3(5) (31.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), 2(3)(b)(ii)
- Words in reg. 10A(3) substituted in earlier amending provision S.I. 2019/425, reg. 3(5) (31.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), 2(3)(b)(iii)

PART 5

Requirements for Regenerated Cellulose Film

Interpretation of this Part

- **11.**—(1) In this Part—
 - (a) "regenerated cellulose film" ("caen cellulos atgynyrchiedig") means a thin sheet material obtained from refined cellulose derived from unrecycled wood or cotton, with or without the addition of suitable substances, either in the mass or on one or both surfaces, but does not include synthetic casings of regenerated cellulose;
 - (b) "URCF" ("CCAH") means uncoated regenerated cellulose film;
 - (c) "CRCF" ("CCAG") means coated regenerated cellulose film with coating derived from cellulose; and
 - (d) "PRCF" ("CCAP") means coated regenerated cellulose film with coating consisting of plastics.
- (2) This Part applies to regenerated cellulose film which—
 - (a) constitutes a finished product in itself; or

- (b) is part of a finished product containing other materials, and is intended to come into contact with food or, by being used for that purpose, does come into contact with food.
- (3) Except in regulation 12(3), any reference in this Part to a numbered Annex is a reference to that Annex to Directive 2007/42/EC.

Controls and limits

- 12.—(1) URCF and CRCF may be manufactured using only the substances or groups of substances listed in Annex II (list of substances authorised in the manufacture of regenerated cellulose film) and subject to the restrictions set out in that Annex but, by way of derogation, substances other than those listed in Annex II may be used when these substances are employed either as—
 - (a) dyes and pigments; or
 - (b) adhesives,

provided that there is no trace of migration of the substances, detectable by a validated method, into or on to foodstuffs.

- (2) PRCF may be manufactured, prior to coating, using only substances or groups of substances listed in the first part of Annex II and subject to the restrictions set out in that part.
- (3) The coating to be applied to PRCF may be manufactured using only substances or groups of substances listed in Annex I to Regulation 10/2011 and subject to the restrictions in that Annex.
- (4) Materials and articles made of PRCF must comply with Article 12 (overall migration limit) as read with Article 17 (expression of migration test results) and Article 18 (rules for assessing compliance with migration limits) of Regulation 10/2011.
 - (5) Printed surfaces of regenerated cellulose film must not come into contact with foodstuffs.
- (6) Any material or article made of regenerated cellulose film that is not by its nature clearly intended to come into contact with food must, at a marketing stage other than the retail stage, be accompanied by a written declaration attesting that it complies with the legislation applicable to it.
- (7) Where special conditions of use are indicated, the material or article made of regenerated cellulose film must be labelled accordingly.
- (8) No person may place on the market any regenerated cellulose film which has been manufactured in contravention of the requirements of paragraphs (1) to (4), or which fails to comply with paragraphs (5)^{F15}... or (7).

Textual Amendments

F15 Word in reg. 12(8) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 5

PART 6

Requirements for Plastic Materials and Articles

Interpretation of Part 6 and [F16Schedule 1]

13. [F17 Except in regulation 14(1), any reference in this Part and in Schedule 1] to a numbered Article or Annex is a reference to that Article of or Annex to Regulation 10/2011.

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

Textual Amendments

- F16 Words in reg. 13 heading substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 6(a)
- F17 Words in reg. 13 substituted (26.7.2018) by The Food and Feed (Miscellaneous Amendments and Revocations) (Wales) Regulations 2018 (S.I. 2018/806), regs. 1(3), 22(2)

Offences of contravening specified provisions of Regulation 10/2011

14.—(1) Subject to the transitional arrangements set out in [F18]Article 2 of Commission Regulation (EU) No 1282/2011, Article 2 of Commission Regulation (EU) No 1183/2012, Article 2 of Commission Regulation (EU) No 202/2014, Article 2 of Commission Regulation (EU) 2015/174, Article 2 of Commission Regulation (EU) 2016/1416, Article 2 of Commission Regulation (EU) 2017/752, Article 2 of Commission Regulation (EU) 2018/79 [F19, Article 2 of Commission Regulation (EU) 2018/831 and Article 6 of Regulation 2018/213]] any person who places on the market a plastic material or article that fails to comply with a requirement of Regulation 10/2011 specified in column 1 of [F20]Schedule 1] is guilty of an offence.

$F^{21}(2)$																																
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Textual Amendments

- **F18** Words in reg. 14(1) substituted (26.7.2018) by The Food and Feed (Miscellaneous Amendments and Revocations) (Wales) Regulations 2018 (S.I. 2018/806), regs. 1(3), 22(3)
- **F19** Words in reg. 14(1) substituted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 4
- **F20** Words in reg. 14(1) substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), **7(a)**
- F21 Reg. 14(2) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 7(b)

Competent authorities for the purposes of Regulation 10/2011

[F2215. The competent authorities for the purposes of Articles 8 and 16(1) of Regulation 10/2011 are the Food Standards Agency, each food authority in its area and each port health authority in its district.]

Textual Amendments

F22 Reg. 15 substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 8

PART 7

Requirements for certain epoxy derivatives

Restrictions on the use of certain epoxy derivatives (BADGE, BFDGE and NOGE)

16.—(1) In this Part—

- (a) any reference to a numbered Article or Annex is a reference to that Article or Annex in Regulation 1895/2005; and
- (b) [F23paragraph (2) is] subject to Article 1(3) (scope) M12.
- (2) [F24No] person may place on the market or use, in the course of a business in connection with the storage, preparation, packaging, sale or service of food—
 - (a) any material or article in contravention of Article 3 (prohibition on use or presence of BFDGE) or Article 4 (prohibition on use or presence of NOGE); or
 - (b) any material or article that fails to comply with the restrictions contained in Article 2 (BADGE) as read with Annex I (specific migration limit for BADGE and certain of its derivatives).

 - (4) Any person who contravenes paragraph (2) F26... is guilty of an offence.

Textual Amendments

- **F23** Words in reg. 16(1)(b) substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), **9(a)**
- **F24** Word in reg. 16(2) substituted (26.7.2018) by The Food and Feed (Miscellaneous Amendments and Revocations) (Wales) Regulations 2018 (S.I. 2018/806), regs. 1(3), **22(4)**
- F25 Reg. 16(3) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 9(b)
- **F26** Words in reg. 16(4) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 9(c)

Marginal Citations

M12 Article 3 contains an exception relating to certain containers and storage tanks and pipelines belonging to them

Competent authorities for the purposes of Regulation 1895/2005

17. The competent authority for the purpose of Article 6(4) is each food authority in its area and each port health authority in its district.

PART 8

Requirements for Vinyl chloride

- **18.**—(1) Materials and articles, other than those materials and articles controlled by Regulation 10/2011, which are manufactured with vinyl chloride polymers or copolymers—
 - (a) must not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram of the material or article; and
 - (b) must be manufactured in such a way that they do not transfer to foods with which they are in contact any quantity of vinyl chloride exceeding 0.01 milligrams of vinyl chloride per kilogram of food.
 - (2) No person may—
 - (a) place on the market; or

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

- (b) use in the course of a business in connection with the storage, preparation, packaging, selling or service of food,
- any material or article that does not comply with paragraph (1).
- [F27(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.]

Textual Amendments

F27 Reg. 18(3)-(6) inserted (31.12.2020) by The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/425), regs. 1(3), 3(6); 2020 c. 1, Sch. 5 para. 1(1)

PART 9

Enforcement

Offences and penalties

- **19.**—(1) Any person who contravenes the provisions of regulation 10(3) ^{F28}..., 12(8) or 18(2) is guilty of an offence.
- (2) Any person who intentionally obstructs any person acting in the execution of Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009, Regulation 10/2011|F29, Regulation 2018/213| or these Regulations is guilty of an offence.
- (3) Any person who, without reasonable excuse, fails to provide any assistance or information that person may reasonably require for the performance of their functions under the Regulations mentioned in paragraph (2) ^{F30}... is guilty of an offence.
- (4) Any person who, in purported compliance with any requirement mentioned in paragraph (3), knowingly or recklessly supplies information that is false or misleading in any material particular, is guilty of an offence.
 - [F31(5)] A person guilty of an offence is liable—
 - (a) in the case of an offence created by paragraph (1) or (4) or by regulation 4(3), 5, 7(1), 14(1), $[^{F32}16(4)$ or 17B]
 - (i) on conviction on indictment to a fine or to a term of imprisonment not exceeding two years or both, or
 - (ii) on summary conviction to a fine; and
 - (b) in the case of an offence created by paragraph (2) or (3), on summary conviction to a fine not exceeding level 4 on the standard scale.]

(6) Nothing in paragraph (2) or (3) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate them.

Textual Amendments

- F28 Words in reg. 19(1) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 10(a)
- F29 Words in reg. 19(2) inserted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 6(a)
- **F30** Words in reg. 19(3) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), **10(b)**
- F31 Reg. 19(5) substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 10(c)
- **F32** Words in reg. 19(5)(a) substituted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), **6(b)**

Execution and enforcement

- **20.**—(1) Each food authority in its area and each port health authority in its district must execute and enforce—
 - (a) Regulation 1935/2004, Regulation 1895/2005, Regulation 450/2009 and Regulation 10/2011; and
 - (b) except in relation to the provisions referred to in paragraph (3), these Regulations.
 - [F33(2)] The Food Standards Agency may also execute and enforce the provisions of—
 - (a) Articles 16(1) and 17(2) of Regulation 1935/2004;
 - (b) Article 13 of Regulation 450/2009; and
 - (c) Article 16(1) of Regulation 10/2011.]
- (3) Each food authority in its area must execute and enforce the provisions of Regulation 2023/2006 specified in regulation 5 and these Regulations.

Textual Amendments

F33 Reg. 20(2) substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 11

Offences by corporate bodies or Scottish partnerships

- **21.**—(1) Where an offence under these Regulations which has been committed by a body corporate is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of—
 - (a) any director, manager, secretary or other similar officer of the body corporate; or
 - (b) any person purporting to act in such a capacity,
- that individual as well as the body corporate is deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.
- (2) Where an offence under these Regulations which has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of a partner, that partner as well as the partnership is deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

Offences due to the act or default of a third party

22. Where the commission by any person of an offence under these Regulations is due to the act or default of some other person, that other person is guilty of the offence; and a person may be charged with and convicted of the offence whether or not proceedings are taken against the first mentioned person.

Time limit for prosecutions

- **23.**—(1) No prosecution for an offence under these Regulations is to be begun after the expiry of three years from the commission of the offence or one year from its discovery by the prosecutor, whichever is the earlier.
 - (2) Paragraph (1) does not apply to an offence under regulation ^{F34}...19(2) or (3).

Textual Amendments

F34 Words in reg. 23(2) omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), **12**

General defences

- **24.**—(1) In any proceedings for an offence under these Regulations it is, subject to paragraph (5), a defence to prove that the person accused ("the accused") took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by the accused or by a person under the control of the accused.
- (2) Without prejudice to the generality of paragraph (1), a person accused of an offence under regulation 4(3), 7(1), 14(1), 16(4) [F35, 17B] or 19(1) who did not import or prepare the material or article in respect of which the offence is alleged to have been committed is to be taken to have established the defence provided by paragraph (1) if the requirements of paragraphs (3) or (4) are satisfied.
 - (3) The requirements of this paragraph are satisfied if it is proved that—
 - (a) the commission of the offence was due to the act or default of some other person who was not under the control of the accused, or to reliance on information supplied by such a person;
 - (b) either—
 - (i) the accused carried out all such checks of the material or article in question as were reasonable in all the circumstances, or
 - (ii) it was reasonable in all the circumstances for the accused to rely on checks carried out by the person who supplied the accused with that material or article; and
 - (c) the accused did not know and had no reason to suspect at the time the offence was committed that the act or omission would amount to an offence under these Regulations.
- (4) The requirements of this paragraph are satisfied if the offence is one of placing on the market and it is proved that—
 - (a) the commission of the offence was due to the act or default of some other person who was not under the control of the accused, or to reliance on information supplied by such a person;
 - (b) the placing on the market of which the offence consisted was not done under the name or mark of the accused; and

- (c) the accused did not know and could not reasonably be expected to know at the time the offence was committed that the act or omission would amount to an offence under these Regulations.
- (5) If in any case the defence provided by this regulation involves the allegation that the commission of the offence was due to the act or default of another person, or to reliance on information supplied by another person, the accused is not without leave of the court to be entitled to rely on that defence unless—
 - (a) at least seven clear days before the hearing; and
 - (b) where the accused has previously appeared before the court in connection with the alleged offence, within one month of the first such appearance,

the accused has served on the prosecutor a written notice giving such information identifying or assisting in the identification of that other person as was then in the possession of the accused.

Textual Amendments

F35 Word in reg. 24(2) inserted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 7

Procedure where a sample is to be analysed

- **25.**—(1) An authorised officer who has procured a sample under section 29 of the Act and who considers it should be analysed must divide the sample into three parts.
- (2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer must divide the sample into parts by putting the containers into three lots, and each lot must be treated as being a part.
 - (3) The authorised officer must—
 - (a) if necessary place each part in a suitable container and seal it;
 - (b) mark each part or container;
 - (c) as soon as is reasonably practicable, give one part to the owner and notify the owner in writing that the sample will be analysed;
 - (d) submit one part for analysis in accordance with section 30 of the Act; and
 - (e) retain one part for future submission under regulation 26.

Secondary analysis by the Government Chemist

- **26.**—(1) Where a sample has been retained under regulation 25(3)(e) and—
 - (a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and
 - (b) the prosecution intends to adduce as evidence the result of the analysis mentioned in regulation 25,

paragraphs (2) to (7) apply.

- (2) The authorised officer—
 - (a) may of the officer's own volition; or
 - (b) must—
 - (i) if requested by the prosecutor (if a person other than the authorised officer),
 - (ii) if the court so orders, or

- (iii) (subject to paragraph (6)) if requested by the accused, send the retained part of the sample to the Government Chemist for analysis.
- (3) The Government Chemist must analyse the part sent under paragraph (2) and send to the authorised officer a certificate specifying the results of the analysis.
- (4) Any certificate of the results of analysis transmitted by the Government Chemist must be signed by or on behalf of the Government Chemist, but the analysis may be carried out by any person under the direction of the person who signs the certificate.
- (5) The authorised officer must immediately on receipt supply the prosecutor (if a person other than the authorised officer) and the accused with a copy of the Government Chemist's certificate of analysis.
- (6) Where a request is made under paragraph (2)(b)(iii) the authorised officer may give notice in writing to the accused requesting payment of a fee specified in the notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3), and in the absence of agreement by the accused to pay the fee specified in the notice the authorised officer may refuse to comply with the request.
- (7) In this regulation "the accused" ("y cyhuddedig") includes a person against whom an authorised officer is intending to commence proceedings.

Application of various provisions of the Act

- [F3627.—(1) Section 10(1) and (2) of the Act (improvement notices) applies for the purposes of these Regulations with the modification (in the case of section 10(1)) set out in Part 1 of Schedule 2 for the purposes of—
 - (a) enabling an improvement notice to be served on a person requiring that person to comply with any of the following provisions—
 - (i) regulations $[^{F37}10A(1), 10A(3)]$ and 12(6);
 - (ii) Article 16 of Regulation 1935/2004;
 - (iii) Article 5 of Regulation 1895/2005;
 - (iv) Articles 12 and 13 of Regulation 450/2009; F38...
 - (v) the second sentence of Article 8, Article 15 as read with Annex IV, and Article 16 of Regulation 10/2011; and
- [F39(vi) Article 4 of Regulation 2018/213; and]
 - (b) making the failure to comply with a notice referred to in sub-paragraph (a) an offence.
 - (2) The provisions of the Act specified in column 1 of the table in Part 2 of Schedule 2 apply, with the modifications (if any) specified in column 2 of that table.
 - (3) Paragraphs (1) and (2) are without prejudice to the application of the Act to these Regulations for purposes other than those specified in paragraph (1).]

Textual Amendments

- F36 Reg. 27 substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 13
- F37 Words in reg. 27(1)(a)(i) substituted (31.12.2020) by S.I. 2019/425, reg. 3(6A) (as inserted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), 2(3)(c))

- F38 Word in reg. 27(1)(a)(iv) omitted (6.9.2018) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 8(a)
- F39 Reg. 27(1)(a)(vi) inserted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 8(b)

PART 10

General and supplementary

Consec 1990	quential amendment to the Food Safety (Sampling and Qualifications) Regulations
F4028	3.
Textu	nal Amendments
F40	Reg. 28 omitted (26.7.2018) by virtue of The Food and Feed (Miscellaneous Amendments and
	Revocations) (Wales) Regulations 2018 (S.I. 2018/806), regs. 1(3), 22(5)
Amend	lment to the Food Labelling Regulations 1996

Textual Amendments

F41 Reg. 29 omitted (26.7.2018) by virtue of The Food and Feed (Miscellaneous Amendments and Revocations) (Wales) Regulations 2018 (S.I. 2018/806), regs. 1(3), **22(5)**

Revocations

- **30.** The following Regulations are revoked—
 - (a) The Ceramic Articles in Contact with Food (Wales) Regulations 2006 M13;
 - (b) The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009 M14;
 - (c) The Materials and Articles in Contact with Food (Wales) Regulations 2010 M15;
 - (d) The Plastic Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2011 M16.

Marginal Citations

M13 S.I. 2006/1704 (W.166), amended by S.I. 2011/1043.

M14 S.I. 2009/481 (W.49), amended by S.I. 2010/2288 (W.200).

M15 S.I. 2010/2288 (W.200).

M16 S.I. 2011/233 (W.45).

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

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

[F42Schedule 1]

Regulation 14(1)

Specified provisions of Regulation 10/2011

Textual Amendments

F42 Sch. 1: Sch. renumbered as Sch. 1 (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 14(a)

Specified provision	Subject matter
Article 4(e), as read with Articles 17 and 18	Prohibition on placing on the market plastic materials or articles if they do not meet specified compositional and declaration requirements
Article 5(1) and Annex I, as read with Article 6	Requirement, subject to certain derogations, to use only authorised substances in the manufacture of plastic layers in plastic materials and articles
Article 8, first sentence	General quality and purity standards that must be observed for substances used in the manufacture of plastic layers in plastic materials and articles
Article 9 as read with Annex I	Particular restrictions and specifications for substances used in the manufacture of plastic layers in plastic materials and articles
Article 10 as read with Annex II	General restrictions on plastic materials and articles
[F43 Article 11(1) and Annex I, as read with Article 11(3) and (4)]	Specific limits on the degree to which constituents of plastic materials and articles are permitted to migrate into foods
Article 12	Overall limits on the permitted level of migration of the constituents of plastic materials and articles into food simulants
Article 13(1), (3), (4) and (5) and Annex I as read with Article 13(2)	Particular restrictions and specifications for the composition of each plastic layer in plastic multi-layer materials and articles
Article 14(1) and (5) and Annex 1, as read with Article 14(2), (3) and (4)	Particular restrictions and specifications for the composition of each plastic layer in multi- material multi-layer materials and articles
F44	F44

Textual Amendments

F43 Words in Sch. 1 substituted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), **14(b)**

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

F44 Words in Sch. 1 omitted (14.9.2017) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), regs. 1(3), 14(c)

[F45SCHEDULE 2

Regulation 27

Textual Amendments

F45 Sch. 2 inserted (14.9.2017) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (S.I. 2017/832), reg. 1(3), Sch.

PART 1

Modification of section 10(1)

- 1. For section 10(1) of the Act (improvement notices) substitute—
 - "(1) If an authorised officer has reasonable grounds for believing that a person is failing to comply with any provision specified in subsection (1A), the authorised officer may, by a notice served on that person (in this Act referred to as an "improvement notice")—
 - (a) state the authorised officer's grounds for believing that the person is failing to comply with the relevant provision;
 - (b) specify the matters which constitute the person's failure to so comply;
 - (c) specify the measures which, in the authorised officer's opinion, the person must take in order to secure compliance; and
 - (d) require the person to take those measures, or measures that are at least equivalent to them, within such period (not being less than 14 days) as may be specified in the notice.
 - (1A) The provisions referred to in subsection (1) are—
 - (a) regulations [F4610A(1), 10A(3)] and 12(6) of the Materials and Articles in Contact with Food (Wales) Regulations 2012;
 - (b) Article 16 of Regulation 1935/2004;
 - (c) Article 5 of Regulation 1895/2005;
 - (d) Articles 12 and 13 of Regulation 450/2009; F47...
 - (e) the second sentence of Article 8, Article 15 as read with Annex IV, and Article 16 of Regulation 10/2011[^{F48}; and]
 - [Article 4 of Regulation 2018/213."] F⁴⁹(f)

Textual Amendments

F46 Words in Sch. 2 para. 1 substituted (31.12.2020) by S.I. 2019/425, reg. 3(6B) (as inserted by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), 2(3)(c))

- F47 Word in Sch. 2 Pt. 1, omitted (6.9.2018) by virtue of The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 9(a)
- **F48** Word in Sch. 2 Pt. 1, substituted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), **9(b)**
- **F49** Words in Sch. 2 Pt. 1, inserted (6.9.2018) by The Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2018 (S.I. 2018/913), regs. 1(3), 9(c)

PART 2 Application and modification of other provisions of the Act

Column 1	Column 2
Provision of the Act	Modification
Section 2 (extended meaning of "sale" etc.)	For "this Act" (in each place it occurs) substitute "the Materials and Articles in Contact with Food (Wales) Regulations 2012".
Section 3 (presumptions that food intended for human consumption)	In subsection (1), for "this Act" substitute "the Materials and Articles in Contact with Food (Wales) Regulations 2012, Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 and Regulation 10/2011".
Section 20 (offences due to fault of another person)	For "any of the preceding provisions of this Part" substitute "section 10(2) as applied by regulation 27 of the Materials and Articles in Contact with Food (Wales) Regulations 2012".
Section 21(1) and (5) (defence of due diligence)	In subsection (1), for "any of the preceding provisions of this Part" substitute "section 10(2) as applied by regulation 27 of the Materials and Articles in Contact with Food (Wales) Regulations 2012".
	In subsection (8), for "this Act" substitute "the Materials and Articles in Contact with Food (Wales) Regulations 2012".
Section 32 (powers of entry)	For "this Act" (in each place it occurs) substitute "the Materials and Articles in Contact with Food (Wales) Regulations 2012, Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 and Regulation 10/2011".
Section 33 (obstruction etc. of officers)	In subsection (1), for "this Act" (in each place it occurs) substitute "section 10(1) of this Act as applied and modified by regulation 27 of, and Part 1 of Schedule 2 to, the Materials and Articles in Contact with Food (Wales) Regulations 2012".

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

Column 1	Column 2								
Provision of the Act	Modification								
Section 35(1) and (2) (punishment of offences)	In subsection (1), after "section 33(1) above" insert ", as applied and modified by regulation 27 of, and Part 2 of Schedule 2 to, the Materials and Articles in Contact with Food (Wales) Regulations 2012,".								
	After subsection (1) insert—								
	"(1A) A person guilty of an offence under section 10(2), as applied by regulation 27 of the Materials and Articles in Contact with Food (Wales) Regulations 2012 shall be liable, on summary conviction, to a fine not exceeding level 4 on the standard scale."								
	In subsection (2), in the opening words, for "any other offence under this Act" substitute "an offence under section 33(2), as applied by regulation 27 of, and Part 2 of Schedule 2 to, the Materials and Articles in Contact with Food (Wales) Regulations 2012,".								
Section 36 (offences by bodies corporate)	In subsection (1), for "this Act" substitute "section 10(2) as applied by regulation 27 of the Materials and Articles in Contact with Food (Wales) Regulations 2012".								
Section 36A (offences by Scottish partnerships)	For "this Act" substitute "section 10(2) as applied by regulation 27 of the Materials and Articles in Contact with Food (Wales) Regulations 2012".								
Section 37(1) and (6) (appeals to a magistrates'	For subsection (1) substitute—								
court)	"Any person who is aggrieved by a decision of an authorised officer to serve an improvement notice under section 10(1), as applied and modified by regulation 27 of, and Part 1 of Schedule 2 to, the Materials and Articles in Contact with Food (Wales) Regulations 2012, may appeal to a magistrates' court."								
	In subsection (6)—								
	for "(3) or (4)" substitute "(1)"; and								
	in paragraph (a), omit "or to the sheriff".								
Section 39 (appeals against improvement notices)	For subsection (1) substitute—								

Column 1	Column 2
Provision of the Act	Modification
-	"(1) On an appeal against an improvement
	notice served under section 10(1), as applied
	and modified by regulation 27 of, and Part 1
	of Schedule 2 to, the Materials and Articles
	in Contact with Food (Wales) Regulations
	2012, the magistrates' court may either cancel
	or affirm the notice and, if it affirms it, may
	do so either in its original form or with such
	modifications as the magistrates' court may in
	the circumstances think fit."
	In subsection (3), omit "for want of prosecution.".]

[F50SCHEDULE 3

Regulation 10

BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

Textual Amendments

F50 Schs. 3-5 inserted (31.12.2020) by The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (S.I. 2019/425), reg. 1(3), Sch.; 2020 c. 1, Sch. 5 para. 1(1)

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 ± 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.

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

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.]

[F50SCHEDULE 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.

Changes to legislation: There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012. (See end of Document for details)

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.]

[F50SCHEDULE 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 [F51Great Britain];
 - (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.

Textual Amendments

- **F51** Words in Sch. 5 para. 1(a) substituted in earlier amending provision S.I. 2019/425, reg. 3(7), Sch. (31.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 (S.I. 2020/1581), regs. 1(2), **2(5)**
- 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.]

EXPLANATORY NOTE

(This note is not part of the Regulations)

- **1.** These Regulations provide for the implementation of the following Directives and the enforcement of the following EU Regulations—
 - (a) Council Directive 78/142/EEC on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs (OJ No. L44, 15.2.1978, p.15) ("Directive 78/142/EEC");
 - (b) 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 (OJ No. L277, 20.10.1984, p.12) ("Directive 84/500/EEC");

- (c) Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ No. L172, 30.6.2007, p.71) ("Directive 2007/42/EC");
- (d) Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ No. L338, 13.11.2004, p.4) ("Regulation 1935/2004");
- (e) Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (OJ No. L302, 19.11.2005, p.28) ("Regulation 1895/2005");
- (f) Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ No. L384, 29.12.2006, p.75) ("Regulation 2023/2006");
- (g) Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food (OJ No. L135, 30.5.2009, p.3) ("Regulation 450/2009"); and
- (h) Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (OJ No. L12, 15.1.2011, p.1) ("Regulation 10/2011").
- **2.** These Regulations revoke the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009 (S.I. 2009/481 (W.49)). They also revoke and re-enact with certain amendments the provisions of the Ceramic Articles in Contact with Food (Wales) Regulations 2006 (S.I. 2006/1704 (W.166)) and the Materials and Articles in Contact with Food (Wales) Regulations 2010 (S.I. 2010/2288 (W.200)).
- **3.** These Regulations provide that references to a specified EU instrument or specified parts of it are to be construed as references to the instrument or parts of it as they may be amended from time to time (regulation 2(3)).
- **4.** These Regulations do not apply to materials or articles outside the scope of Regulation 1935/2004 (*regulation 3*). The materials identified in that Regulation as being outside its scope are materials and articles supplied as antiques, covering or coating materials forming part of the food and which may be consumed with it and fixed public or private water supply equipment.
- **5.** Part 2 of these Regulations contains provisions which make it an offence to contravene certain requirements of Regulation 1935/2004 (*regulation 4*) and Regulation 2023/2006 (*regulation 5*). Regulation 1935/2004 is the principal framework Regulation on materials and articles in contact with food.
- **6.** Part 2 also provides for designation of the competent authorities for the various purposes identified in Regulations 1935/2004 and 2023/2006 (*regulation 6*).
- 7. Part 3 provides for the enforcement of specified provisions of Regulation 450/2009 (regulation 7) and designates the competent authorities for the purposes of that Regulation (regulation 8).
- **8.** Part 4 implements Directive 84/500/EEC, and the definition of a ceramic article is set out in *regulation 9*. It provides that no person may place on the market a ceramic article that does not meet the specifications set out in the Directive (*regulation 10*). This regulation additionally contains requirements relating to documentary proof of compliance which apply to new but not to second hand ceramic articles.
- **9.** Part 5 of these Regulations, which implements Directive 2007/42/EC, contains requirements relating to regenerated cellulose film and identifies the various types of such film to which the provisions apply (*regulation 11*). This Part, in *regulation 12*, contains conditions relating to the substances that may be used for the manufacture of regenerated cellulose film (*paragraphs (1) to*

- (4)), specifies that the printed surface of regenerated film must not come into contact with food (paragraph (5)) and specifies certain documentation and labelling requirements (paragraphs (6) and (7)).
- **10.** Part 6 of these Regulations provides for the enforcement of Regulation 10/2011 and identifies those provisions of the EU Regulation which it constitutes an offence to contravene (*regulation 14 and the Schedule*). The competent authorities for the purposes of certain provisions of Regulation 10/2011 are designated in regulation 15.
- 11. Part 7 provides for the continuing enforcement of Regulation 1895/2005 which maintains a ban on the epoxy derivatives BFDGE and NOGE and restrictions on the use of BADGE (regulation 16). The competent authorities for the purpose of this EU Regulation are designated in regulation 17.
- **12.** Part 8 maintains the controls on the use of vinyl chloride put in place by Directive 78/142/ EEC to the extent that those controls are not now effected by Regulation 10/2011 (*regulation 18*).
 - 13. Part 9 contains enforcement and associated provisions that—
 - (a) penalise contravention of these Regulations or obstruction of those enforcing them (regulation 19);
 - (b) designate enforcement authorities for various functions under the Regulations (regulation 20);
 - (c) provide that individuals responsible for the actions of a corporate body or a Scottish partnership may be co-prosecuted for offences committed by that body or partnership (regulation 21);
 - (d) provide for the prosecution of a person who causes the commission of an offence by another person, whether or not proceedings are taken against the original offender (regulation 22);
 - (e) specify a time limit for commencing a prosecution (regulation 23);
 - (f) provide for a defence of due diligence to an offence under these Regulations (regulation 24);
 - (g) specify the procedure to be followed when sending a sample for analysis (regulation 25);
 - (h) make provision for a reference sample to be analysed by the Laboratory of the Government Chemist (*regulation 26*);and
 - (i) apply certain provisions of the Food Safety Act 1990 for the purposes of these Regulations (*regulation 27*).
 - 14. Part 10 contains general and supplementary provisions which—
 - (a) make consequential amendments to Schedule 1 to the Food Safety (Sampling and Qualifications) Regulations 1990 (regulation 28);
 - (b) maintain an amendment to the Food Labelling Regulations 1996 (S.I. 1996/1499) and provide for that amendment to expire on a date when directly applicable EU food labelling provisions take effect (*regulation 29*); and
 - (c) provide for the revocation of specified Regulations (regulation 30).
- **15.** The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, a regulatory assessment has been prepared as to the likely costs and benefits of complying with these Regulations. A copy can be obtained from the Food Standards Agency at Food Standards Agency Wales, 11th Floor, Southgate House, Wood Street, Cardiff CF10 1EW.

Status:

Point in time view as at 31/12/2020.

Changes to legislation:

There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2012.