#### STATUTORY INSTRUMENTS

# 2012 No. 2619

# FOOD, ENGLAND

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

Made - - - - 17th October 2012

Laid before Parliament 22nd October 2012

Coming into force - - 20th November 2012

The Secretary of State makes 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 MI, and now vested in him 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 Secretary of State 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 <sup>M4</sup> 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 he has 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 <sup>MS</sup>, 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" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to

paragraph 8 of Schedule 5 to the 1999 Act. Those functions, 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). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

- 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. These Regulations may be cited as the Materials and Articles in Contact with Food (England) Regulations 2012, apply in relation to England only and come into force on 20th November 2012.

#### Interpretation

2.—(1) In these Regulations —
"the Act" means the Food Safety Act 1990;
F1...

F2

"Regulation 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<sup>M6</sup>;

"Regulation 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 <sup>M7</sup>:

"Regulation 2023/2006" means Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food M8;

[F3":Regulation 282/2008" means Commission Regulation (EC) No. 282/2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No. 2023/2006;

"Regulation 450/2009" means Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food <sup>M9</sup>;

"Regulation 10/2011" means Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food M10;

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

[F4"Regulation 2018/213" means Commission Regulation (EU) No. 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No. 10/2011 as regards the use of that substance in plastic food contact materials;

"authorised officer" 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" does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple) nor a port health authority;

"port health authority" means —

- (a) in relation to the London port health district (within the meaning given to that phrase for the purposes of the Public Health (Control of Disease) Act 1984 MII by section 7(1) of that Act), the Common Council of the City of London; and
- (b) in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, a port health authority for that district constituted by order under section 2(4) of that Act;

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

- [F5(2) Expressions used in these Regulations and in Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213 bear the same meaning in these Regulations as they bear in those Regulations.]
- [<sup>F6</sup>(3) Any reference in these Regulations to an <sup>F7</sup>... instrument defined in regulation 2(1) is a reference to that <sup>F7</sup>... instrument as amended from time to time.]

#### **Textual Amendments**

- F1 Words in reg. 2(1) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 2(2)(a)(i)
- Words in reg. 2(1) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 2(2)(a)(ii)
- **F3** Words in reg. 2(1) inserted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(2)(a)(i)
- F4 Words in reg. 2(1) inserted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(2)(a)(ii)
- F5 Reg. 2(2) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(2)(b)
- F6 Reg. 2(3) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(2)(c)
- Word in reg. 2(3) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 2(2)(b)

#### **Marginal Citations**

- **M6** 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).
- **M7** OJ No. L302, 19.11.2005, p.28.
- **M8** OJ No. L384, 29.12.2006, p.75.
- **M9** OJ No. L135, 30.5.2009, p.3.

**M10** OJ No. L12, 15.1.2011, p.1, last amended by Commission Regulation (EU) No. 1282/2011 (OJ No. L328, 10.12.2011, p.22).

**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) (F8... 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**

F8 Word in reg. 4(3) omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 4; 2020 c. 1, Sch. 5 para. 1(1)

#### 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
  - (a) in respect of Articles 9 (application for authorisation of a new substance) <sup>F9</sup>..., the Food Standards Agency; and
  - (b) in respect of Articles [F1016] (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.

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

#### **Textual Amendments**

- F9 Words in reg. 6(1)(a) omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 5(a); 2020 c. 1, Sch. 5 para. 1(1)
- **F10** Word in reg. 6(1)(b) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, **5(b)**; 2020 c. 1, Sch. 5 para. 1(1)

#### 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 M12.

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#### **Textual Amendments**

F11 Reg. 7(2) omitted (25.12.2020) by virtue of The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(3)

#### **Marginal Citations**

**M12** Article 4(e) does not apply until the date of application of the EU list of authorised substances that may be used in active and intelligent components.

#### 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" 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.

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

- (ii) is first shaped, with the shape thus obtained having been permanently fixed by firing, and
- (iii) may be glazed, enamelled and/or decorated; F12...

#### **Textual Amendments**

- **F12** Word in reg. 9(a)(ii) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **2(3)(a)**
- F13 Reg. 9(b) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 2(3)(b)

#### Limits for lead and cadmium and declaration of compliance

- [F1410.—[F15(1)] The quantities of lead and cadmium transferred from ceramic articles must not exceed the limits set out in paragraph (4) as read with paragraphs (3) and (5).]
- (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 ceramic articles must be determined by means of a test, the conditions of which are specified in Schedule 2, using the method of analysis described in Schedule 3.
- (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 must be tested separately and under the same conditions. The sum of the two lead or cadmium extraction levels thus obtained must be related as appropriate to the surface area or the volume of the vessel alone.
- (4) 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 2 and Schedule 3 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/dm2 0,07 mg/dm2. 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.
- (5) 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 2 and Schedule 3 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**

- F14 Reg. 10 substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 6; 2020 c. 1, Sch. 5 para. 1(1)
- F15 Reg. 10(1) substituted (31.12.2020 immediately after IP completion day) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(3), 4(17)

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

- [F1610A.—[F17(1)] No person may place on the market a ceramic article that does not comply with the requirements of regulation 10(1) as read with regulation 10(2).]
- (2) At the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs must be accompanied by a written declaration in accordance with Article 16 of Regulation 1935/2004. That declaration is to be issued by the manufacturer or by a seller in Great Britain and must contain the information laid down in Schedule 4.
- (3) Appropriate documentation to demonstrate that the ceramic articles comply with the migration limits for lead and cadmium set out in regulation 10 must be made available by the manufacturer or the importer to the competent authorities on request. That documentation must contain the results of the analysis carried out, the test conditions and the name and the address of the laboratory that performed the testing.
- (4) The documentation specified in paragraph (3) 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.
  - (5) Paragraphs (2) and (3) do not apply in relation to a ceramic article which is second-hand.

#### **Textual Amendments**

- F16 Reg. 10A inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 7 (as amended by S.I. 2020/1504, regs. 1(2), 16(2)); 2020 c. 1, Sch. 5 para. 1(1)
- F17 Reg. 10A(1) substituted (31.12.2020 immediately after IP completion day) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(3), 4(18)

#### PART 5

#### Requirements for Regenerated Cellulose Film

#### Interpretation of this Part

- **11.**—(1) In this Part
  - (a) "regenerated cellulose film" 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" means uncoated regenerated cellulose film;
  - (c) "CRCF" means coated regenerated cellulose film with coating derived from cellulose; and
  - (d) "PRCF" 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.

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#### **Textual Amendments**

**F18** Reg. 11(3) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **2(4)** 

#### **Controls and limits**

- **12.**—(1) URCF and CRCF may be manufactured using only the substances or groups of substances listed in [F19]Schedule 5] (list of substances authorised in the manufacture of regenerated cellulose film) and subject to the restrictions set out in [F20]that Schedule] but, by way of derogation, substances other than those listed in [F19]Schedule 5] 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 [F21]Schedule 5] 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 [F22 paragraphs (5) or (7)].

#### **Textual Amendments**

- F19 Words in reg. 12(1) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 2(5)(a)(i)
- **F20** Words in reg. 12(1) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **2(5)(a)(ii)**
- **F21** Words in reg. 12(2) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **2(5)(b)**
- F22 Words in reg. 12(8) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(4)

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

#### PART 6

# Requirements for Plastic Materials and Articles

#### Interpretation of Part 6 and the Schedule

**13.** In this Part and in the Schedule any reference to a numbered Article or Annex is a reference to that Article of or Annex to Regulation 10/2011.

### Offences of contravening specified provisions of Regulation 10/2011

**14.**—(1) Subject to the transitional arrangements set out in Article 22(4) and (5) and Article 23 M13, 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 the Schedule is guilty of an offence.



#### **Textual Amendments**

F23 Reg. 14(2) omitted (25.12.2020) by virtue of The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(5)

#### **Marginal Citations**

M13 Article 22(4) provides that until 31 December 2015 certain additives used in glass fibre sizing must be assessed under Article 19. Article 22(5) provides that materials and articles lawfully placed on the market before 1 May 2011 may be placed on the market until 31 December 2012. Article 23 provides that as regards certain uses of additives Article 5 applies from 31 December 2015 and that the provisions of Articles 18(2) and (4) and Article 20 apply from 31 December 2012.

#### Competent authorities for the purposes of Regulation 10/2011

[F2415. The competent authorities for the purposes of Articles 8 and 16(1) of and Annex 1, Table 3 (notes on verification of compliance), Notes (23) and (27) to Regulation 10/2011 are the Food Standards Agency, each food authority in its area and each port health authority in its district.]

#### **Textual Amendments**

F24 Reg. 15 substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(6)

# [F25PART 6A

Requirements for Recycled Plastic Materials and Articles

#### **Textual Amendments**

F25 Pt. 6A inserted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(7)

#### **Interpretation of this Part**

**15A.** In this Part any reference to a numbered Article is a reference to that Article of Regulation 282/2008.

#### Offences of contravening Article 3(1) of Regulation 282/2008

**15B.** Subject to the transitional provisions contained in Article 14, any person who places on the market a material or article that fails to comply with Article 3(1) (requirements for plastic materials and articles) is guilty of an offence.

#### Competent authorities for the purposes of Regulation 282/2008

**15**C. The competent authorities for the purposes of Article 10 are the Food Standards Agency and each food authority in its area.]

#### **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) [F26 paragraph (2) is] subject to Article 1(3) (scope) M14.
- (2) Subject to Article 6(1),(2) and (4) (transitional provisions) M15, 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
  - (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 [F28 paragraph (2)] is guilty of an offence.

#### **Textual Amendments**

- F26 Words in reg. 16(1)(b) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(8)(a)
- F27 Reg. 16(3) omitted (25.12.2020) by virtue of The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(8)(b)
- **F28** Words in reg. 16(4) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(8)(c)

#### **Marginal Citations**

**M14** Article 3 contains an exception relating to certain containers and storage tanks and pipelines belonging to them.

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

M15 Article 6(1) (relevant date 1 March 2003) and (2) (relevant date 1 January 2005) provide for transitional arrangements for the application of Articles 2, 3 and 4 to specified materials and articles; Article 6(4) allows the marketing of specified materials and articles if certain labelling requirements are met.

#### 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.

# [F29PART 7A

# Requirements for bisphenol A

#### **Textual Amendments**

F29 Pt. 7A inserted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(9)

#### **Interpretation of Part 7A**

**17A.** In this Part, any reference to a numbered Article is a reference to the Article so numbered in Regulation 2018/213.

#### Offences of contravening Article 2 of Regulation 2018/213

**17B.** Subject to the transitional provisions contained in Article 6, any person who places on the market a material or article that fails to comply with Article 2 is guilty of an offence.

#### Competent authorities for the purposes of Regulation 2018/213

**17C.** The competent authorities for the purposes of Article 4(3) are the Food Standards Agency and each food authority in its area.]

# 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 (England) 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).
- [F30(3)] The criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles are as 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.]

#### **Textual Amendments**

**F30** Reg. 18(3)-(6) inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 8; 2020 c. 1, Sch. 5 para. 1(1)

#### PART 9

#### Enforcement

#### Offences and penalties

- [ $^{\text{F31}}$ **19.**—(1) Any person who contravenes [ $^{\text{F32}}$ regulation 10A(1)], 12(8) or 18(2) is guilty of an offence.
- (2) Any person who fails to comply with a compliance notice served on them under regulation 19A is guilty of an offence.
- (3) Any person who intentionally obstructs a person acting in the execution of Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011, Regulation 2018/213 or these Regulations is guilty of an offence.
- (4) Any person who, without reasonable excuse, fails to provide any assistance or information a person may reasonably require for the performance of their functions under the Regulations mentioned in paragraph (3) is guilty of an offence.
- (5) Any person who, in purported compliance with any requirement under paragraph (4), knowingly or recklessly supplies information that is false or misleading in any material particular is guilty of an offence.
  - (6) A person guilty of an offence is liable—
    - (a) in the case of an offence created by regulation 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 or to a term of imprisonment not exceeding six months or both;

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

- (b) in the case of an offence created by paragraphs (1), (2), (3), (4) or (5) of this regulation or by regulation 4(3), 5, 7(1), 14(1), 15B or 16(4) on summary conviction to a fine.
- (7) Nothing in paragraph (3) or (4) is to be construed as requiring a person to answer any question or give any information if to do so might incriminate that person.]

#### **Textual Amendments**

- F31 Reg. 19 substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(10)
- **F32** Words in reg. 19(1) substituted (31.12.2020 immediately after IP completion day) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(3), 4(19)

#### [F33Compliance notices

- **19A.**—(1) If an authorised officer has reasonable grounds for believing that any person has not complied with, is not complying with, or is not likely to comply with a provision specified in regulation 19B (which provisions concern declarations of compliance with legislative requirements or supporting documentation), the officer may serve a compliance notice on that person.
  - (2) A compliance notice must state—
    - (a) the reason for the service of the notice and the steps the person on whom the notice has been served must take;
    - (b) the date and, if appropriate, the time by which each step must be taken;
    - (d) that a failure to comply with the notice is an offence; and
    - (e) the details of the right to appeal against the notice under regulation 19C.
- (3) An authorised officer may serve a notice on a person withdrawing, varying or suspending a compliance notice.

#### **Textual Amendments**

F33 Regs. 19A-19C inserted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(11)

#### **19B.** The provisions are—

- [F34(a) paragraphs (2) and (3) of regulation 10A;]
  - (b) paragraph (6) of regulation 12;
  - (c) Article 16 of Regulation 1935/2004;
  - (d) Article 5 of Regulation 1895/2005;
  - (e) Articles 10(3) and 12 of Regulation 282/2008;
  - (f) Articles 12 and 13 of Regulation 450/2009;
  - (g) the second sentence of Article 8, Article 15 as read with Annex 4 and Article 16 of Regulation 10/2011;
  - (h) Article 4 of Regulation 2018/213.

#### **Textual Amendments**

- F33 Regs. 19A-19C inserted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(11)
- **F34** Reg. 19B(a) substituted (31.12.2020 immediately after IP completion day) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(3), **4(20)**

#### Appeal against a compliance notice

- **19C.**—(1) Any person served with a compliance notice may appeal against that notice to a magistrates' court.
- (2) The procedure on appeal to a magistrates' court is by way of complaint for an order, and the Magistrates' Courts Act 1980 applies to the proceedings.
- (3) The period within which an appeal may be brought is one month from the date on which the compliance notice was served on the person wishing to appeal and the making of a complaint for an order is deemed for the purposes of this paragraph to be the bringing of the appeal.
  - (4) A compliance notice is not suspended pending an appeal unless—
    - (a) an authorised officer suspends it under regulation 19A(3); or
    - (b) the court directs that it be suspended.
  - (5) The court may—
    - (a) confirm the notice or any requirement contained in it;
    - (b) vary the notice or any requirement contained in it; or
    - (c) revoke the notice or any requirement contained in it.]

#### **Textual Amendments**

F33 Regs. 19A-19C inserted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(11)

#### **Execution and enforcement**

- [F3520.—(1) Each food authority in its area is to execute and enforce Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011, Regulation 2018/213 and these Regulations.
- (2) Each port health authority in its district is to execute and enforce Regulation 1935/2004, Regulation 1895/2005, Regulation 450/2009, Regulation 10/2011, Regulation 2018/213 and these Regulations.
  - (3) The Food Standards Agency may execute and enforce the provisions of—
    - (a) Articles 16 and 17(2) of Regulation 1935/2004;
    - (b) Article 10 of Regulation 282/2008;
    - (c) Article 13 of Regulation 450/2009;
    - (d) Article 8 and 16(1) of and Annex 1, Table 3 (notes on verification of compliance), Notes (23) and (27) to Regulation 10/2011; and
    - (e) Article 4(3) of Regulation 2018/213.]

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

#### **Textual Amendments**

F35 Reg. 20 substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(12)

#### 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 shall be 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 shall be 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 shall be 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 shall 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 [F36 regulation 19(3) or (4)].

#### **Textual Amendments**

F36 Words in reg. 23(2) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(13)

#### General defences

- **24.**—(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be 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 [F37 regulation 4(3), 7(1), 14(1), 15B, 16(4), 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 shall 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 shall not without leave of the court 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**

Words in reg. 24(2) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(14)

#### 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 shall 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 shall divide the sample into parts by putting the containers into three lots, and each lot shall be treated as being a part.
  - (3) The authorised officer shall
    - (a) if necessary place each part in a suitable container and seal it;
    - (b) mark each part or container;

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

- (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(1),

paragraphs (2) to (7) apply.

- (2) The authorised officer
  - (a) may of the officer's own volition; or
  - (b) shall
    - (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 shall 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 shall 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 shall 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" includes a person against whom an authorised officer is intending to commence proceedings.

#### Application of various provisions of the Act

- **27.**—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations
  - (a) section 2 (extending meaning of "sale" etc);
  - (b) section 30(8) (analysis etc. of samples) M16.
- (2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the reference to the Act in subsection (1) is to be construed as including a reference

to Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, [F38 Regulation 282/2008, Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213] as appropriate.

- (3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act is to be construed as including a reference to Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, [F39]Regulation 282/2008, Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213], as appropriate, and to these Regulations
  - (a) section 3 (presumptions that food intended for human consumption) with the modifications that the references to "sold" and "sale" is to be deemed to include references to "placed on the market" and "placing on the market" respectively;
  - (b) section 44 (protection of officers acting in good faith).

#### **Textual Amendments**

- **F38** Words in reg. 27(2) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(15)
- **F39** Words in reg. 27(3) substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(15)

#### **Marginal Citations**

**M16** Section 30(8) sets out the evidential status of certificates of analysis and examination provided by food analysts and examiners.

#### **PART 10**

#### General and supplementary

# Consequential amendment to the Food Safety (Sampling and Qualifications) Regulations 1990

- **28.** In the Food Safety (Sampling and Qualifications) Regulations 1990 M17, in Schedule 1 (provisions to which those Regulations do not apply)
  - (a) omit the title and reference of the Plastic Materials and Articles in Contact with Food (England) Regulations 2009 M18; and
  - (b) for the title and reference of the Materials and Articles in Contact with Food (England) Regulations 2010 M19 substitute the title and reference of these Regulations.

#### **Marginal Citations**

M17 S.I. 1990/2463, amended by S.I. 2009/205 and S.I. 2010/2225; there are other amending instruments but none is relevant.

M18 S.I. 2009/205, amended by S.I. 2010/2225 and S.I. 2011/231.

M19 S.I. 2010/2225.

#### Amendment to the Food Labelling Regulations 1996

**29.**—(1) The Food Labelling Regulations 1996 M20 are amended in accordance with paragraph (2).

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

(2) In regulation 2(1) (interpretation), for the definition of "ingredient" substitute the following definition —

""ingredient" means —

- (a) any substance, including any additive or food enzyme and any constituent of a compound ingredient, which is used in the preparation of a food and which is still present in the finished product, even if in altered form; or
- (b) any released active substance within the meaning of Article 3(f) of Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food,

and a "compound ingredient" shall be composed of two or more such substances;.".

(3) Paragraphs (1) and (2) expire on 13th December 2014.

#### **Marginal Citations**

**M20** S.I. 1996/1499. The definition of ingredient was previously amended by S.I. 2009/3235 and S.I. 2010/2225.

#### **Statutory Review**

- **30.**—(1) The Food Standards Agency must from time to time
  - (a) carry out a review of the operation and effect of regulations 1 to 27;
  - (b) set out the conclusions of the review in a report; and
  - (c) publish the report.
- (2) In carrying out the review the Food Standards Agency must, so far as is reasonable, have regard to [F40] the operation of the relevant retained EU instruments].
  - (3) The report must in particular
    - (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
    - (b) assess the extent to which those objectives are achieved; and
    - (c) assess whether those objectives remain appropriate and, if they do, the extent to which they could be achieved with a system that imposes less regulation.
- (4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.
- (5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.
- (6) In this regulation "the [F41 relevant retained] EU instruments" means F42... Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 and Regulation 10/2011.

#### **Textual Amendments**

- **F40** Words in reg. 30(2) substituted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **2(6)(a)**
- F41 Words in reg. 30(6) inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), 2(6)(b)(i)

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

**F42** Words in reg. 30(6) omitted (31.12.2022) by virtue of The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), regs. 1(1), **2(6)(b)(ii)** 

#### Revocations

- **31.** The following Regulations are revoked
  - (a) The Ceramic Articles in Contact with Food (England) Regulations 2006 M21;
  - (b) The Plastic Materials and Articles in Contact with Food (England) Regulations 2009;
  - (c) The Materials and Articles in Contact with Food (England) Regulations 2010;
  - (d) The Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2011 M22

#### **Marginal Citations**

M21 S.I. 2006/1179, amended by S.I. 2007/2790.

**M22** S.I. 2011/231.

Signed by authority of the Secretary of State for Health.

Department of Health

Anna Soubry
Parliamentary Under-Secretary of State,

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

#### THE SCHEDULE

Regulation 14(1)

#### Specified provisions of Regulation 10/2011

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
[F43Article 11(1) and Annex 1, 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
	Particular restrictions and specifications for the composition of each plastic layer in plastic multi-layer materials and articles
	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. substituted (25.12.2020) by The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), 4(16)(a)
- **F44** Words in Sch. omitted (25.12.2020) by virtue of The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (England) Regulations 2020 (S.I. 2020/1410), regs. 1(2), **4(16)(b)**

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

# [F45SCHEDULE 2

Regulation 10

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

#### **Textual Amendments**

F45 Sch. 2 inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), reg. 1, Sch. 1; 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  $22 \pm 2$  °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 rimof the sample. Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6 mm measured along the sloping rim.

(b) Samples which cannot be filled—

The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4 % (v/v) acetic acid solution. The sample is then immersed in a recipient containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with foodstuffs is completely covered by the test liquid.

#### 4. Determination of the surface area

The surface area of the articles in Category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in paragraph 3 above.]

# [F46SCHEDULE 3

Regulation 10

# METHODS OF ANALYSIS FOR DETERMINATION OF THE MIGRATION OF LEAD AND CADMIUM

#### **Textual Amendments**

F46 Sch. 3 inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), reg. 1, Sch. 2; 2020 c. 1, Sch. 5 para. 1(1)

#### 1. Object and field of application

The method allows the specific migration of lead and/or cadmium to be determined.

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

#### 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 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 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 2.

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.]

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

# [F47SCHEDULE 4

Regulation 10A

#### DECLARATION OF COMPLIANCE

#### **Textual Amendments**

- F47 Sch. 4 inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), reg. 1, Sch. 3 (as amended by S.I. 2020/1504, regs. 1(2), 16(8)); 2020 c. 1, Sch. 5 para. 1(1)
- 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 Great 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.
- 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.]

# [F48SCHEDULE 5

Regulation 12(1)

# LIST OF SUBSTANCES AUTHORISED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

#### **Textual Amendments**

**F48** Sch. 5 inserted (31.12.2022) by The Food and Feed (Miscellaneous Amendments) Regulations 2022 (S.I. 2022/1351), reg. 1(1), **Sch. 1** 

### DESCRIPTION OF REGENERATED CELLULOSE FILM

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

# LIST OF SUBSTANCES AUTHORISED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM

#### Notes:

- The percentages in this Schedule, in the first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.
- The usual technical denominations are given in square brackets.
- The substances used shall be of good technical quality as regards the purity criteria.

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

# First Part: Uncoated regenerated cellulose film

Denominations	Restrictions
A. Regenerated cellulose	Not less than 72 % (w/w)
B. Additives	
1. Softeners	Not more than 27 % (w/w) in total
— Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foodstuffs which are not moist, namely which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
— Ethanediol [= monoethyleneglycol]	
— 1.3-butanediol	
— Glycerol	
— 1.2-propanediol [= 1.2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1200.
— 1.2-polypropylene oxide [= 1.2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1.3-propanediol content not greater than 1% (w/w) in substance.
— Sorbitol	
— Tetraethyleneglycol	
— Triethyleneglycol	
— Urea	
2. Other additives	Not more than 1% (w/w) in total.
First class	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm <sup>2</sup> of the uncoated film.
— Acetic acid and its NH <sub>4</sub> , Ca, Mg, K and Na salts	
— Ascorbic acid and its NH <sub>4</sub> , Ca, Mg, K and Na salts	
— Benzoic acid and sodium benzoate	
— Formic acid and its NH <sub>4</sub> , Ca, Mg, K and Na salts	
— Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to	

20 inclusive and also behenic and ricinoleic acids

Denominations	Restrictions
and the NH <sub>4</sub> , Ca, Mg, K, Na, Al, Zn salts of these acids	
— Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
— Sorbic acid and its NH <sub>4</sub> , Ca, Mg, K and Na salts	
— Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
— Natural edible starches and flours	
<ul> <li>Edible starches and flours modified by chemical treatment</li> </ul>	
— Amylose	
— Calcium and magnesium carbonates and chlorides	
— Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
— Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
<ul> <li>Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium</li> </ul>	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1200 and 4000.
— Sodium propionate	
Second class	The total quantity of the substances may not exceed 1 mg/dm <sup>2</sup> of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0.2 mg/dm <sup>2</sup> (or

epichlorhydrin;

(b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine;

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Denominations	Restrictions				
	a lower limit where one is specified) of the uncoated film.				
— Sodium alkyl (C <sub>8</sub> -C <sub>18</sub> ) benzene sulphonate					
— Sodium isopropyl naphthalene sulphonate					
— Sodium alkyl (C <sub>8</sub> -C <sub>18</sub> ) sulphate					
— Sodium alkyl (C <sub>8</sub> -C <sub>18</sub> ) sulphonate					
— Sodium dioctylsulphosuccinate					
<ul> <li>Distearate of dihydroxyethyl diethylene triamine monoacetate</li> </ul>	Not more than 0.05 mg/dm <sup>2</sup> of the uncoated film.				
— Ammonium, magnesium and potassium lauryl sulphates					
— N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane					
— 2-heptadecyl-4.4-bis(methylene-stearate) oxazoline					
— Polyethylene-aminostearamide ethylsulphate	Not more than 0.1 mg/dm <sup>2</sup> of the uncoated film.				
Third class — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm <sup>2</sup> of the uncoated film.				
— Condensation product of melamine- formaldehyde unmodified, or which may be modified with one or more of the following	Free formaldehyde content not greater than 0.5 mg/dm <sup>2</sup> of the uncoated film.				
butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3.3'-	Free melamine content not greater than 0.3 mg dm <sup>2</sup> of the uncoated film.				
diaminodipropylamine, 4.4'-diaminodibutylamine					
	Free formaldehyde content not greater than 0.5 mg/dm <sup>2</sup> of the uncoated film.				
	Free melamine content not greater than 0.3 mg/dm² of the uncoated film.				
— Cross-linked cationic polyalkyleneamines:					
(a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and					

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Denominations	Restrictions
(c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia;	
(d) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine;	
(e) polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine	
— Polyethyleneamines and polyethyleneimines	Not more than $0.75$ mg/dm $^2$ of the uncoated film.
— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or more of the following products:	Free formaldehyde content not greater than 0.5 mg/dm <sup>2</sup> of the uncoated film.
aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite	
Fourth class	The total quantity of substances may not exceed 0.01 mg/dm <sup>2</sup> of the uncoated film.
— Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
— Monoethanolamine lauryl sulphate	

# Second Part: Coated regenerated cellulose film

Denominations	Restrictions
A. Regenerated cellulose	See first part.
B. Additives	See first part.
C. Coating	
1. Polymers	The total quantity of substances may not exceed 50 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— Cellulose nitrate	Not more than 20 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs; nitrogen content between 10.8 % (w/w) and 12.2 % (w/w) in the cellulose nitrate.

Denominations	Restrictions
2. Resins	The total quantity of substances may not exceed 12.5 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs and which is used solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings.
— Casein	
<ul> <li>Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C<sub>2</sub> to C<sub>6</sub> polyvalent alcohols, or mixtures of these alcohols</li> </ul>	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2.2 bis (4-hydroxyphenyl) propane formaldehyde and esterified with methyl ethyl or C 2 to C 6 polyvalent alcohols or mixtures of these alcohols	
— Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene and/or dipentene and/or diterpene and maleic anhydride	
— Edible gelatine	
— Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
— Natural gum [= damar]	
— Poly-beta-pinene [= terpenic resins]	
<ul> <li>Urea-formaldehyde resins (see anchoring agents)</li> </ul>	
3. Plasticisers	The total quantity of substances may not exceed 6 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Acetyl tributyl citrate	
— Acetyl tri(2-ethylhexyl) citrate	
— Di-isobutyl adipate	
— Di-n-butyl adipate	
— Di-n-hexyl azelate	
— Dicyclohexyl phthalate	Not more than 4.0 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.

Denominations	Restrictions
— 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed:
	(a) 2.4 mg/kg of the foodstuff in contact with this type of film; or
	(b) 0.4 mg/dm <sup>2</sup> in the coating on the side in contact with foodstuffs.
— Glycerol monoacetate [= monoacetin]	
— Glycerol diacetate [= diacetin]	
— Glycerol triacetate [= triacetin]	
— Di-butyl sebacate	
— Di-n-butyl tartrate	
— Di-isobutyl tartrate	
4. Other additives	The total quantity of substances may not exceed 6 mg/dm <sup>2</sup> in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs.
4.1. Additives listed in the first part	Same restrictions as in the first part (however the quantities in mg/dm <sup>2</sup> refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs).
4.2. Specific coating additives	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm <sup>2</sup> (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs.
— 1-hexadecanol and 1-octadecanol	
— Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
— Montan waxes, comprising purified montanic (C <sub>26</sub> to C <sub>32</sub> ) acids and/or their esters with ethanediol and/or 1.3 butanediol and/or their calcium and potassium salts	
— Carnauba wax	
— Beeswax	
— Esparto wax	
— Candelilla wax	

Denominations	Restrictions
— Dimethylpolysiloxane	Not more than 1 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Epoxidised soya-bean oil (oxirane content 6 to 8 %)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyldiethyleneoxide)- phosphates	Not more than 0.2 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Aliphatic acids (C <sub>8</sub> to C <sub>20</sub> ) esterified with mono- or di-(2-hydroxyethyl)amine	
— 2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0.06 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— 2.6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	Not more than 0.06 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
5. Solvents	The total quantity of substances may not exceed 0.6 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Butyl acetate	
— Ethyl acetate	
— Isobutyl acetate	
— Isopropyl acetate	
— Propyl acetate	
— Acetone	
— 1-butanol	
— Ethanol	
— 2-butanol	
— 2-propanol	
— 1-propanol	
— Cyclohexane	
— Ethyleneglycol monobutyl ether	
— Ethyleneglycol monobutyl ether acetate	
— Methyl ethyl ketone	
— Methyl isobutyl ketone	
— Tetrahydrofuran	

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Denominations	Restrictions
— Toluene	Not more than $0.06 \text{ mg/dm}^2$ of the coating on the side in contact with foodstuffs. ]

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

- **1.** The 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");
  - (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");
  - (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");
  - (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 (England) Regulations 2009 (S.I. 2009/205). They also revoke and re-enact with certain amendments the provisions of the Ceramic Articles in Contact with Food (England) Regulations 2006 (S.I. 2006/1179) and the Materials and Articles in Contact with Food (England) Regulations 2010 (S.I. 2010/2225).
- 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, 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, 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 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*);
  - (c) require the Food Standards Agency to carry out a review of the operation and effect of these Regulations within 5 years of their coming into force and at intervals of a maximum 5 years thereafter (*regulation 30*); and
  - (d) provide for the revocation of specified Regulations (regulation 31).
- **15.** A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Food Safety Group of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on www.legislation.gov.uk.

#### **Status:**

Point in time view as at 31/12/2022.

# **Changes to legislation:**

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