

2012 No. 2619

FOOD, ENGLAND

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

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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(a), and now vested in him(b), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(c).

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(d) 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(e), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

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;

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- (a) 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.
- (b) 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.
- (c) 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).
- (d) OJ No. L384, 29.12.2006, p.75, amended by Commission Regulation (EC) No.282/2008 (OJ No. L86, 28.3.2008, p.9).
- (e) 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).

“Directive 84/500/EEC” means 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(a);

“Directive 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(b);

“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(c);

“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(d);

“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(e);

“Regulation 450/2009” means Commission Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food(f);

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

“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(h) 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.

(2) Expressions used in these Regulations and in Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 or Regulation 10/2011 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 any 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.

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.

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- (a) OJ No. L277, 20.10.1984, p.12, amended by Commission Directive 2005/31/EC (OJ No. L110, 30.4.2005, p.36).
 - (b) 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.
 - (c) 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).
 - (d) OJ No. L302, 19.11.2005, p.28.
 - (e) OJ No. L384, 29.12.2006, p.75.
 - (f) OJ No. L135, 30.5.2009, p.3.
 - (g) 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).
 - (h) 1984 c.22.

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) (Community 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.

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) and 13 (competent authorities of Member States), the Food Standards Agency; and
- (b) in respect of Articles 16(1) (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.

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(a).

(2) Any person who fails to comply with the requirements of Article 13 (supporting documentation) of Regulation 450/2009 is guilty of an offence.

(a) 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,
 - (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
- (b) any reference to a numbered Article or Annex is a reference to that Article of or Annex to Directive 84/500/EEC.

Limits for lead and cadmium and declaration of compliance

10.—(1) The quantities of lead or cadmium transferred from a ceramic article must not exceed the limits laid down in Article 2(4) as read with Article 2(3) and (5).

(2) Unless it is demonstrated that the materials used to make the ceramic article did not contain lead or cadmium, compliance with paragraph (1) is to be determined by testing and analysis in accordance with Annexes I and II.

(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) A person who places on the market a ceramic article that is not yet in contact with food must provide a written declaration complying with paragraph (5) to accompany the article at the marketing stages up to and including the retail stage.

(5) The declaration must be issued by the manufacturer or by a person established within the EU who placed the ceramic article on the market and must contain the information laid down in Annex III.

(6) A person who manufactures or, in the course of a business, imports into the EU a ceramic article must on request make available to an authorised officer appropriate documentation to demonstrate compliance with the requirements of paragraph (1) including —

- (a) the results of analysis carried out;
- (b) the test conditions; and
- (c) the name and address of the laboratory that performed the testing.

(7) Paragraphs (4),(5) and (6) do not apply in relation to a ceramic article which is second-hand.

(8) The documentation specified in paragraph 6(a),(b) and (c) is not required where documentary evidence is provided to show that the materials used to make the ceramic article did not contain lead or cadmium.

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.

(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),(6) or (7).

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 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(a), 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.

(2) Any person who fails to comply with the second sentence of Article 8 (general requirements on substances) or, subject to transitional arrangements set out in Article 22(1),(2) and (3)(b), with Article 16 (supporting documents) is guilty of an offence.

Competent authorities for the purposes of Regulation 10/2011

15. The competent authorities for the purposes of Regulation 10/2011 are —

- (a) in respect of Article 8, the Food Standards Agency, each food authority in its area and each port health authority in its district; and
- (b) in respect of Article 16(1), the Food Standards Agency.

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) paragraphs (2) and (3) are subject to Article 1(3) (scope)(c).

(2) Subject to Article 6(1),(2) and (4) (transitional provisions)(d), 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).

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- (a) 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.
 - (b) Paragraphs (1),(2) and (3) of Article 22 provide that the supporting documents referred to in Article 16 must, until 31 December 2012, be based on the rules in Directive 82/711/EEC; that from 1 January 2013 until 31 December 2015 such documents may be based on the rules in Directive 82/711/EEC or Article 18 of Regulation 10/2011 and that from 1 January 2016 such documents must be based on the rules in Article 18 of that Regulation.
 - (c) Article 3 contains an exception relating to certain containers and storage tanks and pipelines belonging to them.
 - (d) 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.

(3) Subject to Article 6(3)(a), no person may place on the market any material or article which fails to comply with the requirements of Article 5 (written declaration)(b).

(4) Any person who contravenes paragraph (2) or (3) is guilty of an offence.

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
- (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).

PART 9

Enforcement

Offences and penalties

19.—(1) Any person who contravenes the provisions of regulation 10(3) or (4), 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 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) or fails to comply with regulation 10(6) 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.

(5) Any person guilty of an offence under these Regulations is liable —

- (a) in the case of an offence created by paragraph (1) or (4) or regulation 4(3), 5, 7(1), 14(1) or 16(4) —

(a) Article 6(3) provides for a transitional provision in relation to the application of Article 5 to specified materials and articles that were brought into contact with food before 1 January 2007.

(b) Article 5 requires materials and articles containing BADGE and its derivatives to be accompanied by specified written material when being marketed at the pre-retail stages.

- (i) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or both, or
 - (ii) on summary conviction to a fine not exceeding the statutory maximum; and
- (b) in the case of an offence created by paragraph (2) or (3) or regulation 7(2) or 14(2), on summary conviction to a fine not exceeding level 5 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.

Execution and enforcement

20.—(1) Each food authority in its area and each port health authority in its district shall 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.
- (2) The Food Standards Agency may also execute and enforce the provisions of —
- (a) Articles 16(1) and 17(2) of Regulation 1935/2004; and
 - (b) Article 13 of Regulation 450/2009.

(3) Each food authority in its area shall execute and enforce the provisions of Regulation 2023/2006 specified in regulation 5 and these Regulations.

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 regulation 7(2), 14(2) or 19(2) or (3).

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 regulation 4(3), 7(1), 14(1), 16(4) 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.

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;
- (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)(a).

(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, Regulation 450/2009 or Regulation 10/2011 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

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

reference to Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 or Regulation 10/2011, 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).

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(a), 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(b); and
- (b) for the title and reference of the Materials and Articles in Contact with Food (England) Regulations 2010(c) substitute the title and reference of these Regulations.

Amendment to the Food Labelling Regulations 1996

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

(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.

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 how the EU instruments are implemented or executed and enforced in other Member States.

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

(b) S.I. 2009/205, amended by S.I. 2010/2225 and S.I. 2011/231.

(c) S.I. 2010/2225.

(d) S.I. 1996/1499. The definition of ingredient was previously amended by S.I. 2009/3235 and S.I. 2010/2225.

- (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 EU instruments” means 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^(a), Directive 84/500/EEC, Directive 2007/42/EC, Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 and Regulation 10/2011.

Revocations

31. The following Regulations are revoked —
- (a) The Ceramic Articles in Contact with Food (England) Regulations 2006^(b);
 - (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^(c)

Signed by authority of the Secretary of State for Health.

Anna Soubry
Parliamentary Under-Secretary of State,
Department of Health

17th October 2012

THE SCHEDULE

Regulation 14(1)

Specified provisions of Regulation 10/2011

<i>Specified provision</i>	<i>Subject matter</i>
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	General restrictions on plastic materials and articles

(a) OJ No. L44, 15.2.1978, p.15.

(b) S.I. 2006/1179, amended by S.I. 2007/2790.

(c) S.I. 2011/231.

Annex II	
Article 11(1) and (2) and Annex I, as read with Article 11(3)	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
Article 15 and Annex IV	Requirements that written declaration of compliance for plastic materials and articles, for products from the intermediate stages of their manufacture and for substances intended for the manufacture of those materials or articles should be available at the marketing stages other than the retail stage

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.

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