

2010 No. 2225

FOOD, ENGLAND

**The Materials and Articles in Contact with Food (England)
Regulations 2010**

<i>Made</i> - - - -	<i>6th September 2010</i>
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CONTENTS

PART 1

Preliminary

1. Title, application and commencement
2. Interpretation
3. Scope

PART 2

General Requirements for Materials and Articles

4. Offences of contravening specified provisions of Regulation 1935/2004
5. Offence of contravening Article 4 of Regulation 2023/2006
6. Offences of contravening specified provisions of Regulation 450/2009
7. Competent authorities

PART 3

Requirements for Vinyl Chloride

8. Limits and migration limits
9. Methods of Analysis

PART 4

Requirements for Regenerated Cellulose Film

10. Controls and limits
11. Migration limits for regenerated cellulose film coated with plastics
12. Saving provision and transitional defence

PART 5

General

13. Offences and penalties
14. Enforcement
15. Offences by corporate bodies or Scottish partnerships
16. Offences due to the act or default of a third party
17. Time limit for prosecutions
18. General defences
19. Procedure where a sample is to be analysed
20. Secondary analysis by the Government Chemist
21. Application of various provisions of the Act
22. Consequential amendment to the Food Safety (Sampling and Qualifications) Regulations 1990
23. Consequential amendment to the 2009 Regulations
24. Amendment to the Food Labelling Regulations 1996
25. Revocation

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 an EU instrument or to an Annex to an EU instrument specified in regulation 2(3) to be construed as references to that instrument or 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(d), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

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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. 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 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 2010, apply in relation to England only and come into force on 20th October 2010.

Interpretation

2.—(1) In these Regulations —

“the Act” means the Food Safety Act 1990;

“the 2009 Regulations” means the Plastic Materials and Articles in Contact with Food (England) Regulations 2009(a);

“Directive 2002/72/EC” means Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs(b);

“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(c);

“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(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);

“authorised officer” means any person, whether or not an officer of the authority having responsibility for execution and enforcement under regulation 14, who is authorised by that authority in writing 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;

“import” means import in the course of a business from a place other than an EEA State;

“plastics” means those materials and articles to which Directive 2002/72/EC applies;

“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(g) 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;

(a) S.I. 2009/205.

(b) OJ No. L220, 15.8.2002, p.18. This Directive was corrected by a corrigendum (OJ No. L39, 13.2.2003, p.1), and has been amended by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45), 2004/19/EC (OJ No. L71, 10.3.2004, p.8), 2005/79/EC (OJ No. L302, 19.11.2005, p.35), 2007/19/EC (OJ No. L97, 12.4.2007, p.50), 2008/39/EC (OJ No. L63, 7.3.2008, p.6) and Commission Regulation (EC) No. 975/2009 (OJ No. L274, 20.10.2009, p.3).

(c) 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.

(d) 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).

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

(f) OJ No. L135, 30.5.2009, p.3.

(g) 1984 c.22.

“preparation” includes manufacture and any form of treatment or process, and “prepare” shall be construed accordingly;

“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; and

“sell” includes offer or expose for sale or have in possession for sale, and “sale” shall be construed accordingly.

(2) Expressions used in these Regulations and in Regulation 1935/2004, Regulation 2023/2006 or Regulation 450/2009 bear the same meaning in these Regulations as they bear in those Regulations.

(3) Any reference to Regulation 2023/2006 or to an Annex to Directive 2002/72/EC or Directive 2007/42/EC 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 to those materials and articles specified in sub-paragraphs (a), (b) and (c) of Article 1(3) of Regulation 1935/2004.

PART 2

General Requirements for Materials and Articles

Offences of contravening specified provisions of Regulation 1935/2004

4. Subject to the transitional provisions contained in Article 27 of Regulation 1935/2004, any person who contravenes any of the following provisions of that Regulation is guilty of an offence

- (a) Article 3 (general requirements);
- (b) Article 4 (special requirements for active and intelligent materials and articles);
- (c) Article 11(4) and (5) (provisions relating to authorisation at EU level);
- (d) Article 15(1), (3), (4), (7) and (8) (labelling);
- (e) Article 16(1) (declaration of compliance); or
- (f) Article 17(2) (traceability).

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.

Offences of contravening specified provisions of Regulation 450/2009

6. Subject to the transitional provisions contained in Article 14 of Regulation 450/2009, any person who contravenes any of the following provisions of that Regulation is guilty of an offence

- (a) Article 4 (placing on the market of active and intelligent materials and articles);
- (b) Article 5(1) (list of substances that may be used in active and intelligent components) as read with Article 5(2);
- (c) Article 9(1) (relating to certain categories of substances not on the authorised list), as read with Article 9(2) and (3);
- (d) Article 10(1) (relating to a category of substances not on the authorised list), as read with Article 10(2);

- (e) Article 11(1) and (2) (rules on labelling);
- (f) Article 12 (requirement for a declaration of compliance); or
- (g) Article 13 (requirements relating to supporting documentation).

Competent authorities

7.—(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 and 13, the Food Standards Agency; and
- (b) in respect of Articles 16(1) and 17(2), the Food Standards Agency and the authority having responsibility for enforcement pursuant to regulation 14(1).

(2) The competent authority for the purposes of Article 6(2) and 7(3) of Regulation 2023/2006 is each food authority in its area.

(3) The competent authorities for the purposes of Article 13 of Regulation 450/2009 are the Food Standards Agency and the authority having responsibility for enforcement pursuant to regulation 14(1).

PART 3

Requirements for Vinyl Chloride

Limits and migration limits

8.—(1) Materials and articles 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 as measured by the method of analysis specified in regulation 9(1); 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 as measured by the method of analysis specified in regulation 9(2).

(2) No person may —

- (a) sell;
- (b) import; or
- (c) use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food,

any material or article that does not comply with paragraph (1).

Methods of Analysis

9.—(1) The method to be used in analysing any sample for the purpose of establishing the quantity of vinyl chloride monomer present in the material or article in order to determine whether it complies with regulation 8(1)(a) is the method specified in the Annex to Commission Directive 80/766/EEC laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs(a).

(2) The method to be used in analysing any food for the purpose of establishing the quantity of vinyl chloride present in the food in order to determine whether a material or article which is or has been in contact with the food complies with regulation 8(1)(b) is the method specified in the

(a) OJ No. L213, 16.8.80, p.42.

Annex to Commission Directive 81/432/EEC laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs^(a).

PART 4

Requirements for Regenerated Cellulose Film

Controls and limits

10.—(1) 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.

(2) Except in paragraph (4), any reference in this regulation to Annex II is a reference to Annex II to Directive 2007/42/EC.

(3) Subject to paragraph (5) and regulation 12, no person may manufacture any regenerated cellulose film intended to come into contact with food using any substance or group of substances other than the substances named or described —

- (a) in the first column (denominations) of Annex II (list of substances authorised in the manufacture of regenerated cellulose film) in the case of —
 - (i) uncoated film; or
 - (ii) coated film where the coating is derived from cellulose;
- (b) in the first column of the First Part (uncoated regenerated cellulose film) of Annex II in the case of film to be coated, where the coating will consist of plastics,

and in each case other than in accordance with the conditions and restrictions specified in the corresponding entry in the second column of the appropriate Part of Annex II, as read with the preamble to that Annex.

(4) Subject to regulation 12, no person may manufacture any coating to be applied to film referred to in paragraph (3)(b) using any substance or group of substances other than those listed in Annex II, III or IV to Directive 2002/72/EC and other than in accordance with the appropriate requirements, restrictions and specifications contained in those Annexes and in the 2009 Regulations.

(5) Substances other than those listed in Annex II may be used as colourants or adhesives in the manufacture of any film to which paragraph (3)(a) applies, provided that such film is manufactured in such a way that it does not transfer any colourant or adhesive to food in any detectable quantity.

(6) Subject to regulation 12 no person may —

- (a) sell;
- (b) import; or
- (c) use in the course of a business in connection with the storage, preparation, packaging, sale or service of food,

any regenerated cellulose film which has been manufactured in contravention of the requirements of paragraphs (3) or (4), or which fails to comply with paragraph (8).

(7) No person may, in the course of a business, use in connection with the storage, preparation, packaging, sale or service of food —

(a) OJ No. L167, 24.6.81, p.6.

- (a) where the food contains water physically free at the surface, any regenerated cellulose film containing bis(2-hydroxyethyl) ether or ethanediol; or
- (b) any regenerated cellulose film in such a way that any printed surface of that film comes into contact with the food.

(8) 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.

Migration limits for regenerated cellulose film coated with plastics

11.—(1) Subject to paragraph (2), no person may manufacture or import any material or article made with regenerated cellulose film coated with plastics which —

- (a) is intended to come into contact with food; and
- (b) is capable of transferring its constituents to food in quantities exceeding an overall migration limit of 10 milligrams per square decimetre of the surface of the material or article in contact with food.

(2) In the case of any material or article made with regenerated cellulose film coated with plastics which —

- (a) is or is comparable to a container or which can be filled to a capacity of not less than 500 millilitres and not more than 10 litres;
- (b) can be filled and for which it is impracticable to estimate the surface area in contact with food; or
- (c) is a cap, gasket, stopper or similar device for sealing,

the overall migration limit shall be 60 milligrams of constituents transferred per kilogram of food.

(3) No person may manufacture or import any material or article made with regenerated cellulose film coated with plastics manufactured with any substance listed in Section A or B of Annex II to Directive 2002/72/EC (authorised monomers and other starting substances) which —

- (a) is intended to come into contact with food; and
- (b) is capable of transferring its constituents to food in quantities exceeding the specific migration limits set out in column 4 of those Sections as read with the general introduction to that Annex.

(4) Where the specific migration limit for a substance mentioned in paragraph (3) is expressed in milligrams per kilogram, in the case of regenerated cellulose film coated with plastics which —

- (a) is or is comparable to a container or which can be filled to a capacity of less than 500 millilitres or more than 10 litres; or
- (b) cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the film and the quantity of food in contact with it,

the migration limit shall be divided by the conversion factor of 6 in order to express it in milligrams of constituents transferred per square decimetre of the material or article in contact with food.

(5) Subject to paragraph (6), the verification of compliance with migration limits shall be conducted in accordance with the provisions of Schedules 2 and 3 to the 2009 Regulations as read with regulation 13 of those Regulations and for the purposes of this paragraph any reference in those provisions to a plastic material or article shall be construed as a reference to regenerated cellulose film coated with plastic.

(6) Paragraph (5) shall not apply in any circumstance to which regulation 9 applies.

Saving provision and transitional defence

12. In any proceedings for an offence of contravening regulation 10(3), (4), (6) or (7), or regulation 11(1) or (3) it shall be a defence to prove that —

- (a) the act constituting the offence was committed in relation to a material or article made with regenerated cellulose film which was manufactured in or imported into the European Union before 29th January 2006; and
- (b) the act constituting the offence would not have constituted an offence under the Materials and Articles in Contact with Food Regulations 1987 as they stood immediately before the coming into force of the Materials and Articles in Contact with Food (England) Regulations 2005(a).

PART 5

General

Offences and penalties

13.—(1) Any person who —

- (a) contravenes the provisions of regulation 8, 10(3), (4), (6), (7) or (8) or 11(1) or (3);
- (b) intentionally obstructs any person acting in the execution of Regulation 1935/2004, Regulation 2023/2006, Regulation 450/2009 or these Regulations or, without reasonable excuse, fails to provide any assistance or information that person may reasonably require; or
- (c) in purported compliance with any requirement mentioned in sub-paragraph (b), knowingly or recklessly supplies information that is false or misleading in any material particular,

is guilty of an offence.

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

- (a) in the case of an offence mentioned in paragraph (1)(a) or (c) or in regulation 4, 5 or 6 —
 - (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 or to a term of imprisonment not exceeding 6 months or both; and
- (b) in the case of an offence mentioned in paragraph (1)(b) on summary conviction to a term of imprisonment not exceeding 3 months or to a fine not exceeding level 5 on the standard scale or both.

(3) Nothing in paragraph (1)(b) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate them.

Enforcement

14.—(1) Each food authority in its area and each port health authority in its district shall execute and enforce —

- (a) the provisions of Regulation 1935/2004 specified in regulation 4;
- (b) the provisions of Regulation 450/2009 specified in regulation 6; and
- (c) except in relation to the provisions referred to 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.

(a) S.I. 2005/898. Those Regulations were amended by S.I. 2005/2626, S.I. 2006/1401 and S.I. 2006/2687, but none of those instruments made amendments that are relevant to this provision.

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

Offences by corporate bodies or Scottish partnerships

15.—(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

16. 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

17. 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.

General defences

18.—(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, 6(a) to (f) or 13(1)(a) who did not —

- (a) prepare the material or article in respect of which the offence is alleged to have been committed; nor
- (b) import it into the United Kingdom,

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 sale 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 sale of which the offence consisted was not a sale 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 he has previously appeared before the court in connection with the alleged offence, within one month of his 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

19.—(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 20.

Secondary analysis by the Government Chemist

20.—(1) Where a sample has been retained under regulation 19 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 above,
- 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 defendant, 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 defendant 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 defendant 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 defendant to pay the fee specified in the notice the authorised officer may refuse to comply with the request.

(7) In this regulation "defendant" includes a prospective defendant.

Application of various provisions of the Act

21.—(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 thereof shall be construed as a reference to these Regulations —

- (a) section 2 (extending meaning of "sale" etc);
- (b) section 30(8) (which relates to documentary evidence).

(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) shall be construed as including a reference to Regulation 1935/2004, Regulation 2023/2006 or Regulation 450/2009 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 shall be construed as including a reference to Regulation 1935/2004, Regulation 2023/2006 or Regulation 450/2009, 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" shall 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).

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

22. In the Food Safety (Sampling and Qualifications) Regulations 1990(a), in Schedule 1 (provisions to which those Regulations do not apply) for the title and reference of the Materials and Articles in Contact with Food (England) Regulations 2007 substitute the title and reference of these Regulations.

Consequential amendment to the 2009 Regulations

23.—(1) The 2009 Regulations are amended in accordance with paragraphs (2) and (3).

(2) In regulation 2 (1) (interpretation) omit the definition of "the 2007 Regulations".

(3) In paragraph (1)(b) of regulation 13 (method of testing the capability of plastic materials or articles to transfer constituents, and methods of analysis), for the expression "regulation 9(2) of

(a) S.I. 1990/2463, amended by S.I. 2007/2790; there are other amending instruments but none is relevant.

the 2007 Regulations” substitute “regulation 9(2) of the Materials and Articles in Contact with Food (England) Regulations 2010”.

Amendment to the Food Labelling Regulations 1996

24.—(1) The Food Labelling Regulations 1996(a) 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;”.

Revocation

25. The Materials and Articles in Contact with Food (England) Regulations 2007(b) are revoked.

Signed by authority of the Secretary of State for Health.

6th September 2010

Anne Milton
Parliamentary Under-Secretary of State,
Department of Health

(a) S.I. 1996/1499. The definition of ingredient was previously amended by S.I. 2009/3235.

(b) S.I. 2007/2790, amended by S.I. 2009/205 and S.I. 2009/2938.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations revoke the Materials and Articles in Contact with Food (England) Regulations 2007 (S.I. 2007/2790 as amended by S.I. 2009/205 and S.I. 2009/2938) (“the 2007 Regulations”) and re-enact, with certain amendments relating to active and intelligent materials and articles, provisions contained in those Regulations. These Regulations provide for the enforcement of 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”).

2. The Regulations also provide for —

- (a) the enforcement of 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”));
- (b) the implementation of 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”). This Directive repealed and consolidated Commission Directive 93/10/EEC (OJ No. L93, 17.4.1993, p.27) as last amended by Commission Directive 2004/14/EC (OJ No. L27, 30.1.2004, p.48); and
- (c) the enforcement of 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”).

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*), Regulation 2023/2006 (*regulation 5*) and Regulation 450/2009 (*regulation 6*). 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, 2023/2006 and 450/2009 (*regulation 7*).

7. Part 3 consists of regulations which re-enact, without amendment, the provisions of the 2007 Regulations relating to vinyl chloride (*regulations 8 and 9*).

8. Part 4 contains regulations which re-enact, without amendment, provisions of the 2007 Regulations relating to regenerated cellulose film (“RCF”) (*regulations 10, 11 and 12*).

9. In particular, regulation 10 of these Regulations —

- (a) controls what substances may be used in the manufacture of RCF, which may vary according to whether or not it is coated with plastics (*paragraph (3)*);
- (b) regulates what substances may be used to manufacture plastic coatings for RCF, and under what conditions (*paragraph (4)*);
- (c) creates a conditional derogation from paragraph (3) in respect of substances used as colourants or adhesives in the manufacture of non-plastic coated RCF (*paragraph (5)*);
- (d) creates offences in relation to the sale, import or business use of non-compliant RCF (*paragraphs (6) & (7)*); and

- (e) creates a conditional requirement for RCF, when marketed prior to the retail stage, to be accompanied by a declaration of legislative compliance (*paragraph (8)*).

10. Regulation 11 applies to plastic coated RCF the existing controls (derived from Commission Directive 2002/72/EC) on migration of constituents of plastic materials and articles into food, in particular by —

- (a) specifying overall migration limits for plastic coated RCF (*paragraphs (1) & (2)*);
- (b) applying to plastic coated RCF the specific migration limits applicable to certain substances used in the manufacture of plastic materials and articles (*paragraphs (3) & (4)*); and
- (c) applying the prescribed methods and procedures for checking compliance with migration limits (*paragraphs (5) & (6)*).

11. Regulation 12 contains saving and transitional provisions which —

- (a) preserve the defences available under the Materials and Articles in Contact with Food Regulations 1987 (S.I. 1987/1523) for any RCF manufactured before 29th April 1994 that may still be in circulation; and
- (b) provide a defence in relation to RCF manufactured in or imported into the European Community before 29th January 2006.

12. Part 5 contains general administrative and enforcement provisions which —

- (a) penalise contravention of these Regulations or obstruction of those enforcing them (*regulation 13*);
- (b) designate enforcement authorities for various functions under the Regulations (*regulation 14*);
- (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 15*);
- (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 16*);
- (e) specify a time limit for commencing a prosecution (*regulation 17*);
- (f) provide for a defence of due diligence to an offence under these Regulations (*regulation 18*);
- (g) specify the procedure to be followed when sending a sample for analysis (*regulation 19*);
- (h) make provision for a reference sample to be analysed by the Laboratory of the Government Chemist (*regulation 20*);
- (i) apply certain provisions of the Food Safety Act 1990 for the purposes of these Regulations (*regulation 21*);
- (j) make a consequential amendment to Schedule 1 to the Food Safety (Sampling and Qualifications) Regulations 1990 (S.I. 1990/2463; relevant amending instrument is S.I. 2007/2790) (*regulation 22*);
- (k) make a consequential amendment to the Plastic Materials and Articles in Contact with Food (England) Regulations 2009 (S.I. 2009/205) (*regulation 23*);
- (l) amend the definition of “ingredient” in the Food Labelling Regulations 1996 (S.I. 1996/1499; relevant amending instrument is S.I. 2009/3235) (*regulation 24*); and
- (m) revoke the 2007 Regulations (*regulation 25*).

13. 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 the OPSI website.

STATUTORY INSTRUMENTS

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