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WELSH STATUTORY INSTRUMENTS

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**2007 No. 3252 (W.287)**

**FOOD, WALES**

**The Materials and Articles in Contact  
with Food (Wales) Regulations 2007**

<i>Made</i>	- - - -	<i>13 November 2007</i>
<i>Laid before the National Assembly for Wales</i>	- -	<i>14 November 2007</i>
<i>Coming into force</i>		
<i>for the purpose of regulations 5, 7 and 14(3)</i>		<i>1 August 2008</i>
<i>for all other purposes</i>		<i>6 December 2007</i>

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), (2)(a) and (3), and 48(1) of the Food Safety Act 1990 <sup>M1</sup>, as read with paragraph 1A of Schedule 2 to the European Communities Act 1972 <sup>M2</sup>.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Welsh Ministers that it is expedient for certain references to a Community instrument or to an Annex to a Community instrument as specified in regulation 2(4) 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 they have had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>M3</sup>, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

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**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 and S.I. 2004/2990. Functions of the Secretary of State, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer

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of Functions) Order 1999 S.I. 1999/672). Those functions were transferred to Welsh Ministers by section 162 and Schedule 11, paragraph 30 of the [Government of Wales Act 2006 \(c. 32\)](#).

**M2** [1972 c. 68](#). Paragraph 1A of Schedule 2 was inserted by section 28 of the [Legislative and Regulatory Reform Act 2006 \(2006, c. 51\)](#).

**M3** OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

## PART 1

### Preliminary

#### Title, application and commencement

1. The title of these Regulations is the Materials and Articles in Contact with Food (Wales) Regulations 2007, apply in relation to Wales and come into force —

- (a) for the purposes of regulations 5, 7 and 14(3), on 1st August 2008; and
- (b) for all other purposes, on 6 December 2007.

#### Interpretation

2.—(1) In these Regulations —

“the Act” (“*the Act*”) means the Food Safety Act 1990;

<sup>F1</sup>  
...

[<sup>F2</sup>“the 2008 Regulations” (“*Rheoliadau 2008*”) means the Plastic Materials and Articles in Contact with Food (Wales) (No. 2) Regulations 2008;]

<sup>F3</sup>  
...

“Directive [2002/72/EC](#)” (“*Cyfarwyddeb 2002/72/EC*”) means Commission Directive [2002/72/EC](#) relating to plastic materials and articles intended to come into contact with foodstuffs <sup>M4</sup>;

“Directive [2007/42/EC](#)” (“*Cyfarwyddeb 2007/42/EC*”) means Commission Directive [2007/42/EC](#) relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs <sup>M5</sup>;

“Regulation 1935/2004” (“*Rheoliad 1935/2004*”) means Regulation (EC) No. [1935/2004](#) of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives [80/590/EEC](#) and [89/109/EEC](#) <sup>M6</sup>;

“Regulation 2023/2006” (“*Rheoliad 2023/2006*”) means Commission Regulation (EC) No. [2023/2006](#) on good manufacturing practice for materials and articles intended to come into contact with food <sup>M7</sup>;

“authorised officer” (“*swyddog awdurdodedig*”) 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” (“*awdurdod bwyd*”) has the same meaning as in section 5(1A) of the Act but does not include port health authorities

“import” (“*mewnforio*”) means import in the course of a business from a place other than a Member State;

“plastics” (“*plastigion*”) means those materials and articles to which Directive [2002/72/EC](#) applies;

“port health authority” (“*awadurdod iechyd porthladd*”) means in relation to any port health district constituted by order under section 2(3) of the Public Health (Control of Disease) Act 1984, a port health authority for that district constituted by order under section 2(4) of that Act; “preparation” (“*paratoad*”) includes manufacture and any form of treatment or process, and “prepare” is to be construed accordingly;

“regenerated cellulose film” (“*caen cellwlos atgynrychiedig*”) 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;

“sell” (“*gwerthu*”) includes offer or expose for sale or have in possession for sale, and “sale” and “sold” is to be construed accordingly.

(2) Except in regulations 5 and 7, any reference in these Regulations to a numbered Article is a reference to the Article bearing that number in Regulation 1935/2004.

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

(4) Any reference to Regulation 2023/2006 or to an Annex of Directive [2002/72/EC](#) or of Directive [2007/42/EC](#) is a reference to that Regulation or that Annex as amended from time to time.

#### Textual Amendments

- F1** Words in reg. 2(1) omitted (1.7.2008) by The Plastic Materials and Articles in Contact with [Food \(Wales\) \(No.2\) Regulations 2008 \(S.I. 2008/1682\)](#), **regs. 1(b), 28(2)(a)**
- F2** Words in reg. 2(1) inserted (1.7.2008) by The Plastic Materials and Articles in Contact with [Food \(Wales\) \(No.2\) Regulations 2008 \(S.I. 2008/1682\)](#), regs. 1(b), 28(2)(b)
- F3** Words in reg. 2(1) omitted (1.5.2008) by The Plastic Materials and Articles in Contact with [Food \(Wales\) Regulations 2008 \(S.I. 2008/1237\)](#), **regs. 1(b), 28(2)(a)**

#### Marginal Citations

- M4** 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 as at the date these Regulations were made 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) and Commission Directive [2007/19/EC](#) (OJ No.L97, 12.4.2007, p.50).
- M5** 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](#).
- M6** OJ No. L338, 13.11.2004, p.4.
- M7** OJ No. L384, 29.12.2006, p.75.

#### 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).

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## PART 2

### General Requirements for Materials and Articles

#### Enforcement of Regulation 1935/2004

4. Subject to the provisions of Article 27 (transitional arrangements), any person who contravenes any of the following provisions of Regulation 1935/2004 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 Community authorisation);
- (d) Article 15(1), (2), (3), (4), (7) and (8) (labelling);
- (e) Article 16(1) (declaration of compliance);
- (f) Article 17(2) (traceability).

VALID FROM 01/08/2008

#### Enforcement 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

6. The following bodies are designated as the competent authorities for the purposes of the provisions of Regulation 1935/2004 as specified below —

- (a) in respect of Articles 9 and 13, the Food Standards Agency;
- (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).

VALID FROM 01/08/2008

#### Competent authority for the purposes of Regulation 2023/2006

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

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

### Methods of Analysis

9.—(1) The method 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](#) (which lays 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) <sup>M8</sup>.

(2) The method 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 Annex to Commission Directive [81/432/EEC](#) (which lays down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs) <sup>M9</sup>.

#### Marginal Citations

**M8** OJ No. L213, 16.8.80, p.42.

**M9** OJ No. L167, 24.6.81, p.6.

## 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), 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 —

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- (a) in the first column (denominations) of Annex II 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 of Annex II in the case of film to be coated, where the coating will consist of plastics,

and 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) No person may manufacture any coating to be applied to film referred to in paragraph (3) (b) using any substance or group of substances except 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 [F<sup>4</sup>2008] Regulations.

(5) Substances other than those listed in Annex II may be used as colourants or adhesives in the manufacture of a 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, selling or serving 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 use in the course of a business in connection with the storage, preparation, packaging, serving or selling of food —

- (a) where the food contains water physically free at the surface, any regenerated cellulose film containing bis(2-hydroxyethyl) ether, ethanediol or both these substances;
- (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, unless by its nature clearly intended to come into contact with food, at a marketing stage other than the retail stage must be accompanied by a written declaration attesting that it complies with the legislation applicable to it.

#### Textual Amendments

**F4** Word in reg. 10(4) substituted (1.5.2008) by The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2008 (S.I. 2008/1327), regs. 1(b), 2(3)

#### 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 with a capacity of not less than 500 millilitres and not more than 10 litres; or
- (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 is to 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 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 with 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 is to 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 is to be conducted in accordance with the provisions of Schedules 2 and 3 of the [F52008] Regulations [F6as 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 is to be construed as a reference to regenerated cellulose film coated with plastic.

(6) Paragraph (5) does not apply in any circumstances to which regulation 9(1) or (2) is applicable.

#### Textual Amendments

- F5** Word in reg. 11(5) substituted (1.5.2008) by The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2008 (S.I. 2008/1237), **regs. 1(b), 28(4)**
- F6** Words in reg. 11(5) substituted (1.7.2008) by The Plastic Materials and Articles in Contact with Food (Wales) (No.2) Regulations 2008 (S.I. 2008/1682), **regs. 1(b), 28(3)**

#### Saving and transitional provisions and defences

12.—(1) Notwithstanding the revocation of the Materials and Articles in Contact with Food Regulations 1987<sup>M10</sup>, in relation to regenerated cellulose film manufactured before 29th April 1994 the defences in regulation 6A of those Regulations apply in relation to offences under these Regulations in like manner as they applied to offences under the equivalent provisions in those Regulations.

(2) In any proceedings for an offence of contravening regulation 10(3), (4), (6) or (7), or regulation 11(1) or (3) it is 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 or imported into the European Community before 29th January 2006; and

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- (b) the act constituting the offence would not have constituted an offence under the Materials and Articles in Contact with Food Regulations 1987 immediately before the coming into force of the Materials and Articles in Contact with Food (Wales) Regulations 2005<sup>M11</sup>.

**Marginal Citations**

**M10** S.I. 1987/1523, as amended by S.I. 1990/2487, S.I. 1991/1476 and S.I. 1994/979.

**M11** S.I. 2005/1647 (W.128). These Regulations were subsequently amended by S.I. 2005/3254 (W.247) and S.I. 2006/2982 (W.273), but none of those amendments are relevant to this provision.

## PART 5

### General

#### Offences and penalties

13.—(1) Any person who —

- (a) contravenes the provisions of regulation 8(2), 10(3), (4), (6) or (7), or 11(1) or (3);
- (b) intentionally obstructs any person acting in the execution of Regulation 1935/2004, Regulation 2023/2006 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 or 5 —
  - (i) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or both;
  - (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 him or her.

#### Enforcement

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

- (a) the provisions of Regulation 1935/2004 mentioned in regulation 4, and
- (b) subject to paragraph (3), these Regulations.

(2) The Food Standards Agency may also execute and enforce the provisions of Articles 16(1) and 17(2).

(3) Each food authority in its area will execute and enforce the provisions of Regulation 2023/2006 mentioned 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 person as well as the body corporate is deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

(2) Where an offence under these Regulations which has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of a partner, that person as well as the partnership is deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

### **Offences due to the act or default of a third party**

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 is guilty of the offence; and a person may be charged with and convicted of the offence whether or not proceedings are taken against the first mentioned person.

### **Time limit for prosecutions**

17. No prosecution for an offence under these Regulations is to be begun after the expiry of three years from the commission of the offence or one year from its discovery by the prosecutor, whichever is the earlier.

### **General defences**

18.—(1) In any proceedings for an offence under these Regulations it is, subject to paragraph (5), a defence for the person accused to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by him or herself or by a person under his or her control.

(2) Without prejudice to the generality of paragraph (1), a person accused of an offence under regulation 4 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,

is to be taken to have established the defence provided by paragraph (1) if that person satisfies the requirements of paragraphs (3) and (4).

(3) A person satisfies the requirements of this paragraph if that person proves—

- (a) that the commission of the offence was due to the act or default of some other person who was not under his or her control, or to reliance on information supplied by such a person;
- (b) that either—

- (i) he or she 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 that person to rely on checks carried out by the person who supplied him or her with that material or article; and

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- (c) that he or she did not know and had no reason to suspect at the time the offence was committed that his or her act or omission would amount to an offence under these Regulations.
- (4) A person satisfies the requirements of this paragraph if the offence is one of sale and he or she proves —
  - (a) that the commission of the offence was due to the act or default of some other person who was not under his or her control, or to reliance on information supplied by such a person;
  - (b) that the sale of which the offence consisted was not a sale under his or her name or mark; and
  - (c) that he or she did not know and could not reasonably be expected to know at the time the offence was committed that his or her 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 person accused will 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 or she has previously appeared before the court in connection with the alleged offence, within one month of his or her first such appearance,he or she 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 his or her possession.

#### **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 is to 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 is to divide the sample into parts by putting the containers into three lots, and each lot is to be treated as being a part.
- (3) The authorised officer will —
- (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 him 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 his or her own volition; or

(b) will —

- (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 will analyse the part sent to him or her 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 will be signed by him or her or on his behalf, but the analysis may be carried out by any person under the direction of the person who signs the certificate.

(5) The authorised officer will 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 is to 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) is construed as including a reference to Regulation 1935/2004 or as appropriate to Regulation 2023/2006.

(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 construed as including a reference to Regulation 1935/2004 or, as appropriate Regulation 2023/2006, and to these Regulations —

- (a) section 3 (presumptions that food is intended for human consumption) with the modifications that the references to “sold” and “sale” is 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).

#### **Amendment of the Ceramic Articles in Contact with Food (Wales) Regulations 2006**

**22.**—(1) The Ceramic Articles in Contact with Food (Wales) Regulations 2006<sup>M12</sup> are amended in accordance with paragraph (2).

(2) In Schedule 3 (declaration of compliance), for sub-paragraph (5) of paragraph 1 substitute the following —

“(5) confirmation that the ceramic article or articles meet the relevant requirements in —

- (a) these Regulations; or
- (b)

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- (i) 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 <sup>M13</sup> as amended by Commission Directive [2005/31/EC](#)<sup>M14</sup>; and
- (ii) 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>M15</sup>.”.

**Marginal Citations**

- M12** [S.I. 2006/1704](#) (W.166)
- M13** OJ No. L277, 20.10.1984, p.12.
- M14** OJ No. L110, 30.4.2005, p.36.
- M15** OJ No. L338, 13.11.2004, p.4.

**Amendment of the Food Safety (Sampling and Qualifications) Regulations 1990**

23. In the Food Safety (Sampling and Qualifications) Regulations 1990 <sup>M16</sup>, 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 Regulations 1987 substitute the title and reference of these Regulations.

**Marginal Citations**

- M16** [S.I. 1990/2463](#). Functions under these Regulations, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 [S.I. 1999/672](#)). Those Functions were transferred to Welsh Ministers by section 162 and Schedule 11, paragraph 30 of the [Government of Wales Act 2006 \(c. 32\)](#).

**Consequential amendments to the 2006 Regulations**

<sup>F7</sup>24. ....

**Textual Amendments**

- F7** Reg 24 revoked (1.7.2008) by The Plastic Materials and Articles in Contact with [Food \(Wales\) \(No.2\) Regulations 2008 \(S.I. 2008/1682\)](#), **regs. 1(b)**, 30(c)

**Revocations**

- 25. The following Regulations or parts thereof are revoked —
  - (a) The Materials and Articles in Contact with Food (Wales) Regulations 2005;
  - (b) Regulation 24 of the 2006 Regulations.

*G. Thomas*  
Under authority of the Minister for Health and  
Social Services, one of the Welsh Ministers

13 November 2007

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations revoke the Materials and Articles in Contact with Food (Wales) Regulations S.I. 2005/1647 (W.128)) (“the 2005 Regulations”) and re-enact or re-enact with amendments 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 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”), and implement 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).

3. These Regulations provide that references to a certain EC instrument or specified parts of certain EC instruments are to be construed as references to the instrument or specified part of it as it may be amended from time to time (*regulation 2(4)*).

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 of Regulation 2023/2006 (*regulation 5*). Regulation 1935/2004 is the principal framework Regulation on materials and articles in contact with food. This Part also provides for designation of the competent authorities for the various purposes identified in Regulations 1935/2004 and 2023/2006 (*regulations 6 and 7*).

6. Part 3 contains regulations which re-enact, without substantive amendments, the provisions of the 2005 Regulations relating to vinyl chloride (*regulations 8 and 9*).

7. Part 4 contains regulations which re-enact provisions of the 2005 Regulations relating to regenerated cellulose film (“RCF”), with minor amendments to implement Directive 2007/42 (*regulations 10 & 11*).

8. 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

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**Changes to legislation:** There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (Wales) Regulations 2007 (revoked). (See end of Document for details)

- (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)*).
- 9.** 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)*).
- 10.** Regulation 12 contains savings and transitional provisions which —
- (a) preserve the defences available under the 1987 Regulations for any RCF manufactured before 29th April 1994 that may still be in circulation; and
  - (b) create a defence in relation to RCF manufactured in or imported into the European Community before 29th January 2006.
- 11.** Part 5 of these Regulations 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*); and
  - (i) apply certain provisions of the Food Safety Act 1990 (*regulation 21*).
- 12.** In Part 5 these Regulations also —
- (a) amend Schedule 3 to the Ceramic Articles in Contact with Food (Wales) Regulations 2006 (S.I. 2006/1704 (W.166)) (*regulation 22*);
  - (b) make consequential amendments to the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2006 (S.I. 2006/2982 W.273)) and the Food Safety (Sampling and Qualifications) Regulations 1990 (S.I. 1990/2463) (*regulations 23 & 24*); and
  - (c) revoke the Materials and Articles in Contact with Food (Wales) Regulations 2005 and subsequent amending legislation (*regulation 25*).

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**13.** A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Food Standards Agency, 11th Floor, Southgate House, Cardiff CF10 1EW

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**Changes to legislation:**

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