

Welsh Statutory Instrument 2005 No. 1647 (W.128)

The Materials and Articles in Contact with Food (Wales) Regulations 2005

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STATUTORY INSTRUMENTS

2005 No. 1647 (W.128)

FOOD, WALES

**The Materials and Articles in Contact with Food (Wales) Regulations
2005**

Made

21 June 2005

Coming into force

24 June 2005

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The National Assembly for Wales, in exercise of the powers conferred on it by sections 16(2), 17(1) and (2), 26(1)(a) and (3), 31 and 48(1) of the Food Safety Act 1990[1] and now vested in it[2], having had regard, in accordance with section 48(4A) of that Act, to relevant advice given by the Food Standards Agency, and after consultation 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[3], makes the following Regulations:

PART 1

Preliminary

Title, application and commencement

1. The title of these Regulations is the Materials and Articles in Contact with Food (Wales) Regulations 2005, they apply in relation to Wales and come into force on 24 June 2005.

Interpretation

2. —(1) In these Regulations —

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

"Directive 93/10/EEC" ("*Cyfarwydddeb 93/10/EEC*") means Commission Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with food[4];

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

"plastics" ("*plastigau*") means those materials and articles to which Commission Directive 2002/72/EC relating to plastic materials intended to come into contact with foodstuffs applies[5];

"preparation" ("*paratoi*") in relation to food includes manufacture and any form of treatment or process;

"regenerated cellulose film" ("*ffilm seliwlos a adfywiwyd*") 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;

"the 1998 Regulations" ("*Rheoliadau 1998*") means the Plastic Materials and Articles in Contact with Food Regulations 1998[6];

"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[7]; and

"sell" ("*gwerthu*") includes offer or expose for sale or have in possession for sale, and "sale" and "sold" shall be construed accordingly.

(2) 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 have the same meaning in these Regulations as in that Regulation.

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).

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) on or after 27 October 2006, Article 17(2) (traceability).

Competent authorities for the purposes of Regulation 1935/2004

5. 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 Agency;
- (b) in respect of Articles 16(1) and 17(2), the Agency and the authority having responsibility for enforcement pursuant to regulation 12(1).

PART 3

Requirements for Vinyl Chloride

Limits and migration limits

6. —(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 7(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 7(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 this regulation.

Methods of Analysis

7. —(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 6(1)(a) shall be the method specified in the Annex to Commission Directive No. 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)[8].

(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 6(1)(b) shall be the method specified in the Annex to Commission Directive No. 81/432/EEC (which lays down the Community method of analysis for the official control of vinyl chloride released by material and articles into foodstuffs)[9].

PART 4

Requirements for Regenerated Cellulose Film

Controls and limits

8. —(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) Any reference in this regulation to Annex II is a reference to Annex II to Directive 93/10/EEC.

(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 —

- (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 other than the substances listed in Schedules 1, 2 or 2A to the 1998 Regulations and other than in accordance with the appropriate requirements, restrictions and specifications contained in those Regulations and in the Schedules thereto.

(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 10 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.

Migration limits for regenerated cellulose film coated with plastics

9. —(1) Subject to paragraph (2), no person shall 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 shall be 60 milligrams of constituents transferred per kilogram of food.

(3) No person shall manufacture or import any material or article made with regenerated cellulose film coated with plastics manufactured with any substance listed in Part I of Schedule 1 to the 1998 Regulations (authorised monomers) 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 that Part as read with Part II of that Schedule.

(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 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 3 and 4 of the 1998 Regulations as read with regulation 6 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 circumstances to which regulation 7(1) or (2) is applicable.

Saving and transitional provisions and defences

10. —(1) Notwithstanding the revocations in regulation 16, in relation to regenerated cellulose film manufactured before 29th April 1994 the defences in regulation 6A of the Materials and Articles in Contact with Food Regulations 1987^[10] shall 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 under regulation 8(3), (4), (6) or (7), or regulation 9(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 or imported into the European Community before 29 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 immediately before the coming into force of these Regulations.

(3) In any proceedings for an offence under these Regulations it shall be a defence to prove that the material or article in respect of which the offence is alleged to have been committed was intended for export to a country which has legislation analogous to these Regulations and that the material or article complies with that legislation.

PART 5

General

Offences and penalties

11. —(1) Any person who contravenes the provisions of regulation 6(2), 8(3), (4), (6) or (7), or 9(1) or (3) is guilty of an offence.

(2) Any person guilty of an offence under paragraph (1) or under regulation 4 is liable —

(a) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both;

(b) on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both.

Enforcement

12. —(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 mentioned in regulation 4, and

(b) these Regulations.

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

Analysis by Government Chemist

13.—(1) The court before which any proceedings are taken under these Regulations may, if it thinks fit for the purposes of the proceedings, cause —

(a) any material or article which is the subject of the proceedings and which, if it has already been tested is capable of being further tested, or

(b) any food which has been in contact with any such material or article,

to be sent to the Government Chemist who shall carry out such testing as is appropriate and transmit to the court a certificate of the result, and the costs of the testing shall be paid by the prosecutor or the person charged as the court may order.

(2) If in a case where an appeal is brought no action has been taken under paragraph (1), the provisions of that paragraph shall apply in relation to the court by which the appeal is heard.

(3) Any certificate of the results of testing transmitted by the Government Chemist under this regulation shall be signed by or on behalf of the Government Chemist, but the testing may be carried out by any person under the direction of the person who signs the certificate.

(4) Any certificate transmitted by the Government Chemist in accordance with paragraph (3) shall be taken as evidence of the facts stated therein unless any party to the proceedings requests that the person by whom the certificate is signed be called as a witness.

(5) In this regulation the term "testing" includes examination and analysis, and "tested" shall be construed accordingly.

Application of various provisions of the Act

14.—(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 20 (offences due to fault of another person);

(c) section 21 (defence of due diligence) with the modification that in subsection (4) the references to "sale" shall be deemed to include references to "placing on the market";

(d) section 30(8) (which relates to documentary evidence);

(e) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (3) below;

(f) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (3) below;

(g) section 36 (offences by bodies corporate);

(h) section 36A (offences by Scottish partnerships).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the reference in subsection (1) to the Act shall be construed as including a reference to Regulation 1935/2004.

(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 and these Regulations —

(a) section 3 (presumptions that food is 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 33(1) (obstruction etc. of officers);

(c) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (b);

(d) section 44 (protection of officers acting in good faith).

(4) Section 34 of the Act (time limit for prosecutions) applies to offences under these Regulations as it applies to offences punishable under section 35(2) of the Act.

Amendments to the 1998 Regulations

15.—(1) The 1998 Regulations are amended in relation to Wales in accordance with paragraphs (2) to (6).

(2) In regulation 2 (interpretation) —

(a) omit the definition of "the 1987 Regulations";

(b) after the definition of "the 1992 Regulations" insert the following definition —

"the 2005 Regulations" means the Materials and Articles in Contact with Food (Wales) Regulations 2005[[11](#)];".

(3) In paragraph (1)(b) of regulation 6 (method of testing the capability of

plastic materials or articles to transfer constituents and methods of analysis) for "regulation 14(2) of the 1987 Regulations" substitute "regulation 7(2) of the 2005 Regulations".

(4) In paragraph (1) of regulation 9 (enforcement) for "the 1987 Regulations" substitute "the 2005 Regulations".

(5) In regulation 11 (presumption as to food with which a plastic material or article, adhesive or material or article covered by a surface coating is to come into contact) for "the 1987 Regulations" substitute "Regulation (EC) No. 1935/2004 of the European Parliament and of the Council[[12](#)]".

(6) For regulation 12 (application of other provisions) substitute the following —

" Application of other provisions

12. —(1) The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of the Act

(a) section 3 (presumption that food is intended for human consumption);

(b) section 30(8) (relating to documentary evidence);

(c) section 44 (protection of officers acting in good faith).

(2) Regulation 13 of the 2005 Regulations shall apply in relation to proceedings taken under these Regulations as it does to proceedings taken under those Regulations."

Revocations

16. The following Regulations or parts thereof are revoked in so far as they apply in relation to Wales —

(a) The Materials and Articles in Contact with Food Regulations 1987[[13](#)];

(b) Regulation 3 of The Food Safety (Export) Regulations 1991[[14](#)];

(c) The Materials and Articles in Contact with Food (Amendment) Regulations 1994[[15](#)].

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998[[16](#)]

D. Elis-Thomas
The Presiding Officer of the National Assembly

21 June 2005

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations revoke the Materials and Articles in Contact with Food Regulations 1987 (S.I. 1987/1523, as amended) ("the 1987 Regulations") in so far as they apply in relation to Wales, and re-enact or re-enact with amendments certain provisions contained in those Regulations. These Regulations also 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 ("Regulation 1935/2004").

2. 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.

3. Part 2 of these Regulations contains provision for the enforcement of Regulation 1935/2004, (regulation 4). Regulation 1935/2004 is a framework Regulation on materials and articles in contact with food, and replaces Directives 80/590/EEC and 89/109/EEC, which were implemented by the 1987 Regulations. This Part also provides for designation of the competent authorities for the various purposes identified in Regulation 1935/2004 (regulation 5).

4. Part 3 contains regulations which re-enact, without substantive amendments, the provisions of the 1987 Regulations relating to vinyl chloride (regulations 6 & 7).

5. Part 4 contains regulations that re-enact provisions of the 1987 Regulations relating to regenerated cellulose film ("RCF"), amended as necessary to implement the requirements of Commission Directive 2004/14/EC amending Directive 93/10/EC (regulations 8 & 9).

6. In particular regulation 8 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)).

7. Regulation 9 applies to plastic coated RCF the existing controls (derived from Commission Directive 2002/72 and implemented by the Plastic Materials and Articles in Contact with Food Regulations 1998, S.I. 1998/1376 as amended) 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)).

8. Regulation 10 contains savings and transitional provisions which —

(a) preserve the defences available under the 1987 Regulations for any RCF manufactured before 29 April 1994 that may still be in circulation;

(b) create a defence in relation to RCF manufactured in or imported into the European Community before 29 January 2006;

(c) provide for a defence in relation to exports.

9. Part 5 of these Regulations contains general administrative and enforcement provisions which —

(a) penalise contravention of these Regulations or of Regulation 1935/2004 (regulation 11);

(b) designate enforcement authorities (regulation 12);

(c) provide that the courts may direct that substances should be submitted to the Government Chemist for analysis (regulation 13);

(d) apply certain provisions of the Food Safety Act 1990 (regulation 14);

(e) make consequential amendments to the Plastic Materials and Articles in Contact with Food Regulations 1998 (S.I. 1998/1376, as amended) (regulation 15);

(f) revoke the 1987 Regulations and subsequent amending legislation (regulation 16).

10. A regulatory appraisal has been prepared for these Regulations and has been placed in the library of the National Assembly for Wales, together with a

transposition note setting out how the main elements of Commission Directive 2004/14/EC have been transposed into domestic law by these Regulations. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW.

Notes:

[1] 1990 c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990.[back](#)

[2] 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 Food Standards Act 1999 (1999 c.28) and paragraphs 12 and 21 of that Schedule amend respectively sections 17(2) and 48 of the 1990 Act. Section 48 was also amended by the Food Safety Act (Amendment) Regulations 2004 (S.I. 2004/2990). Functions of "the Ministers" 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) as read with section 40(3) of the 1999 Act and 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.[back](#)

[3] OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4).[back](#)

[4] OJ No. L93, 17.4.93, p.27, as last amended by Commission Directive 2004/14/EC (OJ No. L27, 30.1.2004, p.48).[back](#)

[5] OJ No. L220, 15.8.2002, p.18, as last amended by Commission Directive 2004/19/EC (OJ No. L71, 10.3.2004, p.8).[back](#)

[6] S.I. 1998/1376, as amended in relation to Wales by S.I. 2000/3162, S.I. 2002/2364, S.I. 2004/3113 and S.I. 2005/325.[back](#)

[7] OJ No. L338, 13.11.2004, p.4.[back](#)

[8] OJ No. L213, 16.8.90, p.42.[back](#)

[9] OJ No. L167, 24.6.81, p.6.[back](#)

[10] S.I. 1987/1523, as amended by S.I. 1991/1476 and S.I. 1994/979.[back](#)

[11] S.I. 2005/1647 (W.128).[back](#)

[12] OJ No. L338, 13.11.2004, p.4.[back](#)

[13] S.I. 1987/1523.[back](#)

[14] S.I. 1991/1476.[back](#)

[15] S.I. 1994/979.[back](#)

[16] 1998 c.38.[back](#)

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