
WELSH STATUTORY INSTRUMENTS

2005 No. 1647

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

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” (“*Cyfarwyddeb 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⁽¹⁾;

“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⁽²⁾;

“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⁽³⁾;

“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](#)⁽⁴⁾; and

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

(1) 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).

(2) 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).

(3) [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](#).

(4) OJ No. L338, 13.11.2004, p.4.

(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)(5).

(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)(6).

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.

(5) OJ No. L213, 16.8.90, p.42.

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

(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(7) 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;

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

- (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(8);”.

(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(9)”.

(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).

(8) S.I. 2005/1647 (W.128).

(9) OJ No. L338, 13.11.2004, p.4.

(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(**10**);
- (b) Regulation 3 of The Food Safety (Export) Regulations 1991(**11**);
- (c) The Materials and Articles in Contact with Food (Amendment) Regulations 1994(**12**).

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(**13**)

21 June 2005

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

(10) S.I. 1987/1523.
(11) S.I. 1991/1476.
(12) S.I. 1994/979.
(13) 1998 c. 38.