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WELSH STATUTORY INSTRUMENTS

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**2005 No. 1647**

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

**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<sup>(1)</sup> 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.

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(1) S.I. 1987/1523, as amended by S.I. 1991/1476 and S.I. 1994/979.