WELSH STATUTORY INSTRUMENTS

2008 No. 1682 (W.162)

FOOD, WALES

The Plastic Materials and Articles in Contact with Food (Wales) (No.2) Regulations 2008

Made - - - -	*27 June 2008*
Laid before the National Assembly for Wales - -	*27 June 2008*
Coming into force	
for the purpose of regulation 30(a)	*30 June 2008*
for all other purposes	*1 July 2008*

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), 31 and 48(1) of the Food Safety Act 1990(**1**), and now vested in them(**2**), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(**3**).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Welsh Ministers that it is expedient for references to the Annexes to the Community instrument specified in regulation 2(5) to be construed as references to those Annexes as amended from time to time.

In accordance with section 48(4A) of the Food Safety Act 1990 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(**4**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

(**1**) 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 1999 Act". 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.

(**2**) 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 of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and thereafter transferred to the Welsh Ministers by section 162 and paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c. 32).

(**3**) 1972 c. 68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006, c. 51).

(**4**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 202/2008 (OJ No. L60, 5.3.2008, p.17).

PART 1

Preliminary

Title, application and commencement

1. The title of these Regulations is the Plastic Materials and Articles in Contact with Food (Wales) (No.2) Regulations 2008, apply in relation to Wales and come into force —

(a) for the purpose of regulation 30(a) on 30 June 2008, and

(b) for all other purposes on 1 July 2008.

Interpretation

2.—(1) In these Regulations —

"the 1998 Regulations" ("*Rheoliadau 1998*") means the Plastic Materials and Articles in Contact with Food Regulations 1998(**5**);

"the 2007 Regulations" ("*Rheoliadau 2007*") means the Materials and Articles in Contact with Food (Wales) Regulations 2007(**6**);

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

"authorised officer" ("*swyddog awdurdodedig*") means any person, whether or not an officer of the enforcement authority, who is authorised by it in writing to act in matters arising under these Regulations;

"BADGE" ("*BADGE*") has the meaning given in Article 1(1)(a) of Regulation 1895/2005;

"BFDGE" ("*BFDGE*") has the meaning given in Article 1(1)(b) of Regulation 1895/2005;

"business" ("*busnes*") is to be construed in accordance with section 1(3) of the Act;

"capable" ("*yn gallu*") means capable as established under regulation 13;

"the Directive" ("*y Gyfarwyddeb*") means Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs(**7**));

"Directive 82/711"("*Cyfarwyddeb 82/711*") means Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs(**8**);

"Directive 85/572" ("*Cyfarwyddeb 85/572*") means Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs(**9**);

"Directive 88/388" ("*Cyfarwyddeb 88/388*") means Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production(**10**);

(**5**) S.I. 1998/1376, as amended in relation to Wales by S.I. 2001/1263 (W.70), S.I. 2002/2834 (W.272), S.I. 2003/302 (W.44), S.I. 2005/182 (W.15) and S.I. 2005/1649 (W.130). It was revoked by S.I. 2006/2982 (W.273).
(**6**) S.I. 2007/3252 (W.287). as amended by S.I. 2008/1237 (W.124).
(**7**) OJ No. L220, 15.8.2002, p.18. This was amended by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45), 2004/19/EC (OJ No. L71, 10.3.2004, p.8), 2005/79/EC (OJ No. L302, 19.11.2005, p.35), and 2007/19/EC (published in revised and corrected form in OJ No. L97, 12.4.2007, p.50).
(**8**) OJ No. L297, 23.10.1982, p.26. This was last amended by Commission Directive 97/48/EC (OJ No. L222, 12.8.1997, p.10).
(**9**) OJ No. L372, 31.12.1985, p.14. This was last amended by Commission Directive 2007/19/EC (OJ No. L97, 12.4.2007 p.50).
(**10**) OJ No. L184, 15.7.1988, p.61.

"Directive 89/107" ("*Cyfarwyddeb 89/107*") means Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised in foodstuffs intended for human consumption(**11**);

"EFSA" ("*EFSA*") means the European Food Safety Authority;

"enforcement authority" ("*awdurdod gorfodi*") means an authority having responsibility under regulation 15 for executing and enforcing these Regulations;

"fatty foods" ("*bwydydd brasterog*") means foods for which, in migration testing, simulant D is specified in Directive 85/572/EEC;

"food" ("*bwyd*") is to be construed in accordance with section 16(5) of the Act;

"good technical quality" ("*ansawdd technolegol da*") means good technical quality as regards the purity criteria;

"handling of food" ("*trin bwyd*") means use in connection with the storage, preparation, packaging, sale or serving of food;

"import" ("*mewnforio*") means import in the course of a business;

"infants" ("*babanod*") means children under the age of twelve months;

"material or article" ("*deunydd neu eitem*") means a material or article falling within the definition of materials and articles in Article 1(2) of Regulation 1895/2005;

"monomer" ("*monomer*") means any substance that is included for the purposes of the Directive among monomers and other starting substances;

"NOGE" ("*NOGE*") has the meaning given in Article 1(1)(c) of Regulation 1895/2005;

"plastic functional barrier" ("*gwahanfur swyddogaethol plastig*") means a barrier consisting of one or more layers of plastics which ensures that the finished material or article complies with Article 3 of Regulation 1935/2004 and with the Directive;

"plastic material or article" ("*deunydd neu eitem plastig*") means anything which for the purposes of the Directive is included among those plastic materials and articles and parts thereof to which the Directive applies;

"plastic multi-layer material or article" ("*deunydd neu eitem amlhaenog plastig*") means a plastic material or article composed of two or more layers of materials each consisting exclusively of plastics, which are bound together by means of adhesives or other means;

"the Purity Directives" ("*y Cyfarwyddebau Purdeb*") means Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs(**12**), Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(**13**) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colours or sweeteners(**14**);

"sell" ("*gwerthu*") includes offer or expose for sale or have in possession for sale, and "sale" ("*gwerthiant*") is construed accordingly;

"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(**15**);

(**11**) OJ No. L40, 11.2.1989, p. 27.
(**12**) OJ No. L178, 28.7.95, p.1. This was last amended by Commission Directive 2004/46, OJ No. L114, 21.4.2004, p.15.
(**13**) OJ No. L226, 22.9.95, p.1. This was last amended by Commission Directive 2004/47, OJ No. L113, 20.4.2004, p.24.
(**14**) OJ No. L339, 30.12.96, p.1. This was last amended by Commission Directive 2003/95, OJ No. L283, 31.10.2003, p.71.
(**15**) OJ No. L338, 13.11.2004, p.4.

"Regulation 1895/2005" ("*Rheoliad 1895/2005*") means Commission Regulation (EC) No. 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food(**16**);

"young children" ("*plant ifanc*") means children aged between one and three years.

(2) For the purposes of these Regulations the supply otherwise than on sale, in the course of a business, of any material or article is deemed to be a sale.

(3) Any other expression used in these Regulations and in the Directive, Directive 82/711, Directive 85/572 or Regulation 1895/2005 bears the same meaning in these Regulations as it bears in that Directive or Regulation.

(4) Except in regulation 11(3) and in Part 5 of Schedule 3, any reference to a numbered Annex is a reference to that Annex to the Directive.

(5) Any reference to an Annex to the Directive is a reference to that Annex as amended from time to time.

PART 2

Requirements for Materials and Articles

Restriction on the use, sale or import of plastic materials and articles

3.—(1) No person may —

(a) use for the handling of food in the course of a business;

(b) sell for the purpose of handling of food; or

(c) import from anywhere other than an EEA State for the purpose of handling of food,

a plastic material or article which fails to meet the required standard.

(2) For the purposes of this regulation a plastic material or article fails to meet the required standard if —

(a) it has been manufactured with a prohibited monomer as described in regulation 4(2) or a prohibited additive as described in regulation 5(2); or

(b) it does not meet the required standards set out in regulation 6, 7, 8, 9, 10 or 11.

Restriction on the use of monomers in the manufacture of plastic materials and articles

4.—(1) Subject to paragraphs (3), (4) and (5), no person may use any prohibited monomer in the manufacture of any plastic material or article.

(2) A prohibited monomer is any monomer which is not —

(a) of good technical quality;

(b) identified by PM/REF No., CAS No. (if any) and name in columns 1, 2 and 3 respectively of Sections A or B of Annex II; and

(c) used in accordance with any restrictions and specifications for that monomer set out or referred to in column 4 of those Sections.

(3) Paragraph (1) does not apply to the use of a monomer in the manufacture of any —

(a) surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, including but not limited to varnishes, lacquers and paints;

(**16**) OJ No. L302, 19.11.2005, p.28.

(b) epoxy resins;

(c) adhesives and adhesion promoters; or

(d) printing inks.

(4) Paragraph (1) is not to be taken to prohibit the manufacture of any plastic material or article with any substance if the substance in question is a mixture which falls within paragraph 3(c) (relating to mixtures of authorised substances) of Annex II and is of good technical quality.

(5) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with paragraph (1) because it was manufactured with any monomer (whether or not of good technical quality) other than one mentioned in paragraph (2)(b) it is a defence for the person accused to prove that each such monomer —

(a) is present in the finished plastic material as an impurity, a reaction intermediate or a decomposition product which falls within paragraph 3(a) of Annex II, or

(b) is an oligomer or a natural or synthetic macromolecular substance or a mixture thereof which falls within paragraph 3(b) of that Annex,

and is of good technical quality.

(6) Schedule 1 has effect to supplement this regulation.

Restriction on the use of additives in the manufacture of plastic materials and articles

5.—(1) Subject to paragraph (3) no person may use in the manufacture of any plastic material or article any prohibited additive.

(2) A prohibited additive is —

(a) any additive identified by PM/REF No., CAS No. (if any) and name in columns 1, 2 and 3 respectively of Section A or B of Annex III which —

(i) is not of good technical quality, or

(ii) is not used in accordance with any restrictions and specifications for that additive set out in the corresponding entry in column 4 of Section A or B of that Annex; or

(b) any food additive authorised by Directive 89/107 or any flavouring authorised by Directive 88/388 that migrates into food —

(i) in a quantity that has a technological function in the final food product, or

(ii) where the food is of a type for which the use of any such food additive or flavouring is so authorised, in quantities exceeding the limits provided for in Directive 89/107 or Directive 88/388 as appropriate, or in Annex III, whichever is the lower.

(3) In any proceedings for an offence under these Regulations where it is alleged that the commission of the offence is due to the manufacture of a plastic material or article with any additive identified in Section A or B of Annex III which is not of good technical quality, it is a defence for the person accused to prove that each such additive is present in the finished plastic material or article as an impurity, a reaction intermediate or a decomposition product.

(4) Schedule 1 has effect to supplement this regulation.

Required standard for non-migration of constituents of monomers

6.—(1) Subject to paragraphs (2) and (3), where a migration limit expressed in mg/kg is indicated in column 4 of the relevant section of Section A or B of Annex II in relation to any monomer, a plastic material or article manufactured from that monomer meets the required standard under this regulation if it is not capable of transferring constituents of that monomer to food with which the