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WELSH STATUTORY INSTRUMENTS

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**2008 No. 1682**

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

**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;
- (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 plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is —

(a) the number of milligrams expressed in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b); and

- (b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises —
  - (i) an article which is a container or is comparable to a container or can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or
  - (ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.

(2) A plastic material or article manufactured from any monomer for which a migration limit in mg/kg is expressed in column 4 of Section A or B of Annex II is not deemed to be capable of transferring constituents of that monomer to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1) if the only food with which that plastic material or article may come into contact is food to which regulation 9(5) applies.

(3) For plastic materials or articles brought or intended to be brought into contact with food for infants and young children the migration limits referred to in paragraph (1) must always be applied in mg/kg.

#### **Required standard for non-migration of constituents of additives**

7.—(1) Subject to paragraphs (2) and (3), where a migration limit expressed in mg/kg is indicated in column 4 of Section A or B of Annex III in relation to any additive, a plastic material or article manufactured containing that additive meets the required standard under this regulation if it is not capable of transferring constituents of that additive to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is —

- (a) the number of milligrams indicated in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b); and
- (b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises —
  - (i) an article which is a container or is comparable to a container or can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or
  - (ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.

(2) A plastic material or article manufactured containing an additive for which a migration limit in mg/kg is expressed in column 4 of Section A or B of Annex III is not deemed to be capable of transferring constituents of that additive to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1) if the only food with which that plastic material or article may come into contact is food to which regulation 9(5) applies.

(3) For plastic materials or articles brought or intended to be brought into contact with food for infants and young children the migration limits referred to in paragraph (1) must always be applied in mg/kg.

#### **Required standard for products obtained by bacterial fermentation**

8. A product obtained by bacterial fermentation meets the required standard under this regulation if it is —

- (a) of good technical quality;
- (b) identified by PM/REF No., CAS No. and name in columns 1, 2 and 3 respectively of Annex IV; and

(c) in compliance with the restrictions and specifications set out in column 4 of that Annex.

#### **Required standards relating to overall migration limits**

9.—(1) Subject to paragraph (5), a plastic material or article meets the required standard under this regulation if it is not capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit specified in paragraphs (2) to (4).

(2) Subject to paragraph (4), in the case of any plastic material or article comprising —

- (a) an article which is a container or comparable to a container or can be filled, with a capacity of less than 500 millilitres or more than 10 litres; or
- (b) sheet, film or any other material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact with it,

the appropriate limit is an overall migration limit of 10 milligrams per square decimetre of the surface area of the plastic material or article.

(3) In the case of any other plastic material or article, the appropriate limit is an overall migration limit of 60 milligrams of the constituents released per kilogramme of food or food stimulant.

(4) For plastic materials or articles intended to be brought into contact or already in contact with food intended for infants and young children, the appropriate limit is always that specified in paragraph (3).

(5) For the purposes of this regulation a plastic material or article is not deemed to fail to meet the required standard under paragraph (1) if the only food with which that material or article may come into contact is food —

- (a) which is specified in the table to Part 4 of Schedule 3; and
- (b) where there is no “X” placed anywhere in the group of columns headed “Simulants to be used” opposite that food.

(6) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with this regulation, the defences available in paragraph 10(2) of Schedule 2 is available as specified in that paragraph.

#### **Required standard for non-migration of primary aromatic amines**

10.—(1) Subject to paragraph (4), a plastic material or article manufactured using primary aromatic amines meets the required standard under this regulation if it is not capable of transferring such amines (expressed as aniline) in a detectable quantity to food with which that plastic material or article may come into contact

(2) Part B of Annex V has effect for the purpose of prescribing, for certain items listed in Section A or B of Annex II, Section A or B of Annex III, or Annex IV, the specifications for those items that are referred to in column 4 of the Annex or Section of Annex concerned.

(3) For the purposes of paragraph (1) a detectable quantity means at least 0.01 milligrams per kilogram of food or food simulant.

(4) The requirement in paragraph (1) does not apply to primary aromatic amines listed in the Directive.

#### **Required standard relating to plastic multi-layer materials and articles**

11.—(1) Subject to paragraph (2), a plastic multi-layer material or article meets the required standard if each layer of which it is composed complies with these Regulations.

(2) A layer which is not in direct contact with food and is separated from such contact by a plastic functional barrier is not obliged to comply with the requirements of these Regulations provided that —

- (a) the finished material or article complies with the relevant specific and overall migration limits; and
- (b) if any substance used in the manufacture of the layer is not included in the Directive or in national lists referred to in that Directive, that substance meets the requirements of paragraphs (3) and (4).

(3) A substance mentioned in paragraph (2)(b) must not belong to the category of those classified —

- (a) as proved or suspect “carcinogenic”, “mutagenic” or “toxic to reproduction” substances in Annex I to Directive 67/548/EEC<sup>(1)</sup>, or
- (b) under the self-responsibility criteria as “carcinogenic”, “mutagenic” or “toxic to reproduction” substances according to the rules of Annex VI to that Directive.

(4) The migration of a substance mentioned in paragraph (2)(b) into a food or simulant must not exceed 0.01 mg/kg, measured and expressed in accordance with the requirements and specifications contained in Article 7a(3) of the Directive.

#### **Provisions relating to the use of certain epoxy derivatives (BADGE, BDGE and NOGE)**

12.—(1) In this regulation —

- (a) any reference to a numbered Article is a reference to that Article in Regulation 1895/2005;
- (b) paragraphs (2) to (5) are subject to Article 1(3) (exception relating to certain storage containers and pipelines); and
- (c) for the purpose of Article 6(4) (requirement to disclose date of filling) the competent authority is the authority identified in regulation 15.

(2) Subject to Article 6(1), (2) (transitional provisions) and (4) (labelling requirements), no person may —

- (a) manufacture,
- (b) use for the handling of food in the course of a business,
- (c) sell for the purpose of the handling of food, or
- (d) import for the purpose of the handling of food

any material or article in contravention of Article 3 or Article 4 (prohibitions relating to BFDGE and NOGE respectively).

(3) No person may manufacture any material or article in such a way as to contravene the requirements of Article 2 (controls on the migration of BADGE from materials and articles).

(4) Subject to Article 6(1), no person may —

- (a) use for the handling of food in the course of a business,
- (b) sell for the purpose of the handling of food, or
- (c) import for the purpose of the handling of food

any material or article that has been manufactured in such a way as to contravene the requirements of Article 2.

(5) Subject to Article 6(3) (transitional provisions relating to materials and articles brought into contact with food before 1 January 2007), no person is to contravene or fail to comply with the

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(1) OJ No. 196, 16.8.1967, p.1.

requirements of Article 5 (obligations regarding the provision of a written statement when marketing materials or articles containing BADGE or its derivatives).

(6) No person may without reasonable excuse fail to comply with a request made under Article 6(4).

### **Method of testing the capability of plastic materials or articles to transfer constituents, and methods of analysis**

**13.**—(1) A plastic material or article must be treated as capable of transferring constituents to food with which it may come into contact to the extent that such capability is established —

- (a) in any case other than one to which sub-paragraph (b) or (c) applies, and subject to Article 8(4) of the Directive (which may be applied on compliance with the conditions stated therein), by the verification methods specified in Schedule 2 (including the analytical tolerances referred to in paragraph 12 of that Schedule) and Schedule 3;
- (b) in any case where the extent to which vinyl chloride, as identified in Section A of Annex II, is capable of such transfer falls to be established, by the method referred to in regulation 9(2) of the 2007 Regulations; or
- (c) in any case where the extent to which a phthalate listed in Section B of Annex III with PM reference number 74640, 74880, 74560, 75100 or 75105 is capable of such transfer falls to be established, by the method referred to in Article 8(5) of the Directive.

(2) In Schedules 2 and 3, references to migration or release of a substance are to be construed as references to the transfer of constituents to the food or simulant representing the food with which the substance may come into contact.

(3) The specific migration of a constituent from a plastic material or article must where applicable be determined in the manner specified in the relevant sub-paragraph of paragraph 8 of Annex II.

(4) The quantity of a constituent in a plastic material or article must where applicable be determined in the manner specified in the sub-paragraph of paragraph 8 of Annex II relating to the term “QM(T)”, “QMA(T)” or, as the case may be, “QMA”.

### **Labelling and documentation**

**14.**—(1) At marketing stages other than the retail stage a person who places on the market any plastic material or article or any substance intended for the manufacture of a plastic material or article must ensure that the plastic material or article or substance is accompanied by a written declaration which —

- (a) accords with Article 16(1) of Regulation (EC) No. 1935/2004;
- (b) contains the information specified in Schedule 4; and
- (c) complies with paragraph (2).

(2) A written declaration made under paragraph (1) must be revised when substantial changes in the production of a plastic material or article for which the declaration is issued bring about changes in the migration or when new scientific information is available.

(3) A person mentioned in paragraph (1) must make available to the enforcement authority on request appropriate documentation to demonstrate that the plastic material or article or substance intended for its manufacture complies with the requirements of these Regulations.

(4) The documentation referred to in paragraph (3) must contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

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