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SCOTTISH STATUTORY INSTRUMENTS

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**2006 No. 517**

**The Plastic Materials and Articles in Contact  
with Food (Scotland) (No. 2) Regulations 2006**

**PART 2**

**Requirements for Plastic Materials and Articles**

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

- 3.**—(1) No person shall—
- (a) use for the handling of food in the course of a business; or
  - (b) for the purpose of the handling of food—
    - (i) sell; or
    - (ii) import from anywhere other than an EEA State,
- 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 it—
- (a) has been manufactured with a prohibited monomer as described in regulation 4(2) or a prohibited additive as described in regulation 5(2);
  - (b) does not meet the required standards set out in regulation 6, 7, 8, 9 or 10.

**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 shall 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 the corresponding entry.
- (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) shall not be taken to prohibit the manufacture of any plastic material or article with any substance 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 shall be a defence for the accused to prove that each 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 shall use any prohibited additive in the manufacture of any plastic material or article.

(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 is not—

(i) of good technical quality; and

(ii) 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 shall be a defence for the 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 paragraph (2), 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 it 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 to be considered capable of transferring constituents of that monomer to food with which it 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(3) applies.

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

7.—(1) Subject to paragraph (2), 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 it 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(3) applies.

#### **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 (3), 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 paragraph (2).

- (a) (2) (a) In the case of any plastic material or article comprising—
- (i) an article which is a container or comparable to a container or can be filled, with a capacity of not less than 500 millilitres and not more than 10 litres;
  - (ii) an article which can be filled and for which it is impracticable to estimate the surface area in contact with food; or
  - (iii) a cap, gasket, stopper or similar device for sealing,
- the appropriate limit is an overall migration limit of 60 milligrams of constituents released per kilogram of food.
- (b) In the case of any other plastic material or article, the appropriate limit is an overall migration limit of 10 milligrams per square decimetre of its surface area.
- (3) 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 it 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” in the entry for that food.
- (4) 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 specified in paragraph 6(2) of Schedule 2 shall be available.

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

**10.**—(1) Subject to paragraph (3), a plastic material or article manufactured using isocyanates or colourants prepared by diazo coupling meets the required standard under this regulation if it is not capable of transferring in a detectable quantity primary aromatic amines (expressed as aniline), not being primary aromatic amines listed in the Directive, to food with which it may come into contact.

(2) Part B of Annex V has effect to prescribe specifications for certain of the substances listed in Section A or B of Annex II, Section A or B of Annex III, or Annex IV.

(3) For the purposes of paragraph (1) a detectable quantity means a quantity of at least DL0.02 milligrams per kilogram of food or food simulant (including analytical tolerance).

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

**11.**—(1) A plastic material or article shall 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) 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 8 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 7(2) of the 2005 Regulations;

(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 simulant representing the food with which it is or may come into contact.

(3) The specific migration of a constituent from a plastic material or article shall 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 shall 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” or “QMA(T)” as the case may be.

## Labelling

**12.**—(1) At marketing stages other than the retail stage a person in possession of any plastic material or article shall ensure that it is accompanied by a written declaration which—

- (a) accords with Article 16.1 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council repealing Directives 80/590/EEC and 89/109/EEC(1); and
- (b) provides, in respect of substances that are subject to a restriction on quantities migrating into food, information obtained from experimental data or theoretical calculation concerning—
  - (i) the levels of migration specific to those substances; and
  - (ii) where appropriate, purity criteria in accordance with the purity Directives, sufficient to enable the user to comply with food law.

(2) In establishing which descriptions of food a material or article may come into contact with, it is to be assumed until the contrary is proved that, for the purposes of these Regulations, if particulars are shown in relation to it in accordance with paragraph (1)(a) those particulars are accurate and that unless the particulars so indicate, there are no restrictions on the intended conditions of contact.

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

**13.**—(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);
- (c) for the purposes of Article 6.4 the competent authority is a food authority.

(2) Subject to Articles 6.1, 6.2 (transitional provisions) and 6.4. (labelling requirements), no person shall—

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

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

(3) No person shall 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 shall—

- (a) use for the handling of food in the course of a business; or
- (b) for the purpose of the handling of food—
  - (i) sell; or
  - (ii) import,

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(1) O.J. No. L 338, 13.11.04, p.4.

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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 1st January 2007), no person shall contravene or fail to comply with the 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 shall without reasonable excuse fail to comply with a request made under Article 6.4 (requirement to disclose date of filling to competent authority).