
STATUTORY INSTRUMENTS

2005 No. 325

**The Plastic Materials and Articles in Contact with
Food (Amendment) (England) Regulations 2005**

Title, application and commencement

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2005, shall apply in relation to England only and shall come into force on 11th March 2005.

Amendments to the Plastic Materials and Articles in Contact with Food Regulations 1998

2. The Plastic Materials and Articles in Contact with Food Regulations 1998⁽¹⁾ are amended, in so far as they apply in relation to England, in accordance with regulations 3 to 16 of these Regulations.

3. In regulation 2 (interpretation) —

(a) in paragraph (1) —

(i) for the definition of “additive” substitute ““additive” means a substance as defined in paragraph 1 of the general introduction to Annex III to the Directive as read with paragraph 3 of Article 4 of the Directive;”;

(ii) in the definition of “Council Directive 82/711”, omit the words “as amended” to the end;

(iii) after the definition of “Council Directive 82/711” insert the following definitions —

““Council Directive 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⁽²⁾;

““Council Directive 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⁽³⁾”;

(iv) omit the definition of “EEA Agreement”;

(v) for the definition of “EEA State” substitute ““EEA State” means a Member State (other than the United Kingdom), Norway, Iceland and Liechtenstein;”;

(vi) after the definition of “EEA State” insert the following definition —

““EFSA” means the European Food Safety Authority;”;

(vii) after the definition of “preparation” insert the following definition —

““the purity Directives” means Commission Directive [95/31/EC](#) laying down specific criteria of purity concerning sweeteners for use in foodstuffs⁽⁴⁾,

(1) [S.I. 1998/1376](#), amended in relation to England by [S.I. 2000/3162](#), [S.I. 2002/2364](#), [S.I. 2002/3008](#) and [S.I. 2004/3113](#).

(2) OJ No. L184, 15.7.88, p.61. This Directive was last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Commission (OJ No. L284, 31.10.2003, p.1).

(3) OJ No. L40, 11.2.89, p.27. This Directive was last amended by Regulation (EC) No 1882/2003.

(4) OJ No. L178, 28.7.95, p.1. This Directive was last amended by Commission Directive 2004/46 (OJ No. L114, 21.4.2004, p.15).

Commission Directive [95/45/EC](#) laying down purity criteria concerning colours for use in foodstuffs⁽⁵⁾ and Commission Directive [96/77/EC](#) laying down specific purity criteria for food additives other than colours or sweeteners⁽⁶⁾”;

(b) after paragraph (5) add —

“(6) Any reference in these Regulations to a Community instrument shall be construed as a reference to that instrument as amended at the time the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2005 were made.”.

4. In regulation 4 (restriction on the use of monomers in the manufacture of plastic materials and articles) —

(a) in paragraph (2) omit sub-paragraphs (a) and (b);

(b) in paragraph (5)(b)(ii) after the word “material” in each case insert the words “or article”.

5. In regulation 5 (restriction on the use of additives in the manufacture of plastic materials and articles) —

(a) in paragraph (1) add after sub-paragraph (d) —

“(e) any food additive authorised by Council Directive 89/107 or any flavouring authorised by Council 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 Council Directive 89/107 or Council Directive 88/388 as appropriate, or in Schedule 2 to these Regulations, whichever is the lower.”;

(b) in paragraph (4)(b)(ii) after the word “material” in each case insert the words “or article”.

6. After regulation 5A insert the following regulation —

“Applications for inclusion of an additive in the Community list of authorised additives

5B.—(1) This regulation applies where a person wishes to make an application for the inclusion of an eligible additive in the Community list referred to in Article 4 of the Directive.

(2) An application mentioned in paragraph (1) including supporting data must be made to EFSA before 1st January 2007.

(3) If, during examination of the data referred to in paragraph (2), EFSA calls for supplementary information, the eligible additive may, if permitted to be used under English law, continue to be so used until EFSA has issued an opinion, provided such information is submitted within the time limits specified by EFSA.

(4) For the purposes of this regulation an eligible additive is one whose use is permitted in one or more Member States before 1st January 2007.”.

7. For regulation 8 (labelling) substitute the following —

“At marketing stages other than the retail stage a person who is in possession of any plastic material or article intended to come into contact with food shall ensure that the plastic material or article is accompanied by a written declaration which —

⁽⁵⁾ OJ No. L226, 22.9.95, p.1. This Directive was last amended by Commission Directive 2004/47 (OJ No. L113, 20.4.2004, p.24).

⁽⁶⁾ OJ No. L339, 30.12.96, p.1. This Directive was last amended by Commission Directive 2003/95 (OJ No. L283, 31.10.2003, p.71).

- (a) attests that it complies with the legislation applicable to it; 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;
 - (ii) where appropriate, purity criteria in accordance with the purity Directives.”.
- 8.** In regulation 10 (offences) —
- (a) in paragraph (1) for the figure “8(1)” substitute the figure “8”;
 - (b) after paragraph (24) add —
 - “(25) In any proceedings for an offence under these Regulations it shall be a defence to prove that —
 - (a) the act constituting the offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st March 2006; and
 - (b) the act constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2005 had not been in force at the time that act occurred.”.
- 9.** In Schedule 1, Part I —
- (a) in Section A (monomers authorised without time limit) —
 - (i) insert in the appropriate numerical order the entries set out in Schedule 1 to these Regulations;
 - (ii) for items 15A, 39, 70, 120B, 147, 147A, 147B and 188 substitute the entries set out in Schedule 2 to these Regulations;
 - (iii) omit items 76B and 76C with their corresponding entries;
 - (b) omit Sections B and C.
- 10.** In Schedule 1, Part II (supplementary) paragraph 4 —
- (a) at the end of note (21) for “and 18670,” substitute “,18670, 54880 and 59280”;
 - (b) after note (25) add the following —
 - “(27) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.
 - (28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.
 - (29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.
 - (32) Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D (unstable).
 - (33) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.”
- 11.** In Schedule 2, Part I (incomplete list of additives used in the manufacture of plastic materials and articles) —
- (a) insert in appropriate numerical order the entries set out in Schedule 3 to these Regulations;

- (b) for items 60A and 198A substitute the entries set out in Schedule 4 to these Regulations;
- (c) omit items 112, 173A, 195C and 240 with their corresponding entries.
- 12.** In Schedule 2, Part II (incomplete list of additives used in the manufacture of plastic materials and articles to which paragraph 5 of Part III of Schedule 2 applies) —
- (a) insert in appropriate numerical order the entries set out in Schedule 5 to these Regulations;
- (b) omit items 28, 80 and 111A with their corresponding entries.
- 13.** In Schedule 2, Part III (supplementary) —
- (a) in paragraph 4 —
- (i) in note (8), insert in the appropriate numerical order “38000” and “67896”;
- (ii) in note (10), after “levels” insert “(expressed as iodine)”;
- (iii) at the end of note (21), for “and 18670,” substitute “,18670, 54880 and 59280”;
- (iv) after note (24) add the following —
- “(26) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as reference Nos. 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.
- (27) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.
- (28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.
- (29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.
- (30) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 86480, 86960 and 87120.
- (31) Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.
- (32) Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D (unstable).
- (33) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.
- (34) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 55200, 55280 and 55360.”;
- (b) in paragraph 5 for “1st January 2004” substitute “1st July 2006”.
- 14.** In Schedule 2A (products obtained by bacterial fermentation) for the entry in the column headed “restrictions and specifications” substitute the following —
- “In compliance with specifications included in Schedule 2B”.
- 15.** For the table in Schedule 2B (specifications) substitute the table set out in Schedule 6 to these Regulations.

16. For paragraph 4(b) of Part I (basic rules) of Schedule 4 (overall and specific migration testing using food simulants) substitute the following —

- “(b) omit the migration, the substitute or the alternative tests where —
- (i) there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article, or
 - (ii) the conditions for non-compulsory testing set out in article 8.2 or 8.3 of the Directive are met.”.

Signed by authority of the Secretary of State for Health

9th February 2005

Melanie Johnson
Parliamentary Under Secretary of State
Department of Health