Changes to legislation: *There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Plastic Materials and Articles in Contact with Food Amendment (Scotland) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

SCOTTISH STATUTORY INSTRUMENTS

2005 No.92

FOOD

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

Made - - - -	*1st March 2005*
Laid before the Scottish Parliament - - - -	*1st March 2005*
Coming into force - -	*24th March 2005*

The Scottish Ministers in exercise of the powers conferred by sections 16(2), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(**1**) and of all other powers enabling them in that behalf, having had regard, in accordance with section 48(4A)(**2**) of that Act, to relevant advice given by the Food Standards Agency, hereby make the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food Amendment (Scotland) Regulations 2005 and come into force on 24th March 2005.

(2) These Regulations extend to Scotland only.

Commencement Information

I1 Reg. 1 in force at 24.3.2005, see **reg. 1(1)**

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(**3**) ("the principal Regulations") are amended in accordance with regulations 3 to 16 of these Regulations.

(**1**) 1990 c. 16; section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990; sections 16(2) and 48(1) were amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 ("the 1999 Act"); section 17(1) was amended by paragraphs 8 and 12 of Schedule 5 to the 1999 Act; section 26(3) was amended by Schedule 6 to the 1999 Act; section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C), inserted by S.I. 2004/2990; amendments made by Schedule 5 to the 1999 Act which extend to Scotland shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c. 46) ("the 1998 Act") by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act.

(**2**) Section 48(4A) was inserted by the 1999 Act, Schedule 5, paragraph 21.

(**3**) S.I. 1998/1376, relevantly amended by S.S.I. 2000/431, S.S.I. 2002/498, S.S.I. 2003/9 and S.S.I. 2004/524.

3. In regulation 2 (interpretation) paragraph (1)–

(a) 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;";

(b) after the definition of "Council Directive 82/711" insert–

> ""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(**4**) as corrected by a corrigendum dated 14th December 1988(**5**) and as amended by Commission Directive 91/71(**6**);
>
> "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(**7**) as amended by European Parliament and Council Directive 94/34(**8**);";

(c) at the end of the definition of "the Directive" insert "and Commission Directive 2004/19/EC"(**9**);

(d) omit the definition of "EEA Agreement";

(e) for the definition of "EEA State" substitute ""EEA State" means a Member State (other than the United Kingdom), Norway, Iceland or Liechtenstein;";

(f) after the definition of "EEA State" insert–

> "EFSA" means the European Food Safety Authority;";

(g) after the definition of "preparation" insert–

> ""the purity Directives" means Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs(**10**) as amended by Commission Directives 98/66(**11**), 2000/51(**12**), 2001/52(**13**) and 2004/46(**14**); Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(**15**) as amended by Commission Directives 1999/75(**16**), 2001/50(**17**) and 2004/47(**18**) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colours or sweeteners(**19**)as amended by Commission Directives 98/86(**20**), 2000/63(**21**), 2001/30(**22**), 2002/82(**23**) and 2003/95(**24**);";

(**4**) O.J. No. L 184, 15.7.88, p.61.
(**5**) O.J. No. L 345, 14.12.88, p.29.
(**6**) O.J. No. L 42, 15.2.91, p.25.
(**7**) O.J. No. L 140, 11.2.89, p.27.
(**8**) O.J. No. L 237, 10.9.94, p.1.
(**9**) O.J. No. L 71, 10.3.04, p.8.
(**10**) O.J. No. L 178, 28.7.95, p.1.
(**11**) O.J. No. L257, 19.9.98, p. 35.
(**12**) O.J. No. L 198, 4.8.00, p.41.
(**13**) O.J. No. L 190, 12.7.01, p.18.
(**14**) O.J. No. L 114, 21.4.04, p.15.
(**15**) O.J. No. L 226, 22.9.95, p.1.
(**16**) O.J. No. L 206, 5.8.99, p.19.
(**17**) O.J. No. L 190, 12.7.01, p.14.
(**18**) O.J. No. L 113, 20.4.04, p.24.
(**19**) O.J. No. L 339, 30.12.96, p.1.
(**20**) O.J. No. L 334, 9.12.98, p.1.
(**21**) O.J. No. L 277, 30.10.00, p.1.
(**22**) O.J. No. L 146, 31.5.01, p.1.
(**23**) O.J. No. L 292, 28.10.02, p.1.
(**24**) O.J. No. L 283, 31.10.03, p.71.

4. In regulation 4 (restriction on manufacture with monomers)–

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

(b) in paragraph (5)(b)(ii) after "material" wherever it appears, insert "or article".

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

(a) at the end of paragraph (1) insert–

"(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 technicological 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 that additive or flavouring 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 "material" wherever it appears, insert "or article"."

6. After regulation 5A insert–

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

5B.—(1) This regulation applies to any person who 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 otherwise lawful, 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–

"**8.** 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–

(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

sufficient to enable the user of those materials and articles to comply with the legislation applicable to food.".

8. In regulation 10 (offences)–

(a) in paragraph (1) for "8(1)" substitute "8";

(b) after paragraph (24) insert–

"(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 (Scotland) 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; and

(iii) omit items 76B and 76C and their corresponding entries; and

(b) omit Sections B and C.

10. In Schedule 1, Part II (supplementary) paragraph 4–

(a) in note (21) for "and 18670" substitute ", 18670, 54880 and 59280";

(b) after note (25) insert–

"(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 having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(27) 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.

(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. 22775 and 69920.

(31) Compliance testing when there is a fat contact should be performed using isoctane as substitute of simulant D (unstable).

(32) 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) delete items 112, 173A, 195C and 240 and their corresponding entries.

12. In Schedule 2, Part II (incomplete list of additives used in the manufacture of plastic materials and articles being additives 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) delete items 28, 80 and 111A and their corresponding entries.

13. In Schedule 2, Part III (supplementary)–

(a) in paragraph 4–

(i) in note (8) after "PM/REF Nos." insert "38000" and after "64320," insert "67896,";

(ii) in note (10) after "levels" insert "(expressed as Iodine"); and

(iii) in note (21) for "and 18670" substitute ", 18670, 54880 and 59280";

(iv) after note (24) add–

"(25) QM(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.

(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 having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(27) 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.

(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. 22775 and 69920.

(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. 86480, 86960 and 87120.

(30) Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.

(31) Compliance testing when there is a fat contact should be performed using isoctane as substitute of simulant D (unstable).

(32) 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.

(33) 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)–

(a) for the entry in Column 2 (CASNo.) substitute "080181-31-3";

(b) for the entry in Column 4 (restrictions and specifications) substitute–

"In compliance with specifications included in Schedule 2B".

15. For Schedule 2B (specifications) substitute the contents of 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–

"(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