

Scottish Statutory Instrument 2002 No. 498

The Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2002

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SCOTTISH STATUTORY INSTRUMENTS

2002 No. 498

FOOD

The Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2002

<i>Made</i>	<i>7th November 2002</i>
<i>Laid before the Scottish Parliament</i>	<i>8th November 2002</i>
<i>Coming into force</i>	<i>30th November 2002</i>

The Scottish Ministers, in exercise of the powers conferred by sections 6(4), 16(2), 17(1), 26(1)(a) and (3), 31 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, and after consultation in accordance with section 48(4) and (4B)^[3] of that Act, 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 2002 and shall come into force on 30th November 2002.

(2) These Regulations shall extend to Scotland only.

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^[4] ("the principal Regulations") shall be amended in accordance with regulations 3 to 18.

3. After regulation 1 (title, commencement and extent) there shall be inserted-

" Scope of these Regulations

1A. Notwithstanding the title to these Regulations-

- (a) regulations 3 and 9 to 12 apply also in relation to adhesives and to materials or articles covered by surface coatings; and
- (b) regulations 8A and 8B apply only to adhesives and to materials or articles covered by surface coatings."

4. In regulation 2 (interpretation)-

(a) in paragraph (1)-

(i) after the definition of "additive" there shall be inserted-

" "adhesive" means anything which, for the purposes of Commission Directive 2002/16, is included among the adhesives to which that Directive applies;

"BADGE" means 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether;

"BFDGE" means bis(hydroxyphenyl) methane bis(2,3- epoxypropyl) ethers;"

(ii) for the definition of "capable" there shall be substituted-

" "capable" means capable as established-

(a) in relation to any plastic material or article, under regulation 6; and

(b) in relation to any adhesive or material or article covered by a surface coating, under regulation 8B;"

(iii) after the definition of "capable" there shall be inserted-

" "Commission Directive 2002/16" means Commission Directive 2002/16 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs^[5];"

(iv) for the definition of "the Directive", there shall be substituted-

" "the Directive" means Commission Directive 2002/72 relating to plastic materials and articles intended to come into contact with foodstuffs^[6];"

(v) after the definition of "import" there shall be inserted-

" "material or article covered by a surface coating" means anything which, for the

purposes of Commission Directive 2002/16, is included among the materials and articles covered by surface coatings to which that Directive applies;";

(vi) after the definition of "monomer" there shall be inserted-

" "NOGE" means novolac glycidyl ethers not covered by Article 1(a) or (b) of Commission Directive 2002/16;"; and

(vii) at the end of the definition of "plastic material or article" there shall be inserted ", except that, in the provisions referred to in paragraph (5) below, to the extent that they implement or relate to the enforcement of Commission Directive 2002/16, it means a material or article made of any type of plastic";

(b) for paragraph (2), there shall be substituted-

" (2) For the purposes of these Regulations, the supply in the course of a business, otherwise than on sale, of any plastic material or article, adhesive or material or article covered by a surface coating shall be deemed to be a sale of the plastic material or article, adhesive or material or article covered by a surface coating concerned."; and

(c) after paragraph (4) there shall be inserted-

" (5) The provisions referred to in the definition of "plastic material or article" in paragraph (1) above are regulations 3, 4, 4A, 5, 6, 10, 11 and 12 and Schedules 3 and 4.".

5. In regulation 3 (restriction on the use, sale or importation of plastic materials and articles)-

(a) in paragraphs (1) and (2), after the words "plastic material or article", wherever they appear, there shall be inserted ", adhesive or material or article covered by a surface coating";

(b) at the end of paragraph (4)(a)(i)(cc) the word "or" shall be deleted;

(c) for sub-paragraph (4)(a)(i)(dd) there shall be substituted-

" (dd) it does not comply with regulation 4(5), (5A) or (5B), 4A(4), (5) or (6), 5(4), (4A), (4B) or (4C), 7 or 7A(1); or";

(d) after sub-paragraph (4)(a)(i)(dd) there shall be inserted-

" (ee) it has been manufactured in contravention of a prohibition contained in regulation 4A(1), (2) or (3); and"; and

(e) there shall be inserted at the end-

" (5) For the purposes of this regulation, an adhesive or a material or article covered by a surface coating fails to meet the requisite standards if-

- (i) it has been manufactured in contravention of a prohibition contained in regulation 8A(1), (2) or (3); or
- (ii) it does not comply with regulation 8A(4), (5) or (6)."

6. In regulation 4 (restriction on manufacture with monomers)-

(a) for paragraph (1) there shall be substituted-

" (1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of any plastic material or article any prohibited monomer, that is to say-

(a) any monomer (not being one to which sub-paragraph (b) or (c) below relates) which is not-

- (i) of good technical quality;
- (ii) identified by PM/REF No. , CAS No. (if any) and name in columns 1, 2 and 3 respectively of the relevant section of Part I of Schedule 1; and
- (iii) used in accordance with the restrictions and specifications (if any) for that monomer set out in the corresponding entry in column 4 of that relevant section;

(b) BFDGE to the extent that they are used in such manufacture-

- (i) on or after 1st January 2005; or
- (ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex; or

(c) NOGE to the extent that they are used in such manufacture-

- (i) on or after 1st January 2005; or
- (ii) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.";

(b) for paragraphs (2)(b) and (c) there shall be substituted-

" (b) in the case of a plastic material or article manufactured on or after 30th November 2002 and before 1st January 2005, section A or B; and

(c) in the case of a plastic material or article manufactured on or after 1st January 2005, section A.";

(c) for paragraph (3) there shall be substituted-

" (3) Paragraph (1)(a) of this regulation 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."

(d) in paragraph (4), for "Paragraph (1)" there shall be substituted "Paragraph (1)(a)";

(e) after paragraph (5) there shall be inserted-

" (5A) No plastic material or article manufactured using BFDGE as a monomer shall be capable of transferring constituents of that monomer to food with which that plastic material or article may come into contact in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(5B) On or after 1st March 2003, no plastic material or article manufactured using NOGE as a monomer shall fail to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."; and

(f) in paragraph (7)-

- (i) for "paragraph (1)" there shall be substituted "paragraph (1)(a)"; and
- (ii) after "Part I of Schedule 1" there shall be inserted "or to which paragraph (1)(b) or (1)(c) above relates".

7. After regulation 4 (restriction on manufacture with monomers) there shall be inserted-

" Restriction on the manufacture of plastic materials and articles using certain substances other than as monomers or additives

4A. - (1) No person shall use BADGE in the manufacture of any plastic material or article, where the use is not as a monomer or an additive-

- (a) on or after 1st January 2005; or
- (b) prior to that date in contravention of the restriction specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(2) No person shall use BFDGE in the manufacture of any plastic material or article, where the use is not as a monomer or an additive-

- (a) on or after 1st January 2005; or

(b) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(3) No person shall use NOGE in the manufacture of any plastic material or article, where the use is not as a monomer or additive-

(a) on or after 1st January 2005; or

(b) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.

(4) No plastic material or article manufactured using BADGE other than as a monomer or an additive shall be capable of transferring constituents of BADGE to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of Annex I to that Directive.

(5) No plastic material or article manufactured using BFDGE other than as a monomer or an additive shall be capable of transferring constituents of BFDGE to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of Annex II to that Directive.

(6) On or after 1st March 2003, no plastic material or article manufactured using NOGE other than as a monomer or an additive shall fail to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."

8. In regulation 5 (restriction on manufacture with additives)-

(a) for paragraph (1) there shall be substituted-

" (1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of any plastic material or article any prohibited additive, that is to say-

(a) any additive identified by PM/REF No. , CAS No. (if any) and name in columns 1, 2 and 3 respectively of Part I of Schedule 2 or columns 1, 2 and 3 respectively of Part II of Schedule 2, which is not-

(i) of good technical quality; and

(ii) used in accordance with the restrictions and specifications (if any) for that additive set out in the corresponding entry in column 4 of Part I or Part II of Schedule 2, as appropriate;

(b) BADGE to the extent that it is used in such manufacture-

(i) on or after 1st January 2005; or

(ii) prior to that date in contravention of the restriction specified in paragraph 1

of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of Annex I to that Directive;

(c) BFDGE to the extent that they are used in such manufacture-

(i) on or after 1st January 2005; or

(ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of Annex II to that Directive; or

(d) NOGE to the extent that they are used in such manufacture-

(i) on or after 1st January 2005; or

(ii) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.";

(b) in paragraph (2), after "Part I" there shall be inserted "or Part II";

(c) for paragraph (3), there shall be substituted-

" (3) Part III of Schedule 2 shall have effect to supplement this regulation and Parts I and II of Schedule 2.";

(d) in paragraph (4)-

(i) after "Schedule 2" there shall be inserted ", or column 4 of Part II of Schedule 2,"; and

(ii) in each of sub-paragraphs (a) and (b), for "therein" there shall be substituted "in column 4 of Part I or Part II of Schedule 2, as appropriate,";

(e) after paragraph (4) there shall be inserted-

" (4A) No plastic material or article manufactured using BADGE as an additive shall 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 specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(4B) No plastic material or article manufactured using BFDGE as an additive shall 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 specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(4C) On or after 1st March 2003, no plastic material or article manufactured using NOGE

as an additive shall fail to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."; and

(f) in paragraph (5), after "Schedule 2" there shall be inserted ", or column 4 of Part II of Schedule 2,".

9. In regulation 6 (method of testing capability of transferring constituents)-

(a) for paragraph (1) there shall be substituted-

" (1) For the purposes of these Regulations, a plastic material or article shall be treated as being capable of transferring constituents other than NOGE 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) below relates, 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 Schedules 3 and 4;

(b) in any case where the extent to which vinyl chloride, as identified in Section A of Part I of Schedule 1, is capable of such transfer falls to be established, by the method referred to in regulation 14(2) of the 1987 Regulations."; and

(b) after paragraph (3) there shall be inserted-

" (4) 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-division of paragraph 8 of Annex II to the Directive.

(5) The specific migration from a plastic material or article of the substances listed in paragraph 1 of Annex I to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(6) The specific migration from a plastic material or article of the substances listed in paragraph 1 of Annex II to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(7) Whether or not the detection requirement specified in Article 4 of Commission Directive 2002/16 is complied with in relation to a plastic material or article shall be determined in the manner specified in the second and third sentences of that Article.

(8) 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 to the Directive relating to the term "QM(T)" or, as the case may be, the sub-paragraph of paragraph 8 of that Annex relating to the term "QMA".

10. For regulation 7A (specifications) there shall be substituted-

" Specifications

7A. - (1) Subject to paragraph (3), no plastic material or article manufactured using isocyanates or colourants prepared by diazo-coupling shall be capable of transferring in a

detectable quantity primary aromatic amines (expressed as aniline), not being primary aromatic amines listed in these Regulations, to food with which the plastic material or article may come into contact.

(2) Schedule 2B shall have effect for the purpose of prescribing, for certain items listed in Part I of Schedule 1, Part I or II of Schedule 2 or Schedule 2A, the specifications for those items which are referred to in column 4 of the relevant Part or, as the case may be, Schedule concerned.

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

11. After regulation 8 (labelling) there shall be inserted-

" Restriction on manufacture with certain substances of adhesives and materials and articles covered by surface coatings

8A. - (1) No person shall (in any case not covered by Article 1(2) of Commission Directive 2002/16) use BADGE in the manufacture of any-

- (a) adhesive; or
- (b) material or article covered by a surface coating,

on or after 1st January 2005, or, prior to that date, in contravention of the restriction specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(2) No person shall (in any case not covered by Article 1(2) of Commission Directive 2002/16) use BFDGE in the manufacture of any-

- (a) adhesive; or
- (b) material or article covered by a surface coating,

on or after 1st January 2005, or, prior to that date, in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(3) No person shall (in any case not covered by Article 1(2) of Commission Directive 2002/16) use NOGE in the manufacture of any-

- (a) adhesive; or
- (b) material or article covered by a surface coating,

on or after 1st January 2005 or, prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.

(4) No adhesive, or material or article covered by a surface coating, manufactured using BADGE and not covered by Article 1(2) of Commission Directive 2002/16, shall be capable

of transferring constituents of BADGE to food with which the adhesive or, as the case may be, material or article, may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex I to that Directive, as read with the second sentence of paragraph 2 of that Annex.

(5) No adhesive, or material or article covered by a surface coating, manufactured using BFDGE and not covered by Article 1(2) of Commission Directive 2002/16, shall be capable of transferring constituents of BFDGE to food with which that adhesive or, as the case may be, material or article, may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to that Directive, as read with the second sentence of paragraph 2 of that Annex.

(6) On or after 1st March 2003, no adhesive, or material or article covered by a surface coating, manufactured using NOGE and not covered by Article 1(2) of Commission Directive 2002/16, shall fail to comply with the requirements of the first sentence of Article 4 of that Directive.

Method of testing the capability of adhesives and of materials or articles covered by surface coatings to transfer constituents and methods of analysis

8B. - (1) Subject to paragraphs (2) and (3) below, for the purposes of regulation 8A(1), (2), (4) and (5), an adhesive or a material or article covered by a surface coating shall be treated as being capable of transferring BADGE, or as the case may be, BFDGE, to food with which the adhesive or, as the case may be, material or article may come into contact to the extent that such capability is established for those purposes by the verification methods specified in Section A of Schedule 3 and in Schedule 4.

(2) Subject to paragraph (3) below, in Section A of Schedule 3 and in Schedule 4, references to migration or release of a substance shall be construed as references to the transfer of constituents to the simulant representing the food or, as the case may be, the food with which the substance may come into contact.

(3) For the purposes of paragraphs (1) and (2) above, Schedules 3 and 4 shall have effect as if-

(a) the references in Section A of Schedule 3 and in Schedule 4 to "plastic material or article" were references to "adhesive or a material or article covered by a surface coating";

(b) the references in paragraph 4(3) and (4) of Section A of Schedule 3 to "a migration limit specified in regulation 7, Schedule 1 or Schedule 2" were references to "a migration limit specified in regulation 8A(4) or (5)"; and

(c) the references in paragraph 5 of Part II of Schedule 4 and paragraph 2(1)(b) of Part III of that Schedule to "regulation 7 or Schedule 1" were references to "regulation 8A(4) or (5)".

(4) The specific migration from an adhesive or a material or article covered by a surface coating of the substances listed in paragraph 1 of Annex I to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(5) The specific migration from an adhesive or a material or article covered by a surface coating of the substances listed in paragraph 1 of Annex II to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(6) Whether or not the detection limit specified in Article 4 of Commission Directive 2002/16 is complied with in relation to an adhesive or a material or article covered by a

surface coating shall be determined in the manner specified in the second sentence and third sentences of that Article."

12. In regulation 10 (offences)-

(a) in paragraph (1), for "regulation 3, 4(1), 5(1) or 8" there shall be substituted "regulation 3, 4(1), 4A(1), (2) or (3), 5(1), 8(1) or 8A(1), (2) or (3)";

(b) in each of paragraphs (9) and (10), after "plastic material or article" there shall be inserted "or, as the case may be, adhesive or material or article covered by a surface coating,"; and

(c) after paragraph (15) there shall be inserted-

" (16) 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 intended to come into contact with food which was put into free circulation in the European Community on or before 30th November 2002; and

(b) the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by the provisions referred to in paragraph (17) below had not been in force at the time that matter occurred.

(17) For the purposes of paragraph (16) above, "free circulation" shall have the same meaning as it bears in Article 23.2 of the Treaty establishing the European Community.

(18) The provisions referred to in paragraph (16) above are regulations 5(c), 6(b), 8(a), (b) and (d), 10, 12(a), 15, 16 and 17 of the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2002 to the extent that they implement or provide for the enforcement of those requirements of Commission Directive 2001/62/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs[7] to which Article 2 of that Directive applies.

(19) In any proceedings for an offence under these Regulations, it shall be a defence to prove that-

(a) the act constituting the offence was the sale of-

(i) an adhesive; or

(ii) a material or article covered by a surface coating,

which was brought into contact with food on or before 28th February 2003, provided that the date of filling appeared on the materials and articles at the time of sale and that the labelling or marking of which complied at the time of sale with the requirements of Directive 2000/13 of the European Parliament and the Council on the approximation of the laws of the member states relating to the labelling, presentation and advertising of foodstuffs[8]; and

(b) the sale would not have constituted an offence under these Regulations if the

amendments made to them by the provisions referred to in paragraph (20) below had not been in force at the time of sale.

(20) The provisions referred to in paragraph (19) above are regulations 5(a) and (e), 11 and 12(a) of the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2002 which implement or provide for the enforcement of those requirements of Commission Directive 2002/16 which relate to adhesives or materials and articles covered by surface coatings."

13. In regulation 11 (presumption as to food with which a plastic material or article is to come into contact) after the words "plastic material or article", wherever they appear, there shall be inserted ", adhesive or material or article covered by a surface coating,".

14. In regulation 12 (application of other provisions)-

(a) in paragraph (1) after "plastic materials or articles" there shall be inserted ", adhesives and materials or articles covered by a surface coating"; and

(b) in paragraph (3) for "relate to plastic materials or articles" there shall be substituted "apply to plastic materials or articles, adhesives, or materials or articles covered by a surface coating".

15. In Schedule 1 (monomers authorised without time limit, monomers authorised up to the end of 2001, monomers authorised up to the end of 1998 and supplementary)-

(a) in Section A of Part I-

(i) in the case of each monomer listed in Part I of Schedule 1 to these Regulations, the item number and letter, PM/REF No, CAS No. (if any), name and restriction or specification specified for that monomer in that Part shall be inserted in the appropriate numerical position for that item number and letter;

(ii) in the case of each monomer listed in the third column of Part II of Schedule 1 to these Regulations, for the item number and letter for that monomer specified opposite to it in the first column of Section A of Part I of Schedule 1 to the principal Regulations (item) there shall be substituted the item number and letter for it specified in the second column (new item) of Part II of Schedule 1 to these Regulations; and

(iii) in the case of each monomer listed in the first column of Part III of Schedule 1 to these Regulations, for the entry for that monomer specified opposite to it in column 4 of Section A of Part I of Schedule 1 to the principal Regulations (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of Part III of Schedule 1 to these Regulations;

(b) for Section B of Part I there shall be substituted Part IV of Schedule 1 to these Regulations; and

(c) in Part II, for paragraph 4 there shall be substituted-

" **4.** Where an entry in column 4 of Part I of this Schedule (restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as

follows, the following bracketed numbers corresponding with those appearing in that Part:

(1) Warning: there is a risk that the specific migration limit could be exceeded in fatty food simulants.

(2) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.

(3) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.

(4) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.

(5) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.

(14) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(21) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260 and 18670."

16. In Schedule 2 (additives and supplementary)-

(a) in Part I-

(i) for the heading "Part I Additives" there shall be substituted the heading "Part I: Incomplete list of additives used in the manufacture of plastic materials and articles (not being additives to which paragraph 5 of Part III of this Schedule applies)";

(ii) in the case of each additive listed in Part I of Schedule 2 to these Regulations, the item number and letter, PM/REF No. , CAS No. (if any), name and restriction or specification (if any) specified for that additive in that Part shall be inserted in the appropriate numerical position for that item number and letter;

(iii) in the case of each additive listed in the third column of Part II of Schedule 2 to these Regulations, for the item number and letter for that additive specified opposite to it in the first column in Part I of Schedule 2 to the principal Regulations (item) there shall be substituted the item number and letter for it specified in the second column (new item) of Part II of Schedule 2 to these Regulations;

(iv) in the case of each additive listed in the first column of Part III of Schedule 2 to these Regulations, for the entry for that additive specified opposite to it in column 4 in Part I of Schedule 2 to the principal Regulations (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of Part III of Schedule 2 to these Regulations; and

(v) all the entries for the additive Silicic acid, salts, (item 241) shall be omitted;

(b) after Part I there shall be inserted Part IV of Schedule 2 to these Regulations (which shall become Part II of Schedule 2 to the principal Regulations on the coming into force of these Regulations);

(c) in Part II-

- (i) in the heading, for "Part II" there shall be substituted "Part III";
- (ii) in paragraph 1, for "Part I" there shall be substituted "Parts I and II";
- (iii) in each of paragraphs 2, 3 and 4, after "Part I" there shall be inserted "or Part II";
- (iv) for paragraph 4 there shall be substituted-

" 4. Where an entry in column 4 of Part I or in column 4 of Part II of this Schedule (in each case restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in those Parts:

- (1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.
- (2) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.
- (3) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.
- (4) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.
- (5) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.
- (6) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 66560 and 66580.
- (7) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.
- (8) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 42400, 64320, 73040, 85760, 85840, 85920 and 95725.
- (9) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.
- (10) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 45200, 64320, 81680 and 86800.
- (11) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 36720, 36800 and 92000.
- (12) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 39090 and 39120.
- (13) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 44960, 68078, 82020 and

89170.

(14) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(15) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 49600, 67520 and 83599.

(16) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.

(17) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 67600, 67680 and 67760.

(18) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 60400, 60480 and 61440.

(19) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 66400 and 66480.

(20) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 93120 and 93280.

(21) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260 and 18670."; and

(d) after paragraph 4 there shall be inserted-

" 5. In the case of the substances listed in Part II of this Schedule, the specific migration limits specified in column 4 of that Part (restrictions and specifications) shall have effect with effect from 1st January 2004 where the verification of compliance is carried out in simulant D or in test media of substitute tests as prescribed in Council Directive 82/711/EEC[9] and Council Directive 85/572/EEC[10].".

17. In Schedule 2B (specifications)-

(a) in the case of each substance listed in Schedule 3 to these Regulations, the item number and letter, PM/REF No. and specification set out for that substance in that Schedule shall be inserted in the appropriate numerical position for that item number and letter; and

(b) at the end there shall be inserted-

" Notes:-

Where an entry in column 2 of this Schedule (specification) includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in this Schedule:-

(1) Quantity of substance/quantity of formulation.".

18. In Schedule 3 (provisions applicable when testing compliance with the migration limits)-

(a) in paragraph 4(3) and (4) of section A, after "specified in regulation" there shall be inserted "4(5A), 4A(4) or (5), 5(4A) or (4B) or"; and

(b) for sub-paragraph (2)(b) of paragraph 8 of section B there shall be substituted-

" (b) 12 mg/kg or, as the case may be, 2 milligrams per square decimeter in migration tests using other simulants referred to in Schedule 4."

MARY MULLIGAN
Authorised to sign by the Scottish Ministers

St Andrew's House, Edinburgh
7th November 2002

SCHEDULE 1

Regulation 15(a) and (b)

PART I

LIST OF MONOMERS TO BE ADDED TO SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
"15A	11530	00999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0.05 mg/6 dm ²
28B	12763	00141-43-5	2-Aminoethanol	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
28C	12765	84434-12-8	N-(2-aminoethyl)-beta-alanine, sodium salt	SML = 0.05 mg/kg
38A	13395	04767-03-7	2,2-Bis(hydroxymethyl)propionic acid	QMA = 0.05 mg/6 dm ²
47A	13617	00080-09-1	Bisphenol S	As item 86A
49B	13810	00505-65-7	1,4-Butanediol formal	QMA = 0.05 mg/6 dm ²
52A	13932	00598-32-3	3-Buten-2-ol	QMA = ND (DL = 0.02 mg/6 dm ²).

				To be used only as a co-monomer for the preparation of polymeric additive
70A	15030	00931-88-4	Cyclooctene	SML = 0.05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Council Directive 85/572/EEC
76A	15370	03236-53-1	1,6-Diamino-2,2,4-trimethylhexane	QMA = 5 mg/6 dm ²
76B	15400	03236-54-2	1,6-Diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm ²
77A	15610	00080-07-9	4,4'-Dichlorodiphenyl sulphone	SML = 0.05 mg/kg
86A	16090	00080-09-01	4,4'-Dihydroxydiphenyl sulphone	SML = 0.05 mg/kg
88B	16390	00126-30-7	2,2-Dimethyl-1,3-propanediol	SML = 0.05 mg/kg
121B	19110	04098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg in FP (as NCO)
122A	19243	00078-79-5	Isoprene	As item 145A
126A	19490	00947-04-6	Lauro lactam	SML = 5 mg/kg
135A	20260	00101-43-9	Methacrylic acid, cyclohexyl ester	SML = 0.05 mg/kg
135B	20410	02082-81-7	Methacrylic acid, diester with 1,4-butanediol	SML = 0.05 mg/kg
135D	20590	00106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QMA = 0.02 mg/6 dm ²
144A	21520	01561-92-8	Methallylsulphonic acid, sodium salt	SML = 5 mg/kg
145A	21640	00078-79-5	2-Methyl-1,3-butadiene	QM = 1 mg/kg in FP or SML = ND (DL = 0.02 mg/kg, analytical tolerance included)
145C	21765	106246-33-7	4,4'-Methylenebis(3-chloro-2,6-diethylaniline)	QMA = 0.05 mg/6 dm ²
145D	21821	00505-65-7	1,4-(Methylenedioxy)butane	As item 49B
148A	22360	01141-38-4	2,6-Naphthalenedicarboxylic acid	SML = 5 mg/kg
150A	22437	00126-30-7	Neopentylglycol	As item 88B
156A	22778	07456-68-0	4,4'-Oxybis(benzenesulphonyl	QMA = 0.05 mg/6 dm ²

			azide)	
159A	22900	00109-67-1	1-Pentene	SML = 5 mg/kg
184A	24073	000101-90-6	Resorcinol diglycidyl ether	QMA = 0.005 mg/6 dm ² . Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer.
214A	25380		Trialkyl acetic acid (C7-C17), vinyl esters (= vinyl versatate)	QMA = 0.05 mg/6 dm ²
215A	25450	26896-48-0	Tricyclodecanedimethanol	SML = 0.05 mg/kg
217A	25900	00110-88-3	Trioxane	SML = 0.05 mg/kg"

PART II

LIST OF MONOMERS FOR WHICH THE ENTRY CONTAINED IN THE FIRST COLUMN (ITEM) OF SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS IS TO BE AMENDED

<i>Previous Item</i>	<i>New Item</i>	<i>Name</i>
52A	52B	4-tert-Butylphenol
88B	88C	1.3 Dioxolane
121B	121C	Isophthalic acid
135A	135C	Methacrylic acid, 2-(dimethylamino) ethyl ester
145A	145B	3-Methyl-1-butene
159A	159B	Perfluoropropyl perfluorovinyl ether
214A	214B	Triallylamine"

PART III

LIST OF MONOMERS FOR WHICH THE ENTRY CONTAINED IN COLUMN 4 (RESTRICTIONS AND SPECIFICATIONS) OF SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS IS TO BE AMENDED

<i>Name</i>	<i>Restrictions and specifications</i>

"2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (= BADGE)	Use must be before 1st January 2005 and prior to that date be as specified in paragraph 1 of Annex I to Commission Directive 2002/16 as read with the second sentence of paragraph 2 of that Annex
4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
Formaldehyde	SML(T) = 15 mg/kg (21)
Hexamethylenetetramine	SML(T) = 15 mg/kg (expressed as formaldehyde (21)
1,3-Phenylenediamine	SML = ND (DL = 0.02 mg/kg, analytical tolerance included)"

PART IV

PROVISIONS SUBSTITUTED FOR SECTION B OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS

" SECTION B :

MONOMERS AUTHORISED UP TO THE 31st DECEMBER 2004

<i>Item</i>	<i>PM/REF No.</i>	<i>CAS No.</i>	<i>Name</i>	<i>Restrictions and specifications</i>
1	10599/90A	61788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	
2	10599/91	61788-89-4	Acids, fatty, unsaturated (C18), dimers, non-distilled	
3	10599/92A	68783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled	
4	10599/93	68783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non-distilled	
5	11500	00103-11-7	Acrylic acid, 2-ethylhexyl ester	
6	13050	00528-44-9	1,2,4-Benzenetricarboxylic acid	As item 23
7	13075	00091-76-9	Benzoguanamine	
8	13720	00110-63-4	1,4-Butanediol	
9	14260	00502-44-3	Caprolactone	
10	14800	03724-65-0	Crotonic acid	
11	15310	00091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	

12	15730	00077-73-6	Dicyclopentadiene	
13	16210	06864-37-5	3,3'-Dimethyl-4-4'-diaminodicyclo-hexylmethane	
14	16690	01321-74-0	Divinylbenzene	
15	16697	00693-23-2	Dodecanedioic acid	
16	17110	16219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	
17	18370	00592-45-0	1,4-Hexadiene	
18	18700	00629-11-8	1,6-Hexanediol	
19	21370	10595-80-9	Methacrylic acid, 2-sulphoethyl ester	
20	21400	54276-35-6	Methacrylic acid, sulphopropyl ester	
21	21970	00923-02-4	N-methylolmethacrylamide	
22	22210	00098-83-9	Alpha-methylstyrene	
23	25540	00528-44-9	Trimellitic acid	QM(T) = 5 mg/kg in FP
24	25550	00552-30-7	Trimellitic anhydride	QM(T) = 5 mg/kg in FP (expressed as trimellitic acid)
25	25840	03290-92-4	1,1,1-Trimethylopropane trimethacrylate	
26	26230	00088-12-0	Vinylpyrrolidone"	

SCHEDULE 2

Regulation 16(a) and (b)

PART I

LIST OF ADDITIVES TO BE ADDED TO PART I OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS

<i>Item</i>	<i>PM/REF</i>	<i>CAS</i>	<i>Name</i>	<i>Restrictions and specifications</i>
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	No.	No.		
"19A	35160	06642-31-5	6-Amino-1,3-dimethyluracil	SML = 5 mg/kg
19B	35170	00141-43-5	2-Aminoethanol	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
19C	35284	00111-41-1	N-(2-aminoethyl)ethanolamine	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
36E	38840	154862-43-8	Bis(-2,4-dicumylphenyl) pentaerythritoldiphosphite	SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol))
38A	39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethyl hexane	SML = 0.05 mg/kg
41A	41120	10043-52-4	Calcium chloride	
45A	41840	00105-60-2	Caprolactam	SML(T) = 15 mg/kg (5)
72B	47210	26427-07-6	Dibutylthiostannoic acid polymer [= thiobis(butyl-tin sulphide), polymer]	In compliance with the specifications laid down in Schedule 2B
73A	47540	27458-90-8	Di-tert-dodecyl disulfide	SML = 0.05 mg/kg
73D	48620	00123-31-9	1,4-Dihydroxybenzene	SML = 0.6 mg/kg
73E	48720	00611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
77A	52645	10436-08-5	Cis-11-eicosenamide	
164A	64800	00110-16-7	Maleic acid	SML(T) = 30 mg/kg (4)
167A	65920	66822-60-4	[N-methacryloyloxyethyl-N,N-dimethyl-N-carboxymethyl-ammonium chloride, sodium salt-octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-	

			pyrrolidone, copolymers	
191A	73160		Phosphoric acid, mono-and di-n-alkyl (C16 and C18) esters	SML = 0.05 mg/kg
195B	76730		Polydimethylsiloxane, gamma-hydroxypropylated	SML = 6 mg/kg
208A	81220	192268-64-7	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidiny)-n-butylamino)-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidiny)imino]-1,6-hexanediyl-[(2,2,6,6-tetramethyl-4-piperidiny)imino]]-alpha-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidiny)-N''-[6,(2,2,6,6-tetramethyl(-4-piperidinylamino)-hexyl][1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	SML = 5 mg/kg
229A	83599	68442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	SML(T) = 0.18 mg/kg (15) (expressed as tin)
240B	85680	01343-98-2	Silicic acid	
271A	92150	01401-55-4	Tannic acids	According to the JECFA specifications
279A	93270	00108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
281A	95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl 2-butyl-2-ethyl-1,3-propanediol phosphite	SML = 2 mg/kg (as sum of phosphite, phosphate and the hydrolysis product = TTBP)"

PART II

LIST OF ADDITIVES FOR WHICH THE ENTRY CONTAINED IN THE FIRST COLUMN (ITEM) OF PART I OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS IS TO BE AMENDED

<i>Previous Item</i>	<i>New Item</i>	<i>Name</i>
"36E	36F	Bis(3-4-dimethylbenzylidene)sorbitol
38A	38B	Bis(polyethyleneglycol)hydroxymethyl-phosphonate
73A	73B	Diethyleneglycol
73B	73C	1,1-Difluoroethane

73C	73F	2,4-Dimethyl-6-(1-methylpentadecyl)phenol
191A	191B	Phosphoric acid, trichloroethyl ester
195B	195C	Polyesters of 1,2-propanediol and/or 1,3-and/or 1,4 butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and or n-decanol
208A	208B	Poly (zinc glycerolate)
240B	240C	Silicic acid, lithium, magnesium, sodium salt
281A	281B	Vermiculite, reaction product with citric acid, lithium salt
281B	281C	Water
281C	281D	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feed stocks
281D	281E	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feed stocks"

PART III

LIST OF ADDITIVES FOR WHICH THE ENTRY CONTAINED IN COLUMN 4
(RESTRICTIONS AND SPECIFICATIONS) OF PART I OF SCHEDULE 2 TO THE
PRINCIPAL REGULATIONS IS TO BE AMENDED)

<i>Name</i>	<i>Restrictions and specifications</i>
"Benzaldehyde	In compliance with regulation 4(2) of the 1987 Regulations
Bis(polyethylenelycol) hydroxymethyl-phosphonate	SML = 0.6 mg/kg. Authorised until 1st January 2004.
Camphor	In compliance with the regulation 4(2) of the 1987 Regulations.
Copper iodide	SML(T) = 30 mg/kg (7) (expressed as copper) and the specific migration of this substance shall not exceed 1 mg/kg (10) (expressed as iodine).
2'-(2-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg (18)"

PART IV

PROVISIONS INSERTED AFTER PART I OF SCHEDULE 2 TO THE PRINCIPAL
REGULATIONS

" 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 THIS SCHEDULE APPLIES)

<i>Item</i>	<i>PM/REF No.</i>	<i>CAS No.</i>	<i>Name</i>	<i>Restrictions and specifications</i>
1	30180	02180-18-9	Acetic acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
2	31520	61167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	SML = 6 mg/kg
3	31920	00103-23-1	Adipic acid, bis(2-ethylhexyl) ester	SML = 18 mg/kg (1)
4	34230		Alkyl(C8-C22)sulphonic acids	SML = 6 mg/kg
5	35760	01309-64-4	Antimony trioxide	SML = 0.02 mg/kg (expressed as antimonium and analytical tolerance included)
6	36720	17194-00-2	Barium hydroxide	SML(T) = 1 mg/kg (11) (expressed as barium)
7	36800	10022-31-8	Barium nitrate	SML(T) = 1 mg/kg (11) (expressed as barium)
8	38240	00119-61-9	Benzophenone	SML = 0.6 mg/kg
9	38560	07128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML = 0.6 mg/kg
10	38700	63397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctylmercaptoacetate)	SML = 18 mg/kg
11	38800	32687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	SML = 15 mg/kg
12	38820	26741-53-7	Bis(2,4-di-tert-butylphenyl)pentaerythritol diphosphite	SML = 0.6 mg/kg
13	39060	35958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	SML = 5 mg/kg
14	39090		N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine	SML(T) = 1.2 mg/kg (12)
15	39120		N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochlorides	SML(T) = 1.2 mg/kg (12) (expressed as N,N-bis(2-hydroxyethyl)alkyl(C8-

				C18)amine)
16	40000	00991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	SML = 30 mg/kg
17	40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	SML = 6 mg/kg
18	40160	61269-61-2	N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	SML = 2.4 mg/kg
19	40800	13003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	SML = 6 mg/kg
20	40980	19664-95-0	Butyric acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
21	42000	63438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctylmercaptoacetate)	SML = 30 mg/kg
22	42400	10377-37-4	Carbonic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
23	42480	00584-09-8	Carbonic acid, rubidium salt	SML = 12 mg/kg
24	43600	04080-31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	SML = 0.3 mg/kg
25	43680	00075-45-6	Chlorodifluoromethane	SML = 6 mg/kg and in compliance with the specifications laid down in Schedule 2B
26	44960	11104-61-3	Cobalt oxide	SML(T) = 0.05 mg/kg (13) (expressed as cobalt)
27	45440	-	Cresols, butylated, styrenated	SML = 12 mg/kg
28	46720	04130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4.8 mg/6 dm ²
29	47600	84030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML = 12 mg/kg
30	48640	00131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
31	48800	00097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	SML = 12 mg/kg
32	48880	00131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg (14)
33	49600	26636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	SML(T) 0.18 mg/kg (15) (expressed as tin)
34	49840	02500-88-1	Diocetadecyl disulphide	SML = 3 mg/kg

35	50160		Di-n-octylin bis(n-alkyl(C10-C16) mercapto acetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
36	50240	10039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
37	50320	15571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
38	50360		Di-n-octyltin bis(ethyl maleate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
39	50400	33568-99-9	Di-n-octyltin bis(isooctyl maleate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
40	50480	26401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
41	50560		Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
42	50640	03648-18-8	Di-n-octyltin dilaurate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
43	50720	15571-60-5	Di-n-octyltin dimaleate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
44	50800	-	Di-n-octyltin dimaleate, esterified	SML(T) = 0.04 mg/kg (16) (expressed as tin)
45	50880	-s	Di-n-octyltin dimaleate, polymers (n = 2-4)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
46	50960	69226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
47	51040	15535-79-2	Di-n-octyltin mercaptoacetate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
48	51120		Di-n-octyltin thiobenzoate 2-ethyl-hexyl mercaptoacetate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
49	51570	00127-63-9	Diphenyl sulphone	SML = 3 mg/kg
50	51680	00102-08-9	N,N'-diphenylthiourea	SML = 3 mg/kg
51	52000	27176-87-0	Dodecylbenzenesulphonic acid	SML = 30 mg/kg
52	52320	52047-59-3	2-(4-Dodecylphenyl)indole	SML = 0.06 mg/kg
53	52880	23676-09-7	4-Ethoxybenzoic acid, ethyl ester	SML = 3.6 mg/kg
54	53200	23949-66-8	2-Ethoxy-2'-ethyloxanilide	SML = 30 mg/kg
55	58960	00057-09-0	Hexadecyltrimethylammonium bromide	SML = 6 mg/kg
56	59120	23128-	1,6-Hexamethylene-bis(3-(3,5-di-	SML = 45 mg/kg

		74-7	tert-butyl-4-hydroxyphenyl)propionamide)	
57	59200	35074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 6 mg/kg
58	60320	70321-86-7	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl)benzotriazole	SML = 1.5 mg/kg
59	60400	03896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg (18)
60	60800	65447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl, piperidine-succinic acid, dimethyl ester, copolymer	SML = 30 mg/kg
61	61280	03293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	SML(T) = 6 mg/kg (14)
62	61360	00131-57-7	2-Hydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg (14)
63	61440	02440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole	SML(T) = 30 mg/kg (18)
64	61600	01843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	SML(T) = 6 mg/kg (14)
65	63200	51877-53-3	Lactic acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
66	64320	10377-51-2	Lithium iodide	SML(T) = 1 mg/kg (10) (expressed as iodine) and SML(T) = 0.6 mg/kg (8) (expressed as lithium)
67	65120	07773-01-5	Manganese chloride	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
68	65200	12626-88-9	Manganese hydroxide	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
69	65280	10043-84-2	Manganese hypophosphite	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
70	65360	11129-60-5	Manganese oxide	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
71	65440		Manganese pyrophosphite	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
72	66360	85209-91-2	2-2'-Methylene bis(4,6-di-tert-butylphenyl)sodium phosphate	SML = 5 mg/kg

73	66400	00088-24-4	2-2'-Methylenebis(4-ethyl-6-tert-butylphenol)	SML(T) = 1.5 mg/kg (19)
74	66480	00119-47-1	2-2'-Methylenebis(4-methyl-6-tert-butylphenol)	SML(T) = 1.5 mg/kg (19)
75	67360	67649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML = 24 mg/kg
76	67520	54849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	SML(T) = 0.18 mg/kg (15) (expressed as tin)
77	67600		Mono-n-octyltin tris(alkyl(C10-C16)-mercaptoacetate)	SML(T) = 1.2 mg/kg (17) (expressed as tin)
78	67680	27107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	SML(T) = 1.2 mg/kg (17) (expressed as tin)
79	67760	26401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	SML(T) = 1.2 mg/kg (17) (expressed as tin)
80	68078	27253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0.05 mg/kg (expressed as neodecanoic acid) and SML(T) = 0.05 mg/kg (13) (expressed as cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC
81	68320	02082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6 mg/kg
82	68400	10094-45-8	Octadecylceramide	SML = 5 mg/kg
83	69840	16260-09-6	Oleoyl palmitamide	SML = 5 mg/kg
84	72160	00948-65-2	2-Phenylindole	SML = 15 mg/kg
85	72800	01241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	SML = 2.4 mg/kg
86	73040	13763-32-1	Phosphoric acid, lithium salts	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
87	73120	10124-54-6	Phosphoric acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
88	74400		Phosphorous acid, tris(nonyl- and/or dimonylphenyl) ester	SML = 30 mg/kg
89	77440		Polyethyleneglycol diricinoleate	SML = 42 mg/kg
90	77520	61791-12-6	Polyethyleneglycol ester of castor oil	SML = 42 mg/kg

91	78320	09004-97-1	Polyethyleneglycol monoricinoleate	SML = 42 mg/kg
92	81200	71878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]	SML = 3 mg/kg
93	81680	07681-11-0	Potassium iodide	SML(T) = 1 mg/kg (10) (expressed as iodium)
94	82020	19019-51-3	Propionic acid, cobalt salt	SML(T) = 0.05 mg/kg (13) (expressed as cobalt)
95	83595	119345-01-6	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with friedel craft reaction product of phosphorus trichloride and biphenyl	SML = 18 mg/kg and in compliance with the specifications in Schedule 2B
96	83700	00141-22-0	Ricinoleic acid	SML = 42 mg/kg
97	84800	00087-18-3	Salicylic acid, 4-tert-butylphenyl ester	SML = 12 mg/kg
98	84880	00119-36-8	Salicylic acid, methyl ester	SML = 30 mg/kg
99	85760	12068-40-5	Silicic acid, lithium aluminium salt (2:1:1)	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
100	85920	12627-14-4	Silicic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
101	86800	07681-82-5	Sodium iodide	SML(T) = 1 mg/kg (10) (expressed as iodium)
102	86880		Sodium monoalkyl dialkylphenoxybenzenedisulphonate	SML = 9 mg/kg
103	89170	13586-84-0	Stearic acid, cobalt salt	SML(T) = 0.05 mg/kg (13) (expressed as cobalt)
104	92000	07727-43-7	Sulphuric acid, barium salt	SML(T) = 1 mg/kg (11) (expressed as barium)
105	92320		Tetradecyl-polyethyleneglycol (EO = 3-8) ether of glycolic acid	SML = 15 mg/kg
106	92560	38613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl) -4-4'-biphenylene diphosphonite	SML = 18 mg/kg

107	92800	00096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	SML = 0.48 mg/kg
108	92880	41484-35-9	Thiodiethanol bis(3-(3-5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 2.4 mg/kg
109	93120	00123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5 mg/kg (20)
110	93280	00693-36-7	Thiodipropionic acid, dioctadecyl ester	SML(T) = 5 mg/kg (20)
111	94560	00122-20-3	Triisopropanolamine	SML = 5 mg/kg
112	95280	40601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML = 6 mg/kg
113	95360	27676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML = 5 mg/kg
114	95600	01843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	SML = 5 mg/kg"

SCHEDULE 3

Regulation 17

LIST OF SUBSTANCES TO BE ADDED TO SCHEDULE 2B TO THE PRINCIPAL REGULATIONS

Item	PM/REF No.	Specifications
"4A	43680	CHLORODIFLUOROMETHANE
	-	Content of chlorofluoromethane less than 1 mg/kg of the substance
4B	47210	DIBUTYLTHIOSTANNOIC ACID POLYMER
	-	Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂) _n (n = 1,5-2)
5A	83595	REACTION PRODUCT OF DI-TERT-BUTYLPHOSPHONITE WITH BIPHENYL, OBTAINED BY CONDENSATION OF 2,4-DI-TERT-BUTYLPHENOL WITH FRIEDEL CRAFT REACTION PRODUCT OF PHOSPHORUS TRICHLORIDE AND BIPHENYL
		Composition
		- 4,4'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite]

	<p>(CAS No. 38613-77-3) (36-46% w/w (1))</p> <p>- 4,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite]</p> <p>(CAS No. 118421-00-4) (17-23% w/w)</p> <p>- 3,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite]</p> <p>(CAS No. 118421-01-5) (1-5% w/w)</p> <p>- 4-Biphenylene-0,0-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite]</p> <p>(CAS No. 91362-37-7) (11-19% w/w)</p> <p>- Tris(2,4-di-tert-butylphenyl)phosphite</p> <p>(CAS No. 31570-04-4) (9-18% w/w)</p> <p>- 4,4'-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite</p> <p>(CAS No. 112949-97-0) (<5% w/w)</p> <p>Other specifications</p> <p>- Phosphor content of minimum 5.4% to 5.9%</p> <p>- Acid value of maximum 10 mg KOH per gram</p> <p>- Melt range of 85-110°C"</p>
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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, amend for the second time the Plastic Materials and Articles in Contact with Food Regulations 1998 (S.I. 1998/1376, "the 1998 Regulations"). The Regulations implement-

- (a) Commission Directive 2001/62/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (O.J. No. L 221, 17.8.2001, p.18);
- (b) Commission Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs (O.J. No. L 51, 22.2.2002, p.27); and
- (c) (in relation to camphor and benzaldehyde only) Commission Directive 2002/17/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (O.J. No. L 58, 28.2.2002, p.19).

The Regulations also reflect the revocation, with effect from 4th September 2002, of Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (O.J. No. L 75, 21.3.1990) as amended and its re-enactment in consolidated form by Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (O.J. No. L 220 15.8.2002, p.18).

The Regulations amend the 1998 Regulations by-

- (a) adding a provision declaring that, in addition to regulating (as previously) the contact with food of certain types of plastic materials and articles, the 1998 Regulations now also include provisions which regulate the contact with food of certain other types of food contact materials, namely adhesives and materials or articles covered by surface coatings (regulation 3);
- (b) providing for the definition of "plastic material or article" to have an extended meaning where that term is used in the context of provisions added to the 1998 Regulations in implementation of Commission Directive 2002/16/EC (regulation 4(a)(vii) and (c));
- (c) extending, so as to apply to adhesives and materials and articles covered by surface coatings, the provisions in the 1998 Regulations which-
 - (i) give to the term "sale" an extended meaning for the purposes of those Regulations;
 - (ii) prohibit the use, sale or importation of plastic materials and articles not meeting specified standards;
 - (iii) make available the defence of "due diligence" in the case of offences relating to plastic materials and articles;
 - (iv) create a presumption as to the accuracy of any particulars shown in relation to a plastic material or article which may come into contact with food; and
 - (v) apply for the purposes of those Regulations, in relation to plastic materials and articles, various provisions of the Food Safety Act 1990 (regulations 4(b), 5, 12(b), 13 and 14 respectively);
- (d) adding to the provisions restricting the use of certain substances as monomers or additives in the manufacture of plastic materials or articles, provisions restricting the use of 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether ("BADGE"), bis(hydroxyphenyl) methane bis(2,3-epoxypropyl) ethers ("BFDGE") and novolac glycidyl ethers ("NOGE") as monomers or additives in such manufacture (regulations 6(a) and 8(a));
- (e) changing (from 31st December 2001 to 31st December 2004) the date beyond which the monomers listed in Section B of Schedule 1 to the 1998 Regulations may no longer be used in the manufacture of plastic materials or articles and modifying the list of the types of plastic materials and articles to which the restrictions on the use of monomers in their manufacture do not apply (regulation 6(b) and (c));
- (f) introducing new restrictions on the manufacture of plastic materials and articles using BADGE, BFDGE or NOGE other than as monomers or additives (regulation 7);
- (g) amending the provisions governing the testing of the capability of plastic materials and articles to transfer their constituents to food, in particular by adding provisions governing the testing of that capability in the case of BADGE, BFDGE and NOGE (regulations 9 and 18);

(h) adding a provision restricting the extent to which certain plastic materials or articles are allowed to transfer certain substances to food (regulation 10);

(i) introducing new restrictions on the manufacture of adhesives or materials and articles covered by surface coatings using BADGE, BFDGE or NOGE and new provisions governing the testing of the capability of such adhesives, materials or articles to transfer those substances to food (regulation 11);

(j) making it an offence to contravene any of the restrictions referred to in sub-paragraphs (d), (f) or (i) above and including transitional provisions (regulation 12(a) and (c));

(k) adding new substances to the list of monomers which may be used in the manufacture of plastic materials or articles and amending the conditions of use of certain monomers used in such manufacture (regulation 15);

(l) adding new substances to the non-exhaustive list of additives used in the manufacture of plastic materials or articles, amending the conditions of use of certain additives used in such manufacture and deleting one additive from that list (regulations 8(a) and 16);

(m) adding certain substances to the list of substances whose specifications are set out in Schedule 2B to the 1998 Regulations (regulation 17).

A Regulatory Impact Assessment, which includes a compliance cost assessment of the effect which these Regulations are likely to have on business costs, has been prepared and has been placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.

Notes:

[1] 1990 c.16; section 6(4) was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c.40) and by paragraph 10(3) of Schedule 5 to the Food Standards Act 1999 (c.28) ("the 1999 Act"). Sections 16(2) and 48(1) were amended by paragraph 8 of Schedule 5 to 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; 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) 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 Scotland Act 1998.[back](#)

[2] Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the Food Standards Act 1999.[back](#)

[3] Section 48(4B) was inserted by paragraph 21 of Schedule 5 to the Food Standards Act 1999.[back](#)

[4] S.I. 1998/1376, amended by S.S.I. 2000/431.[back](#)

[5] O.J. No. L 51, 22.2.02, p.27.[back](#)

[6] O.J. No. L 220, 15.8.02, p.18.[back](#)

[7] O.J. No. L 221, 17.8.01, p.18.[back](#)

[8] O.J. No. L 109, 6.5.00, p.29.[back](#)

[9] O.J. No. L 297, 23.10.82, p.26, last amended by Commission Directive 97/48/EC (O.J. No. L

222, 12.8.97, p.10).[back](#)

[10] O.J. No. L 372, 31.12.85, p.14.[back](#)

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