2002 No. 2364

FOOD, ENGLAND

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

Made - - - - -	*16th September 2002*
Laid before Parliament	*16th September 2002*
Coming into force - -	*30th November 2002*

The Secretary of State, in exercise of the powers conferred on him by sections 16(2), 17(1), 26(1)(a) and (3), 31 and 48(1) of the Food Safety Act 1990(**a**) and now vested in him(**b**), having had regard, in accordance with section 48(4A) of that Act, to relevant advice given by the Food Standards Agency, and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**), and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

Title, commencement and extent

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002, shall come into force on 30th November 2002 and shall extend to England 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(**d**) ("the principal Regulations") shall be amended, in so far as they extend to England, in accordance with regulations 3 to 18.

3. Immediately after regulation 1 (title, commencement and extent) there shall be inserted the following regulation—

"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

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(**a**) 1990 c. 16.

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act. Section 17(1) was amended by paragraph 12(a), and section 48 by paragraph 21, of Schedule 5 to the 1999 Act. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend existing Regulations made by the Minister of Agriculture, Fisheries and Food (whether or not with others) under the Food Safety Act 1990.

(**c**) OJ No. L31, 1.2.2002, p.1.

(**d**) S.I. 1998/1376, amended by S.I. 2000/3162.

(b) regulations 8A and 8B apply only in relation to adhesives and to materials or articles covered by surface coatings.".

4. In regulation 2 (interpretation)—

(a) in paragraph (1)—

(i) immediately after the definition of "additive" there shall be inserted the following definitions—

""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 the following definition—

""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) immediately after the definition of "capable" there shall be inserted the following definitions—

""Commission Directive 2001/62" means Commission Directive 2001/62/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs(**a**);

"Commission Directive 2002/16" means Commission Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs(**b**);

(iv) for the definition of "the Directive" there shall be substituted the following definition—

""the Directive" means Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs(**c**);",

(v) immediately after the definition of "import" there shall be inserted the following definition—

""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) immediately after the definition of "monomer" there shall be inserted the following definition—

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

(vii) at the end of the definition of "plastic material or article" there shall be added the following words ", 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", and

(viii) after the definition of "sell" there shall be added the following definition—

""QMA" has the same meaning as it bears in the first sentence of the sub-paragraph relating to that term in paragraph 8 of Annex II to the Directive;";

(b) for paragraph (2) there shall be substituted the following provision—

"(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

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(**a**) OJ No. L221, 17.8.2001, p.18.
(**b**) OJ No. L51, 22.2.2002, p.27.
(**c**) OJ No. L220, 15.8.2002, p.18.

(c) immediately after paragraph (4) there shall be inserted the following paragraph—

"(5) The provisions referred to in the definition of "plastic material or article" in paragraph (1) of this regulation 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) for the heading there shall be substituted the following heading—

"Restriction on the use, sale or importation of plastic materials and articles, adhesives and materials and articles covered by surface coatings";

(b) in paragraphs (1) and (2), immediately after each reference to "plastic material or article" there shall be inserted a reference to ", adhesive or material or article covered by a surface coating";

(c) at the end of paragraph (4)(a)(iii) the word "or" shall be deleted;

(d) for paragraph (4)(a)(iv) there shall be substituted the following provision—

"(iv) 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";

(e) immediately after paragraph (4)(a)(iv) there shall be inserted the following provision—

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

(f) there shall be added at the end the following paragraph—

"(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 the heading and paragraph (1) there shall be substituted the following provisions—

"Restriction on the use of monomers in the manufacture of plastic materials and articles

(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 or referred to in the corresponding entry in column 4 of that 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 it is 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)—

(i) for sub-paragraphs (b) and (c) there shall be substituted the following provisions—

"(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 the following paragraph—

"(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 the expression "Paragraph (1)" there shall be substituted the expression "Paragraph (1)(a)";

(e) immediately after paragraph (5) there shall be inserted the following provisions—

"(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 the expression "paragraph (1)" there shall be substituted the expression "paragraph (1)(a)", and

(ii) after the words "Part I of Schedule 1" there shall be inserted the words "or to which sub-paragraph (b) or (c) of that paragraph relates".

7. Immediately after regulation 4 there shall be inserted the following regulation—

"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 1 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 that Annex.

(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 that Annex.

(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 the heading and paragraph (1) there shall be substituted the following provisions—

"Restriction on the use of additives in the manufacture of plastic materials and articles

(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 that Schedule, which—

(i) is not of good technical quality, or

(ii) is not 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, 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 that Annex;

(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 that Annex; or

(d) NOGE to the extent that it is 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), immediately after the expression "Part I" there shall be inserted the expression "or Part II";

(c) for paragraph (3), there shall be substituted the following paragraph—

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

(d) in paragraph (4)—

(i) for the expression "Part I of Schedule 2" there shall be substituted the expression "Part I or II of Schedule 2", and

(ii) in each of sub-paragraphs (a) and (b), for the word "therein" there shall be substituted the expression "that column";

(e) between paragraphs 4 and 5 there shall be inserted the following paragraphs—

"(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), for the expression "Part I of Schedule 2" there shall be substituted the expression "Part I or Part II of Schedule 2".

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

(a) for the heading, the introductory words and paragraph (1)(a) there shall be substituted the following provisions—

"Method of testing the capability of plastic materials or articles to transfer constituents and methods of analysis

(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;"; and

(b) after paragraph (3) there shall be added the following provisions—

"(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-paragraph 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 sentence 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 that paragraph relating to the term "QMA".".

10. For regulation 7A (specifications) there shall be substituted the following regulation—

"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 that 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 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. Immediately after regulation 8 (labelling) there shall be inserted the following regulations—

"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 1 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 1 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 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 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 materials or articles covered by surface coatings to transfer constituents and methods of analysis

8B.—(1) Subject to paragraphs (2) and (3) of this regulation, for the purposes of regulation 8A(1), (2), (4) and (5), an adhesive or 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 material or article may come into contact to the extent that such capability is established by the verification methods specified in Section A of Schedule 3 and in Schedule 4.

(2) Subject to paragraph (3) of this regulation, 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) of this regulation, 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 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 referred to in regulation 8A(4) or (5)"; and

(c) the reference 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 a reference 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 requirement 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 of that Article.".

12. In regulation 10 (offences)—

(a) in paragraph (1), for the expression "regulation 3, 4(1), 5(1) or 8" there shall be substituted the expression "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), immediately after the words "plastic material or article" there shall be inserted the words "or, as the case may be, adhesive or material or article covered by a surface coating"; and

(c) immediately after paragraph (15) there shall be added the following paragraphs—

"(16) Subject to paragraph (18) of this regulation, 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 put into free circulation in the European Community 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) of this regulation had not been in force at the time that matter occurred.

(17) The provisions referred to in paragraph (16) of this regulation are regulations 5(d), 6(b), 8(a), (b) and (d), 10, 12(a) and 15 to 17 of the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002, to the extent that they implement those requirements of Commission Directive 2001/62 to which Article 2 of that Directive applies.

(18) For the purposes of paragraph (16) of this regulation, "free circulation" shall have the same meaning as in Article 2 of Commission Directive 2001/62.

(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 an adhesive or a material or article covered by a surface coating—

(i) which was brought into contact with food before 28th February 2003,

(ii) on which (in the case of a material or article covered by a surface coating) the date of filling of the material or article concerned appeared at the time of the sale, and

(iii) the labelling or marking of which at the time of sale (in the case of a material or article covered by a surface coating) complied with the requirement as regards labelling relating to durability contained in Article 2.1(a) of Directive 2000/13/EC 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(**a**); 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) of this regulation had not been in force at the time of sale.

(20) The provisions referred to in paragraph (19) of this regulation are regulations 5(b) and (f), 8A and 12(a) of the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002.".

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

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

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

(b) in paragraph (3), for the words "relate to plastic materials or articles" there shall be substituted the words "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, 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,

(ii) in the case of each monomer named in the second column of Part II of Schedule 1 to these Regulations, for the item number for that monomer specified opposite to it in the column headed "Item" there shall be substituted the item number for it specified in the first column (item) of that Part, and

(iii) in the case of each monomer named 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 (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of that Part;

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

(c) in Part II, for paragraph 4 there shall be substituted the following paragraph—

"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.

(**a**) OJ No. L109, 6.5.2000, p.29.

(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, 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,

(iii) in the case of each additive named in the second column of Part II of Schedule 2 to these Regulations, for the item number for that additive specified opposite to it in the column headed "Item" there shall be substituted the item number for it specified in the first column (item) of that Part, and

(iv) in the case of each additive named 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 (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of that Part, and

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

(b) immediately after Part I there shall be inserted the contents of 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 the expression "*Part II*" there shall be substituted the expression "*Part III*";

(ii) in paragraph 1, for the expression "Part I" there shall be substituted the expression "Parts I and II";

(iii) in each of paragraphs 2, 3 and 4, immediately after the expression "Part I" there shall be added the expression "or Part II"; and

(iv) for paragraph 4 there shall be substituted the following paragraph—

"4. Where an entry in column 4 of Part I or 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) immediately after paragraph 4 there shall be inserted the following paragraph—

"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(**a**) and Council Directive 85/572/EEC(**b**).".

17. In Schedule 2B (specifications) in the case of each substance listed in Schedule 3 to these Regulations, the item number, 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.

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

(a) in each of sub-paragraphs (3) and (4) of paragraph 4, immediately after the words "specified in regulation" there shall be inserted the expression "4(5A), 4A(4) or (5), 5(4A) or (4B) or"; and

(b) for sub-paragraph (2)(b) of paragraph 8 there shall be substituted the following sub-paragraph—

"(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.".

Amendment of the Food Safety (Sampling and Qualifications) Regulations 1990

19. In Schedule 1 to the Food Safety (Sampling and Qualifications) Regulations 1990(**c**) (provisions to which those Regulations do not apply) the reference in the second column, opposite the reference in the first column to the Plastic Materials and Articles in Contact with Food Regulations 1998, shall be amended in relation to England so as to read "S.I. 1998/1376 as amended by S.I. 2000/3162 and S.I. 2002/[ ]".

Signed by authority of the Secretary of State for Health

Hazel Blears
Parliamentary Under-Secretary of State,
Department of Health

16th September 2002

(**a**) OJ No. L297, 23.10.82, p.26, last amended by Commission Directive 97/48/EC (OJ No. L222, 12.8.97, p.10).
(**b**) OJ No. L372, 31.12.85, p.14.
(**c**) S.I. 1990/2463; to which there are amendments not relevant to these Regulations.

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 polmeric 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	Laurolactam	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

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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-Naphthalenedicar-boxylic acid	SML = 5 mg/kg
150A	22437	00126-30-7	Neopentylglycol	As item 88B
156A	22778	07456-68-0	4,4'-Oxybis(benzenesul-phonyl azide)	QMA = 0.05 mg/6 dm^2
159A	22900	00109-67-1	1-Pentene	SML = 5 mg/kg
184A	24073	000101-90-6	Resorcinol diglycidyl ether	QMA = 0.005 mg/g 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/g dm^2
215A	25450	26896-48-0	Tricyclodecanedime-thanol	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

Item	Name
52B	4-tert-Butylphenol
88C	1.3 Dioxolane
121C	Isophthalic acid
135C	Methacrylic acid, 2-(dimethylamino) ethyl ester
145B	3-Methyl-1-butene
159B	Perfluoropropyl perfluorovinyl ether
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

Name	Restrictions and specifications
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 31st DECEMBER 2004

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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	

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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-methylolmethacry-lamide	
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

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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)ethano-lamine	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

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
36E	38840	154862-43-8	Bis(-2,4-dicumylphenyl) pentaerythritoldiphos-phite	SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pen-taerythritol-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'-Dihydroxybenzophe-none	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-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[2,2,6,6-tetramethyl-4-piperidinyl)imino]]-alpha-[N,N,N',N'-tetrabutyl-N""-(2,2,6,6-tetramethyl-4-piperidinyl)-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

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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 1 TO THE PRINCIPAL REGULATIONS IS TO BE AMENDED

Item	Name
36F	Bis(3-4-dimethylbenzylidene)sorbitol
38B	Bis(polyethyleneglycol)hydroxymethyl-phosphonate
73B	Diethyleneglycol
73C	1,1-Difluoroethane
73F	2,4-Dimethyl-6-(1-methylpentadecyl)phenol
191B	Phosphoric acid, trichloroethyl ester
195C	Polyesters of 1,2-propanediol and/or 1,3-and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and or n-decanol
208B	Poly (zinc glycerolate)
240C	Silicic acid, lithium, magnesium, sodium salt
281B	Vermiculite, reaction product with citric acid, lithium salt
281C	Water
281D	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feed stocks
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

Name	Restrictions and specifications
Benzaldehyde	In compliance with regulation 4(2) of the 1987 Regulations
Bis(polyethyleneglycol)hydroxymethyl-phosphonate	SML = 0.6 mg/kg. Authorised until 1st January 2004
Camphor	In compliance with 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)

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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 anti-monium 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)thio- phene	SML = 0.6 mg/kg
10	38700	63397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctylmercapto-acetate)	SML = 18 mg/kg

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
11	38800	32687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)pro-pionyl)hydrazide	SML = 15 mg/kg
12	38820	26741-53-7	Bis(2,4-di-tert-butylphenyl)pentaery-thritol 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)hexamethy-lenediamine-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(isooctylmercapto-acetate)	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

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
29	47600	84030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML = 12 mg/kg
30	48640	00131-56-6	2,4-Dihydroxybenzophe-none	SML(T) = 6 mg/kg ([14])
31	48800	00097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylme-thane	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	Dioctadecyl 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-ethyllhexyl 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	-	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	Dodecylbenzenesul-phonic acid	SML = 30 mg/kg

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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	Hexadecyltrimethy-lammonium bromide	SML = 6 mg/kg
56	59120	23128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)pro-pionamide)	SML = 45 mg/kg
57	59200	35074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)pro-pionate)	SML = 6 mg/kg
58	60320	70321-86-7	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phe-nyl)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)benzo-triazole	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 iodium) 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)

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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-hydroxylphenyl)pro-pionate	SML = 6 mg/kg
82	68400	10094-45-8	Octadecylerucamide	SML = 5 mg/kg
83	69840	16260-09-6	Oleylpalmitamide	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

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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)limino]	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 dialkylphenoxybenze-nedi-sulphonate	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'-biphenylylene 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)pro-pionate)	SML = 2.4 mg/kg
109	93120	00123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5 mg/kg ([20])

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
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 IN 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 = $(C_8H_{18}S_3Sn_2)n$ (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](CAS No. 38613-77-3) (36-46% w/w ([1])) — 4,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite](CAS No. 118421-00-4) (17-23% w/w) — 3,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite](CAS No. 118421-01-5) (1-5% w/w) — 4-Biphenylene-0,0-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite](CAS No. 91362-37-7) (11-19% w/w) — Tris(2,4-di-tert-butylphenyl)phosphite(CAS No. 31570-04-4) (9-18% w/w) — 4,4'-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite(CAS No. 112949-970) (5% w/w) **Other specifications** — Phosphor content of minimum 5.4% to 5.9% — Acid value of maximum 10 mg KOH per gram — Melt range of 85-110°C

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which extend to England only, amend for the second time the Plastic Materials and Articles in Food Regulations 1998 (S.I. 1998/1376, "the 1998 Regulations"), which extend to the whole of Great Britain. 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 (OJ No. L221, 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 (OJ No. L51, 22.2.2002, p.27); and

(c) (in minor respects) Commission Directive 2002/17/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (OJ No. L58, 28.2.2002, p.19).

2. 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 (OJ No. L75, 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 (OJ No. L220, 15.8.2002, p.18).

3. 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*); and

(n) making a consequential amendment to the Food Safety (Sampling and Qualifications) Regulations 1990 *(regulation 19*).

4. A regulatory impact assessment, which includes a compliance cost assessment of the effect that they are likely to have on business costs, has been prepared for these Regulations and has been placed in the Library of each House of Parliament, together with a transposition note setting out how the main elements of the Directives referred to in paragraph 1 above are transposed into domestic law by these Regulations. Copies may be obtained from the Chemical Safety and Toxicology Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

STATUTORY INSTRUMENTS

2002 No. 2364

FOOD, ENGLAND

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

ISBN 0-11-042796-3

9 780110 427966

£4.50

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Printed and published in the UK by The Stationery Office Limited
under the authority and superintendence of Carol Tullo, Controller of
Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.
E1027 9/2002 121027 19585