

**2002 No. 3008**

**FOOD, ENGLAND**

**The Plastic Materials and Articles in Contact with Food  
(Amendment) (England) (No. 2) Regulations 2002**

*Made* - - - - - *4th December 2002*

*Laid before Parliament* *11th December 2002*

*Coming into force* - - *28th February 2003*

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, extent and commencement**

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) (England) (No. 2) Regulations 2002, shall extend to England only and shall come into force on 28th February 2003.

**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 6.

3. In regulation 10 (offences), immediately after paragraph (20) there shall be added the following paragraphs—

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

(a) the act constituting the offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st March 2004 and the matter constituting the offence

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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 and S.I. 2002/2364.

would not have constituted an offence under these Regulations if the amendments made to them by the provisions specified in paragraph (22) had not been in force at the time that matter occurred; or

- (b) the act constituting the offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st March 2003, and the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by regulation 4(a)(i) and (b) (in so far as they relate to the monomer divinylbenzene) and 6 of the Plastic Materials and Articles in Contact with Food (Amendment) (England) (No. 2) Regulations 2002 had not been in force at the time that matter occurred.

(22) The provisions referred to in paragraph (21)(a) of this regulation are the provisions of the Plastic Materials and Articles in Contact with Food (Amendment) (England) (No. 2) Regulations 2002, except in so far as they relate to the monomer divinylbenzene.”.

**4.** 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, 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,
- (iii) in the case of the monomer Bis (4-isocyanatocyclohexyl) methane (item 43), for the entry for that monomer specified in column 1 (PM/REF/No) there shall be substituted the entry “13560”, and
- (iv) 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) in Section B of Part I, all the entries for the monomers named in Part IV of Schedule 1 to these Regulations shall be deleted; and

(c) in Part II, at the end of paragraph 4 there shall be inserted the following provisions—

“(22) 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. 13620, 36840, 40320 and 87040.

(23) 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. 13720 and 40580.

(24) 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. 16650 and 51570.

(25) QM(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the substances having PM/REF/Nos. 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.”.

**5.** In Schedule 2 (additives and supplementary)—

(a) in Part I—

- (i) in the case of each additive listed in Part I of Schedule 2 to these Regulations, the item number, PM/REF No, CAS No, name and restriction or specification specified for that additive in that Part shall be inserted in the appropriate numerical position for that item number,
- (ii) in the case of the additive Bis (polyethyleneglycol) hydroxymethylphosphonate, there shall be inserted in column 2 (CAS No) the entry “68951 - 50 - 8”, and

- (iii) in the case of the additive named in the first column of Part II 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
- (b) in Part II—
  - (i) in the case of each additive listed in Part III of Schedule 2 to these Regulations, the item number, PM/REF/No, CAS No, name and restriction or specification specified for that additive in that Part shall be inserted in the appropriate numerical position for that item number, and
  - (ii) in the case of each additive named in the first column of Part IV 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
- (c) in Part III—
  - (i) in note (11) of paragraph 4, after the figure “36800” there shall be inserted the figure “, 36840”, and
  - (ii) at the end of that paragraph there shall be added the following provisions—
    - “(22) 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. 13620, 36840, 40320 and 87040.
    - (23) 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. 13720 and 40580.
    - (24) 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. 16650 and 51570.”.

6. In Schedule 2B (specifications) in the case of the substance specified 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 and letter.

#### **Amendment to the Food Safety (Sampling and Qualifications) Regulations 1990**

7. In Schedule 1 to the Food Safety (Sampling and Qualifications) Regulations 1990(a) (provisions to which those Regulations do not apply) the reference in the second column, opposite the entry in the first column relating 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, S.I. 2002/2364 and S.I. 2002/ ”.

Signed by authority of the Secretary of State for Health

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

4th December 2002

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(a) S.I. 1990/2463. The relevant amending instruments are S.I. 1998/1376 and S.I. 2002/2364.

## SCHEDULE 1

Regulation 4(a)(i), (ii) and  
(iv) and (b)

## PART I

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

<i>Item</i>	<i>PM/REF No</i>	<i>CAS No</i>	<i>Name</i>	<i>Restrictions and specifications</i>
33B	13075	00091-76-9	Benzoguanamine	see "2,4-Diamino-6-Phenyl-1,3,5-Triazine"
47B	13620	10043-35-3	Boric acid	SML(T) - 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/ 83/EC on water for human consumption(a).
49A	13720	00110-63-4	1,4-Butanediol	SML(T) = 0.05 mg/kg (23)
76A	15310	00091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	QMA = 5 mg/6 dm <sup>2</sup>
92A	16650	00127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg (24)
93A	16690	01321-74-0	Divinylbenzene	QMA = 0.01 mg/6 dm <sup>2</sup> of SML = ND (DL = 0.02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Schedule 2B.
93C	16697	00693-23-2	n-Dodecanedioic Acid	
120A	18897	16712-64-4	6-Hydroxy-2- naphthalenecarboxylic acid	SML = 0.05 mg/kg
120B	18898	103-90-2	N-(4- Hydroxyphenyl) acetamide	Only to be used in liquid crystals and behind a barrier layer in multi- layered plastics.
147B	22332	28679-16-5	Mixture of (40% w/w) 2,2,4- trimethylhexane-1,6- diisocyanate and (60% w/w) 2,4,4- trimethylhexane-1,6- diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
217A	25840	03290-92-4	1,1,1- trimethylolpropane trimethacrylate	SML = 0.05 mg/kg

(a) OJ No. L330, 5.12.1998, p.32.

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>Item</i>	<i>Name</i>
49B	1,4-Butanediol bis(2,3-epoxypropyl)ether
49C	1,4-Butanediol formal
76B	1,6-Diamino-2,2,4-trimethylhexane
76C	1,6-Diamino-2,4,4-trimethylhexane
93B	N,N'-Divinyl-2-imidazolidone
93D	1-Dodecene
217B	Trioxane

PART III

LIST OF MONOMERS FOR WHICH THE ENTRY CONTAINED IN COLUMN 4 (RESTRICTIONS) 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>
Chlorotrifluoroethylene	QMA = 0.5 mg/6 dm <sup>2</sup>
Cyclohexyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Dicyclohexylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	QM(T) = 1 mg/kg (expressed as NCO) (25)
Diphenylether-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Diphenylmethane-2,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Diphenylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Hexamethylene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg (expressed as NCO) (25)
1,5-Naphthalene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Octadecyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
2,4-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
2,6-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg (expressed as NCO) (25)

PART IV

LIST OF MONOMERS FOR WHICH ALL THE ENTRIES CONTAINED IN SECTION B OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS ARE TO BE DELETED

Benzoguanamine  
 1,4-Butanediol  
 2,4-Diamino-6-phenyl-1,3,5-triazine  
 Divinylbenzene  
 n-Dodecanedioic acid  
 1,1,1-Trimethylolpropane trimethacrylate

SCHEDULE 2 Regulation 5(a)(i) and (iii) 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 No</i>	<i>CAS No</i>	<i>Name</i>	<i>Restrictions and specifications</i>
27B	36840	12007-55-5	Barium tetraborate	SML(T) = 1 mg/kg expressed as barium (11) and SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption.
38C	40320	10043-35-3	Boric acid	SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption.
40A	40580	00110-63-4	1,4-Butanediol	SML(T) = 0.05 mg/kg (23)
188B	71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	SML(T) = 0.05 mg/kg
246A	87040	01330-43-4	Sodium tetraborate	SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption.

PART II

ADDITIVE 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>
Bis(polyethyleneglycol) hydroxymethylphosphonate	SML = 0.6 mg/kg

PART III

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

<i>Item</i>	<i>PM/REF No</i>	<i>CAS No</i>	<i>Name</i>	<i>Restrictions and specifications</i>
27A	45650	6197-30-4	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	SML = 0.05 mg/kg
82A	68860	04724-48-5	n-Octylphosphonic acid	SML = 0.05 mg/kg
111A	95000	28931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer	

PART IV

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

<i>Name</i>	<i>Restrictions and specifications</i>
N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides	SML(T) = 1.2 mg/kg (12) expressed as tertiary amine (expressed excluding HCl)
Diphenyl sulphone	SML(T) = 3 mg/kg (24)

SCHEDULE 3

Regulation 6

SUBSTANCE TO BE ADDED TO SCHEDULE 2B TO THE PRINCIPAL REGULATIONS

<i>Item</i>	<i>PM/REF No</i>	<i>Specifications</i>
1	16690	Divinylbenzene - must not contain more than 40% ethylvinylbenzene

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations, which extend to England only, amend for the third time the Plastic Materials and Articles in Contact with Food Regulations 1998 (S.I. 1998/1376, “the 1998 Regulations”), which extend to the whole of Great Britain. These Regulations implement 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), except paragraph 1(a) of the Annex and paragraph 2(a)(ii) of the Annex in so far as it relates to the additives benzaldehyde and camphor, which were implemented by the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002 (S.I. 2002/2364).

2. The Regulations amend the 1998 Regulations by—

- (a) adding a transitional provision in respect of proceedings for an offence under them (*regulation 3*);
- (b) 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 4*);
- (c) adding new substances to the non-exhaustive list of additives used in the manufacture of plastic materials or articles and amending the conditions of use of certain additives used in such manufacture (*regulation 5*);
- (d) adding certain substances to the list of substances whose specifications are set out in Schedule 2B to the 1998 Regulations (*regulation 6*); and
- (e) making a consequential amendment to the Food Safety (Sampling and Qualifications) Regulations 1990 (*regulation 7*).

3. A regulatory impact assessment 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 Commission Directive 2002/17/EC 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.

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