2000 No. 3162

FOOD, ENGLAND

The Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2000

Made - - - - -	*28th November 2000*
Laid before Parliament	*6th December 2000*
Coming into force - -	*31st December 2000*

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

Title, commencement and extent

1.—(1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2000 and shall come into force on 31st December 2000.

(2) These Regulations apply to England.

Amendment of Regulations

2. The Plastic Materials and Articles in Contact with Food Regulations 1998(**b**) ("the principal Regulations") shall be amended (in so far as they apply to England) as follows.

3. In regulation 2(1) (interpretation), in the definition of "the Directive" for the words "and 96/11/EC" there shall be substituted ", 96/11/EC and 1999/91/EC(**c**) (as corrected(**d**))".

4. For paragraph (4)(a) of regulation 3 (restriction on the use, sale or importation of plastic materials and articles) there shall be substituted—

"(a) if—

(i) it has been manufactured with a prohibited monomer as described in regulation 4(1);

(ii) it has been manufactured with a prohibited additive as described in regulation 5(1);

(**a**) 1990 c.16. Functions formerly exercisable by "the Ministers" 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 (c. 28), and paragraphs 12 and 21 of that Schedule amend sections 17(1) and 48 of the 1990 Act. Functions of "the Ministers" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) and those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (c. 46). 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.

(**b**) S.I. 1998/1376.

(**c**) OJ No. L310, 4.12.1999, p.41.

(**d**) OJ No. L249, 4.10.2000, p.26.

(iii) being a product obtained by bacterial fermentation, it does not comply with regulation 5A; or

(iv) it does not comply with regulation 4(5), 5(4) or 7,

and no defence indicated in regulation 4(7), 5(2) or 7(5) would be available in proceedings for an offence under these Regulations relating to that manufacture or want of compliance; or";

5. In regulation 4 (restriction on manufacture with monomers)—

(a) in paragraph (1)(c), for the words "restrictions (if any) specified" there shall be substituted the words "restrictions and specifications (if any) set out"; and

(b) paragraph (3)(d) shall be deleted.

6. 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 plastic materials or articles any prohibited additive, that is to say an additive identified by PM/REF No., CAS No. (if any) and name respectively in columns 1, 2 and 3 of Part 1 of Schedule 2 which—

(a) is not of good technical quality, or

(b) is not used in accordance with the restrictions and specifications (if any) set out in the corresponding entry in column 4 of the relevant section of that Part of that Schedule."; and

(b) there shall be inserted at the end the following paragraphs—

"(4) Subject to paragraph (5) of this regulation, where column 4 of Part I of Schedule 2 expresses a migration limit of mg/kg in relation to any additive, no plastic material or article manufactured containing that additive shall be capable of transferring constituents of that additive to food with which that plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is—

(a) the number of milligrams expressed therein released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b) below; and

(b) one sixth of the number of milligrams expressed therein per square decimetre of surface area of the plastic material or article if the plastic material or article comprises—

(i) an article which is a container or is comparable to a container or which can be filled, with a capacity of less than 500 millilitres or more than 10 litres, or

(ii) sheet, film or other material which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of that material and the quantity of food in contact with that surface area.

(5) A plastic material or article manufactured containing an additive in respect of which column 4 of Part I of Schedule 2 expresses a migration limit of mg/kg shall not be considered capable of transferring constituents of that additive to food with which that plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (4) of this regulation if the only food which that plastic material or article may come into contact with is food to which regulation 7(3) applies.".

7. After regulation 5 there shall be inserted the following regulation—

"Products obtained by bacterial fermentation

5A. A product obtained by bacterial fermentation complies with this regulation if it is—

(a) of good technical quality;

(b) identified by PM/REF No., CAS No. and name respectively in columns 1, 2 and 3 of Schedule 2A; and

(c) in compliance with the restrictions and specifications set out in column 4 of that Schedule.".

8. After regulation 7 (transfer of constituents) there shall be inserted the following regulation—

"Specifications

7A. Schedule 2B shall have effect for the purpose of giving the specifications referred to in column 4 in Schedule 1, 2 and 2A.".

9. In regulation 10 (offences) the following paragraph shall be inserted at the end—

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

(a) the act was committed in relation to a plastic material or article intended to come into contact with food which was manufactured in the European Community, or imported into the European Community, before 1st January 2003, and

(b) the matters constituting the offence would not have constituted an offence under these Regulations before the amendments made by the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2000 came into force.".

10. In Schedule 1 (monomers)—

(a) in Part I, in Section A in column 4, for the heading "Restrictions" there shall be substituted "Restrictions and specifications";

(b) the item number and letter, PM/REF No., CAS No., name, restriction and specification (if any) for each monomer identified in Part I of Schedule 1 to these Regulations shall be inserted in Section A of Part I of Schedule 1 to the principal Regulations at the place corresponding to the number and letter (if any) specified for that monomer in the column headed "item" in that Part of that Schedule to these Regulations;

(c) in Part I, in Section A, for the entries in column 4 (restrictions and specifications) opposite to and corresponding to the items listed in Part II of Schedulue 1 to these Regulations there shall be substituted the corresponding entries specified in the said Part II;

(d) in Part I, in Section A, in item 196 the entry in column 4 (restrictions and specifications) shall be deleted;

(e) in Part I, in Section B, item 67 and the entries for it shall be deleted;

(f) in Part I, in Section B, for the entries in column 4 (restrictions) opposite to and corresponding to the items listed in Part III of Schedule 1 to these Regulations there shall be substituted the corresponding entries specified in Part III of Schedule 1 to these Regulations;

(g) in Part I, in Section B, after the entries relating to item 77 there shall be inserted the item number and letter, PM/REF No., CAS No., name and restriction for the monomer identified in Part IV of Schedule 1 to these Regulations;

(h) in Part I, the items in Section B which are listed in Part V of Schedule 1 to these Regulations, and the entries for those items in that Section, shall be deleted and there shall be inserted in Section A at the place corresponding to the number and letter (if any) specified for each item in the column headed "Item No. for Section A" in Part V of Schedule 1 to these Regulations the entries relating to that item in the said Part V; and

(i) in Part II there shall be inserted at the end the following paragraph—

"4. Where an entry in column 4 in Part I of this Schedule includes a bracketed number, that entry shall be subject to the note relating to that number as follows:

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

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

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

(4) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 19540, 19960.

(5) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 14200, 14230.

(9) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances;

(a) Badge (= 2,2 − bis(4 − hydroxyphenyl)propane bis(2,3 − epoxypropyl) ether

(b) Badge.H_2O

(d) Badge.HCi

(e) Badge.2HCi

(f) Badge.H_2O.HCi

However in aqueous food simulants, the SML (T) shall also include Badge.$2H_2O$(c) unless the material or article is labelled for use in contact only with those foods and beverages for which it has been demonstrated that the sum of the migration levels of the five above mentioned substances (a)(b)(d)(e)(f) cannot exceed 1 mg/kg.".

11. In Schedule 2 (additives)—

(a) in Part I there shall be inserted an extra column, numbered "4" and headed "Restrictions and specifications";

(b) the item number and letter, PM/REF No., CAS No., name, restriction and specification (if any) for each additive identified in Schedule 2 to these Regulations shall be inserted in Part I of Schedule 2 to the principal Regulations at the place corresponding to the number and letter specified for that additive in the column headed "Item" in Schedule 2 to these Regulations;

(c) in Part I, for the entries in column 2 (CAS No.) and column 3 (name) for item 38 there shall be substituted the following—

"087826–41–3	Bis(methylbenzylidene) sorbitol		
069158–41–4	″	″	″
054686–97–4	″	″	″
081541–12–0	″	″	″ ″;

(d) in Part I, for the entry in column 2 (CAS No.) for item 179 there shall be substituted the entry "037244–96–5";

(e) in Part I, item 195 and the entries for it shall be deleted; and

(f) in Part II, there shall be inserted at the end the following paragraph—

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

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

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

(6) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF/Nos: 66560 and 66580.

(7) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200, 92030.

(8) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 85840 and 95725.

(10) Warning: there is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then that the finished product does not comply with regulation 4(2) of the Materials and Articles in Contact with Food Regulations 1987(**a**).".

12. After Schedule 2 there shall be inserted as Schedules 2A and 2B the contents of Schedules 3 and 4 to these Regulations.

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

(a) in paragraph 4(3) and (4), for "regulation 7 or Schedule 1" in each case there shall be substituted "regulation 7, Schedule 1 or Schedule 2"; and

(b) in paragraph 7(2)(c) for "M_1 and M_2" there shall be substituted "M_2 and M_3".

Signed by authority of the Secretary of State for Health.

Gisela Stuart
Parliamentary Under-Secretary of State,
Department of Health

28th November 2000

(**a**) S.I. 1987/1523, to which there are amendments not relevant to these Regulations.

SCHEDULE 1

Regulation 10

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*
28A	12761	000693-57-2	12-Aminododecanoic acid	The specific migration of this substance shall not exceed 0.05 mg/kg
35A	13180	000498-66-8	Bicyclo [2.2.1] hept-2-ene (= norbornene)	The specific migration of this substance shall not exceed 0.05 mg/kg
35B	13210	001761-71-3	Bis(4-aminocyclohexyl)methane	The specific migration of this substance shall not exceed 0.05 mg/kg
63A	14650	000079-38-9	Chlorotrifluoroethylene	The quantity of this substance in the finished plastic material or article shall not exceed 0.05mg/6 dm^2
68A	14841	000599-64-4	4-Cumylphenol	The specific migration of this substance shall not exceed 0.05 mg/kg
93A	16694	013811-50-2	N,N'-Divinyl-2-imidazolidinone	The quanitity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
93B	16704	000112-41-4	1-Dodecene	The specific migration of this substance shall not exceed 0.05 mg/kg
147A	22331	025513-64-8	Mixture of (40% w/w) 1,6-diamino-2,2,4-trimethylhexane and (60% w/w) 1,6-diamino-2,4,4-trimethylhexane	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/6dm^2
152A	22550	000498-66-8	Norbornene	The specific migration of this substance shall not exceed 0.05 mg/kg
163A	23175	000122-52-1	Phosphorous acid, triethyl ester	The quantity of this substance in the finished plastic material or article shall be not detectable (when measured by a method with a detection limit of 1 mg/kg)
169A	23547	009016-00-6 063148-62-9	Polydimethylsiloxane (MW > 6800)	In compliance with the specifications laid down in Schedule 2B
206A	25080	001120-36-1	1-Tetradecene	The specific migration of this substance shall not exceed 0.05 mg/kg
214A	25385	000102-70-5	Triallylamine	In compliance with the specifications laid down in Schedule 2B
218A	25927	027955-94-8	1,1,1-Tris(4-hydroxyphenyl)ethane	The quantity of this substance in the finished plastic material or article shall not exceed 0.5 mg/kg. For use only in polycarbonates
223	26155	001072-63-5	1-Vinylimidazole	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
225	26320	002768-02-7	Vinyltrimethoxysilane	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
226	26360	007732-18-5	Water	In compliance with Directive 98/83/EC on the quality of water intended for human consumption(**a**)

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

PART II

LIST OF MONOMERS IN SECTION A Of PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS FOR WHICH THE CONTENT OF THE COLUMN "RESTRICTIONS AND SPECIFICATIONS" IS MODIFIED

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
2	10060	000075-07-0	Acetaldehyde	SML(T) = 6mg/kg (2)
40	13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (=BADGE)	SML(T) = 1 mg/kg (9) Authorised only until 1st January 2005
56	14200	000105-60-2	Caprolactam	SML(T) = 15 mg/kg (5)
57	14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg (5) (expressed as caprolactam)
79	15760	000111–46–6	Diethyleneglycol	SML(T) = 30 mg/kg (3)
98	16990	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg (3)
102	17160	000097-53-0	Eugenol	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
128	19540	000110-16-7	Maleic acid	SML(T) = 30 mg/kg (4)
129	19960	000108-31-6	Maleic anhydride	SML(T) = 30 mg/kg (4) (expressed as maleic acid)
214	25360	—	Trialkyl(C5-C15) acetic acid, 2,3-epoxypropyl ester	The quanitity of this substance in the finished plastic material or article shall not exceed 1 mg/kg (expressed as epoxy group, molecular weight = 43)

PART III

LIST OF MONOMERS IN SECTION B OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS FOR WHICH THE CONTENT OF THE COLUMN "RESTRICTIONS" IS MODIFIED

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions*
34	16690	001321-74-0	Divinylbenzene	The quantity of this material in the finished plastic material or article shall not exceed 1 mg/kg or the specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
56	20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	The quantity of this material in the finished plastic material or article shall not exceed 5 mg/kg (expressed as epoxy group, molecular weight = 43)
68	22720	000140-66-9	4-tert-Octylphenol	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 mg/kg, analytical tolerance included)

PART IV

MONOMER TO BE ADDED TO SECTION B OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions*
77A	25185	000140-66-9	4-(1,1,3,3-Tetramethylbutyl) phenol (= 4-tert-octylphenol)	As item 68

PART V

LIST OF MONOMERS TRANSFERRED FROM SECTION B TO SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS

Item No. in Section B	*Item No. for Section A*	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
5	13A	11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 dm^2
6	13B	11245	002156-97-0	Acrylic acid, dodecyl ester	The specific migration of this substance shall not exceed 0.05 mg/kg (1)
9	23A	12265	004074-90-2	Adipic acid, divinyl ester	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg. For use only as comonomer
12	33A	13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 dm^2 (measured as 1,3,5-benzenetricarboxylic acid)
16	49A	13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg (expressed as epoxy group, molecular weight equal to 43)
19	52A	14020	000098-54-4	4-tert-Butylphenol	The specific migration of this substance shall not exceed 0.05 mg/kg
22	73A	15130	000872-05-9	1-Decene	The specific migration of this substance shall not exceed 0.05mg/kg
30	88A	16360	000576-26-1	2,6-Dimethylphenol	The specific migration of this substance shall not exceed 0.05 mg/kg
32	88b	16450	000646-06-0	1,3-Dioxolane	The specific migration of this substance shall not exceed 0.05 mg/kg
37	111A	18220	068564-88-5	N-Heptylaminoundecanoic acid	The specific migration of this substance shall not exceed 0.05 mg/kg (1)
41	118A	18820	000592-41-6	1-Hexene	The specific migration of this substance shall not exceed 3 mg/kg
42	121A	19060	000109-53-5	Isobutyl vinyl ether	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg

Item No. in Section B	*Item No. for Section A*	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
43	121B	19150	000121-91-5	Isophthalic acid	The specific migration of this substance shall not exceed 5 mg/kg
49	130A	19990	000079-39-0	Methacrylamide	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
50	131A	20050	000096-05-9	Methacrylic acid, allyl ester	The specific migration of this substance shall not exceed 0.05 mg/kg
55	135A	20530	002867-47-2	Methacrylic acid, 2-(dimethylamino)ethyl ester	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
61	145A	21730	000563-45-1	3-Methyl-1-butene	The quantity of this substance in the finished plastic material or article shall not exceed 0.006 mg/6 dm^2. For use only in polypropylene
70	159A	22937	001623-05-8	Perfluoropropyl perfluorovinyl ether	The specific migration of this substance shall not exceed 0.05 mg/kg
71	173A	23770	000504-63-2	1,3-Propanediol	The specific migration of this substance shall not exceed 0.05 mg/kg
72	177A	23920	000105-38-4	Propionic acid, vinyl ester	SML(T) = 6 mg/kg (2) (expressed as acetaldehyde)
74	198A	24760	026914-43-2	Styrenesulphonic acid	The specific migration of this substance shall not exceed 0.05 mg/kg
83	224	26170	003195-78-6	N-Vinyl-N-methylacetamide	The quantity of this substance in the finished plastic material or article shall not exceed 2 mg/kg

SCHEDULE 2

Regulation 11

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

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
2A	30080	004180-12-5	Acetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
7A	30610	—	Acids C2-C24 aliphatic, linear monocarboxylic, from natural oils and fats and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	
7B	30612	—	Acids C2-C24 aliphatic linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
9A	31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1(3,5-di-tert-pentyl-2-hydroxyphenyl) ethyl] phenyl ester	The specific migraton of this substance shall not exceed 5 mg/kg
12A	33801	—	n-Alkyl (C10-C13) benzenesulphonic acid	The specific migration of this substance shall not exceed 30 mg/kg
12B	34240	—	Alkyl(C10-C20) sulphonic acid, esters with phenols	The specific migration of this substance shall not exceed 6 mg/kg. Authorised only until 1st January 2002
27A	36640	000123-77-3	Azodicarbonamide	For use only as a blowing agent
31A	37360	000100-52-7	Benzaldehyde	(10)
36A	38320	005242-49-9	4-(2-benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl) stilbene	In compliance with the specifications laid down in Schedule 2B
36B	38510	136504-96-6	1,2-Bis(3-aminopropyl) ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	The specific migration of this substance shall not exceed 5 mg/kg
36C	38515	001533-45-5	4,4'-Bis(2-benzoxazolyl)stilbene	The specific migration of this substance shall not exceed 0.05 mg/kg (1)
36D	38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl) pentaerythritol diphosphite	The specific migration of this substance shall not exceed 5 mg/kg (sum of phosphite and phosphate)
36E	38879	135861-56-2	Bis(3,4-dimethylbenzylidene) sorbitol	
37A	39200	006200-40-4	Bis (2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy) methylammonium chloride	The specific migration of this substance shall not exceed 1.8 mg/kg
37B	39815	182121-12-6	9, 9 bis(methoxymethyl) fluorene	The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 dm^2
38A	40120	–	Bis(polyethyleneglycol) hydroxymethylphosphonate	The specific migration of this substance shall not exceed 0.6 mg/kg. Authorised only until 1st January 2002
44A	41680	000076-22-2	Camphor	(10)
47A	42320	007492-68-4	Carbonic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
57A	43515	–	Chlorides of choline esters of coconut oil fatty acids	The quantity of this substance in the finished plastic material or article shall not exceed 0.9 mg/6 dm^2
59A	45195	007787-70-4	Copper bromide	SML(T) = 30 mg/kg (7) (expressed as copper)
59B	45200	001335-23-5	Copper iodide	SML(T) = 30 mg/kg (7) (expressed as copper) and the specific migration of this substance shall not exceed 1 mg/kg (expressed as iodine)
60A	45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	The specific migration of this substance shall not exceed 0.05 mg/kg (1)
72A	46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzyl phosphonic acid, monoethyl ester, calcium salt	The specific migration of this substance shall not exceed 6 mg/kg
73A	47680	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg (3)

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
73B	48460	000075-37-6	1,1-Difluoroethane	
73C	49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)phenol	The specific migration of this substance shall not exceed 1 mg/kg
75A	51700	147315-50-2	2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5- (hexyloxy) phenol	The specific migration of this substance shall not exceed 0.05 mg/kg
86A	53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
86B	53650	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg (3)
90A	54300	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butyl-phenyl) fluorophosphonite	The specific migration of this substance shall not exceed 6 mg/kg
92A	54930	025359-91-5	Formaldehyde-1-naphthol, copolymer [= Poly (1-hydroxynaphthyl-methane)]	The specific migration of this substance shall not exceed 0.05 mg/kg
125A	57800	018641-57-1	Glycerol tribehenate	
140A	60480	003864-99-1	2-(2-Hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole	The specific migration of this substance shall not exceed 30 mg/kg
169A	66560	004066-02-8	2,2'-Methylenebis (4-methyl-6-cyclohexylphenol)	SML(T) = 3 mg/kg (6)
169B	66580	000077-62-3	2,2'-Methylenebis [4-methyl-6-(1-methylcyclo-hexyl) phenol]	SML(T) = 3 mg/kg (6)
172A	66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
173A	67170	–	Mixture of (80 to 100% w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and (0-20% w/w) 5,7-di-tert-butyl-3-(2,3-di-methylphenyl)-2(3H)-benzofuranone	The specific migration of this substance shall not exceed 5 mg/kg
173B	67180	–	Mixture of (50% w/w) phthalic acid n-decyl n-octyl ester, (25% w/w) phthalic acid di-n-decyl ester, and (25% w/w) phthalic acid di-n-octyl ester	The specific migration of this substance shall not exceed 5 mg/kg (1)
179A	68145	080410-33-9	2,2',2"-Nitrilo[triethyl tris(3,3',5,5'-tetra-tert-butyl-1-1'-bi-phenyl-2,2'-diyl) phosphite]	The specific migration of this substance shall not exceed 5 mg/kg (sum of phosphite and phosphate)
188A	71635	025151-96-6	Pentaerythritol dioleate	The specific migration of this substance shall not exceed 0.05 mg/kg. Not for use with foods for which simulant D is laid down in Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs(**a**)

(**a**) OJ No. L372, 31.12.85, p.14.

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
191A	73720	0000115-96-8	Phosphoric acid, trichloroethyl ester	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
191B	74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester	The specific migration of this substance shall not exceed 5 mg/kg (covering the sum of phosphite and phosphate)
195A	76721	009016-00-6 063148-62-9	Polydimethylsiloxane (mw > 6800)	In compliance with the specifications laid down in Schedule 2B
195B	76865	–	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	The specific migration of this substance shall not exceed 30 mg/kg
198A	77895	068439-49-6	Polyethy leneglycol (EO = 2-6) monoalkyl (C16-C18) ether	The specific migration of this substance shall not exceed 0.05 mg/kg
208A	81515	087189-25-1	Poly(zinc glycerolate)	
210A	81760	–	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 30 mg/kg (7) (expressed as copper); the specific migration of this substance shall not exceed 48 mg/kg (expressed as iron)
239A	85360	000109-43-3	Sebacic acid, dibutyl ester	
240A	85610	–	Silicates, natural, silanated (with the exception of asbestos)	
240B	85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
244A	86285	–	Silicon dioxide, silanated	
259A	88640	008013-07-8	Soybean oil, epoxidized	In compliance with the specifications laid down in Schedule 2B
263A	89200	007617-31-4	Stearic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
263B	89440	–	Stearic acid, esters with ethyleneglycol	SML(T) = 30 mg/kg (3)
270A	92030	010124-44-4	Sulphuric acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
276A	92700	078301-43-6	2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	The specific migration of this substance shall not exceed 5 mg/kg
276B	92930	120218-34-0	Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropri-dine-3-carboxylate)	The specific migration of this substance shall not exceed 6 mg/kg
280A	94960	000077-99-6	1,1,1-Trimethylolpropane	The specific migration of this substance shall not exceed 6 mg/kg
281A	95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
281B	95855	007732-18-5	Water	In compliance with Directive 98/83/EC
281C	95859	–	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	In compliance with the specifications laid down in Schedule 2B
281D	95883	–	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifications laid down in Schedule 2B

SCHEDULE 3

Regulation 12

"SCHEDULE 2A

Regulation 5A

PRODUCTS OBTAINED BY BACTERIAL FERMENTATION

Item	*PM/REF No.*	*CAS No.*	*Name*	*Restrictions and specifications*
1	18888	80181-31-3	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	The specific migration of this substance shall not exceed 0.05 mg/kg for crotonic acid (as impurity), and in compliance with the specifications laid down in Schedule 2B

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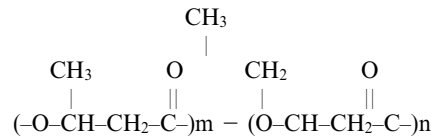
SCHEDULE 4

Regulations 8 and 12

"SCHEDULE 2B

Regulation 7A

SPECIFICATIONS

Item	*PM/REF No.*	*Specifications*	
1	18888	3-HYDROXYBUTANOIC ACID-3-HYDROXYPENTANOIC ACID, COPOLYMER	
		Definition	These copolymers are produced by the controlled fermentation of *Alcaligenes eutrophus* using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism *Alcaligenes eutrophus* strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications.
		Chemical name	Poly (3-D-hydroxybutanoato-co-3-D-hydroxypentanoate).
		CAS number	80181-31-3.
		Structural formula	 where n/(m + n) greater than 0 and less or equal to 0.25
		Average molecular weight	Not less than 150,000 Daltons (measured by gel permeation chromatography).
		Assay	Not less than 98% poly (3-D- hydroxybutanoato-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids.
		Description	White to off-white powder after isolation.
		Characteristics Identification tests:	
		Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water.
		Migration	The migration of crotonic acid should not exceed 0.05 mg/kg food.

Item	*PM/REF No.*	*Specifications*
		Purity — Prior to granulation the raw material copolymer powder must contain: – Nitrogen — Not more than 2,500 mg/kg of plastic – Zinc — Not more than 100 mg/kg of plastic – Copper — Not more than 5 mg/kg of plastic – Lead — Not more than 2 mg/kg of plastic – Arsenic — Not more than 1 mg/kg of plastic – Chromium — Not more than 1 mg/kg of plastic
2	23547	POLYDIMETHYLSILOXANE (MW > 6800) Minimum viscosity 100 centistokes at 25°C
3	25385	TRIALLYLAMINE 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1.5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use.
4	38320	4–(2–BENZOXAZOLYL)–4'–(5-METHYL–2–BENZOXAZOLYL) STILBENE Not more than 0.05% w/w (quantity of substance used/quantity of the formulation)
5	76721	POLYDIMETHYLSILOXANE (Mw > 6800) Minimum viscosity 100 × 10^{-6} m^2/s (= 100 centistokes) at 25°C
6	88640	SOYBEAN OIL, EPOXIDIZED Oxirane < 8%, iodine number < 6
7	95859	WAXES, REFINED DERIVED FROM PETROLEUM BASED OR SYNTHETIC HYDROCARBON FEEDSTOCKS The product shall have the following specifications: — Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w) — Viscosity not less than 11 × 10^{-6} m^2/s (= 11 centistokes) at 100°C — Average molecular weight not less than 500
8	95883	WHITE MINERAL OILS, PARAFFINIC DERIVED FROM PETROLEUM BASED HYDROCARBON FEEDSTOCKS The product shall have the following specifications: — Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w) — Viscosity not less than 8.5 × 10^{-6} m^2/s (= 8.5 centistokes) at 100°C — Average molecular weight not less than 480

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EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations amend, for England, the Plastic Materials and Articles in Contact with Food Regulations 1998 ("the 1998 Regulations"), which apply to Great Britain. These Regulations implement Commission Directive 1999/91/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs.

2. These Regulations—

(a) update the lists of monomers and additives which can be used in the manufacture of plastic materials and articles intended to come into contact with food (regulations 10 and 11 and Schedules 1 and 2);

(b) impose restrictions and specifications in respect of some of those monomers and additives (regulations 5(a), 6, 8, 10, 11 and 12 and Schedules 1, 2 and 4); in particular, a new type of restriction is introduced (maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm^2 of the surface in contact with food);

(c) bring products obtained by bacterial fermentation within the scope of the 1998 Regulations and impose restrictions and specifications for such products (regulations 4, 5(b), 7 and 12 and Schedule 3);

(d) include a transitional provision (regulation 9); and

(e) make some consequential amendments (regulations 3 and 13(a)) and correct two errors in the 1998 Regulations (regulations 10(d) and 13(b)).

3. A regulatory impact assessment, which includes a compliance cost assessment of the effect which these Regulations have on business costs, has been prepared and placed in the Library of each House of Parliament. Copies may be obtained from Branch 4 of the Chemical Safety and Toxicology Division of the Food Standards Agency, Ergon House, P.O. Box 31037, Horseferry Road, London SW1P 3WG.

STATUTORY INSTRUMENTS

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