SCOTTISH STATUTORY INSTRUMENTS

2005 No.92

FOOD

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

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

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

Citation, commencement and extent

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

(2) These Regulations extend to Scotland only.

Amendments to the Plastic Materials and Articles in Contact with Food Regulations 1998

2. The Plastic Materials and Articles in Contact with Food Regulations 1998(**3**) ("the principal Regulations") are amended in accordance with regulations 3 to 16 of these Regulations.

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

(a) for the definition of "additive" substitute–

> ""additive" means a substance as defined in paragraph 1 of the general introduction to Annex III to the Directive as read with paragraph 3 of article 4 of the Directive;";

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

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

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

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

""Council Directive 88/388" means Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production(**4**) as corrected by a corrigendum dated 14th December 1988(**5**) and as amended by Commission Directive 91/71(**6**);

"Council Directive 89/107" means Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised in foodstuffs intended for human consumption(**7**) as amended by European Parliament and Council Directive 94/34(**8**);";

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

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

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

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

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

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

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

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

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

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

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

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

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

"(e) any food additive authorised by Council Directive 89/107 or any flavouring authorised by Council Directive 88/388 that migrates into food–

(i) in a quantity that has a technicological function in the final food product; or

(ii) where the food is of a type for which the use of any such food additive or flavouring is so authorised, in quantities exceeding the limits provided for that additive or flavouring in Council Directive 89/107 or Council Directive 88/388 as appropriate, or in Schedule 2 to these Regulations, whichever is the lower;

(b) in paragraph (4)(b)(ii) after "material" wherever it appears, insert "or article"."

6. After regulation 5A insert–

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

5B.—(1) This regulation applies to any person who wishes to make an application for the inclusion of an eligible additive in the Community list referred to in Article 4 of the Directive.

(2) An application mentioned in paragraph (1) including supporting data must be made to EFSA before 1st January 2007.

(3) If, during examination of the data referred to in paragraph (2), EFSA calls for supplementary information, the eligible additive may, if otherwise lawful, continue to be so used until EFSA has issued an opinion, provided such information is submitted within the time limits specified by EFSA.

(4) For the purposes of this regulation an eligible additive is one whose use is permitted in one or more Member States before 1st January 2007.".

7. For regulation 8 (labelling) substitute–

"**8.** At marketing stages other than the retail stage a person who is in possession of any plastic material or article intended to come into contact with food shall ensure that the plastic material or article is accompanied by a written declaration which–

(a) attests that it complies with the legislation applicable to it; and

(b) provides, in respect of substances that are subject to a restriction on quantities migrating into food, information obtained from experimental data or theoretical calculation concerning–

(i) the levels of migration specific to those substances;

(ii) where appropriate, purity criteria in accordance with the purity Directives

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

8. In regulation 10 (offences)–

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

(b) after paragraph (24) insert–

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

(a) the act constituting the offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st March 2006; and

(b) the act constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by the Plastic Materials and Articles in Contact with Food Amendment (Scotland) Regulations 2005 had not been in force at the time that act occurred.".

9. In Schedule 1, Part I–

(a) in Section A (monomers authorised without time limit)–

(i) insert in the appropriate numerical order the entries set out in Schedule 1 to these Regulations;

(ii) for items 15A, 39, 70, 120B, 147, 147A, 147B and 188 substitute the entries set out in Schedule 2 to these Regulations; and

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

(b) omit Sections B and C.

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

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

(b) after note (25) insert–

"(26) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(27) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.

(28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.

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

(32) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600."

11. In Schedule 2, Part I (incomplete list of additives used in the manufacture of plastic materials and articles)–

(a) insert in appropriate numerical order the entries set out in Schedule 3 to these Regulations;

(b) for items 60A and 198A substitute the entries set out in Schedule 4 to these Regulations;

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

12. In Schedule 2, Part II (incomplete list of additives used in the manufacture of plastic materials and articles being additives to which paragraph 5 of Part III of Schedule 2 applies) —

(a) insert in appropriate numerical order the entries set out in Schedule 5 to these Regulations;

(b) delete items 28, 80 and 111A and their corresponding entries.

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

(a) in paragraph 4–

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

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

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

(iv) after note (24) add–

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

(26) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(27) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.

(28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.

(29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 86480, 86960 and 87120.

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

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

(32) QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.

(33) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 55200, 55280 and 55360.";

(b) in paragraph 5 for "1st January 2004" substitute "1st July 2006".

14. In Schedule 2A (products obtained by bacterial fermentation)–

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

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

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

15. For Schedule 2B (specifications) substitute the contents of Schedule 6 to these Regulations.

16. For paragraph 4(b) of Part I (basic rules) of Schedule 4 (overall and specific migration testing using food simulants) substitute–

"(b) omit the migration, the substitute or the alternative tests where–

(i) there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article, or

(ii) the conditions for non–compulsory testing set out in article 8.2 or 8.3 of the Directive are met.".

St Andrew's House, Edinburgh
1st March 2005

RHONA BRANKIN
Authorised to sign by the Scottish Ministers

SCHEDULE 1 Regulation 9(a)(ii)

(ENTRIES TO BE INSERTED IN SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS)

Item	"1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
6A	10599/90A	061788–89–4	Acids, fatty, unsaturated (C_{18}), dimers, distilled	QMA(T) = 0.05 mg/6 dm^2 (26)
6B	10599/91	061788–89–4	Acids, fatty, unsaturated (C_{18}), dimers, non distilled	QMA(T) = 0.05 mg/6 dm^2 (26)
6C	10599/92A	068783–41–5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled	QMA(T) = 0.05 mg/6 dm^2 (26)
6D	10599/93	068783–41–5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, non distilled	QMA(T) = 0.05 mg/6 dm^2 (26)
37A	13323	000102–40–9	1,3-Bis(2-hydroxyethoxy) benzene	SML = 0.05 mg/kg
68MA	14800	003724–65–0	Crotonic acid	QMA(T) = 0.05 mg/6 dm^2 (32)
87A	16210	006864–37–5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	SML = 0.05 mg/kg ([31]). To be used only in polyamides.
89A	16540	000102–09–0	Diphenyl carbonate	SML = 0.05 mg/kg
101A	17110	016219–75–3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	QMA = 0.05 mg/6 dm^2. The ratio surface / quantity of food shall be lower than 2 dm^2/kg
118MA	18700	000629–11–8	1,6-Hexanediol	SML = 0.05 mg/kg

Item	“1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
120ZA	18896	001679–51–2	4&-(Hydroxymethyl)-1-cyclohexene	SML = 0.05 mg/kg
135BM	20440	000097–90–5	Methacrylic acid, diester with ethyleneglycol	SML = 0.05 mg/kg
142A	21400	054276–35–6	Methacrylic acid, sulphopropyl ester	QMA = 0.05 mg/6 dm^2
156XA	22775	000144–62–7	Oxalic acid	SML(T) = 6 mg/kg[28]
161A	23070	000102–39–6	(1,3-Phenylenedioxy)diacetic acid	QMA = 0.05 mg/6 dm^2”

SCHEDULE 2

Regulation 9(a)(ii)

(ENTRIES TO BE SUBSTITUTED FOR ENTRIES IN SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS)

Item	“1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
15A	11530	00999–61–1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0.05 mg/6 dm^2 for the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester and in compliance with the specifications laid down in Schedule 2B
39	13480	000080–05–7	2,2-Bis(4-hydroxyphenyl) propane	SML(T) = 0.6 mg/kg [27]
70	14950	003173–53–3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg in FP (expressed as NCO) [25]

Item	"1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
120B	18898	000103–90–2	N-(4-Hydroxyphenyl) acetamide	SML = 0.05 mg/kg
147	22150	000691–37–2	4-Methyl-1-pentene	SML = 0.05 mg/kg
147A	22331	025513–64–8	Mixture of (35–45% w/w) 1,6-diamino-2,2,4-trimethylhexane and (55–65% w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm^2
147B	22332	—	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)
188	24190	065997–05–9	Rosin Wood"	

SCHEDULE 3

Regulation 11(a)

(ENTRIES TO BE INSERTED IN PART I OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS)

Item	"1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
18A	34850	143925–92–2	Amines, bis(hydrogenated tallow alkyl) oxidised	QM = For use only: (a) in polyolefines at 0.1% (w/w) but not in LDPE when it is in contact with foods for which the Directive 85/572/EEC establishes a reduction

Item	"1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
				factor less than 3; (b) in PET at 0.25% (w/w) in contact with foods other of those for which the simulant D is laid down in Directive 85/572/EEC
18B	34895	000088–68–6	2-Aminobenzamide	SML = 0.05 mg/kg. To be used only for PET for water and beverages
37AA	39680	000080–05–7	2,2-Bis(4-hydroxyphenyl) propane	SML(T) = 0.6 mg/kg [27]
51A	42880	008001–79–4	Castor oil	
61A	45600	003724–65–0	Crotonic acid	QMA(T) = 0.05 mg/6 dm^2 [32]
61B	45640	005232–99–5	2-Cyano-3,3-dipheneylacrylic acid, ethyl ester	SML = 0.05 mg/kg
69A	46700	—	5,7-di-tert-Butyl-3-(3,4- and 2,3-di-methylphenyl)-3H-benzofuran-2-one containing: (a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80–100% w/w); and (b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-	SML = 5 mg/kg

Item	"1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
			one (0–20% w/w)	
69B	46720	004130–42–1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4.8 mg/6 dm^2
109A	56535	—	Glycerol, esters with nonanoic acid	
131A	59280	000100–97–0	Hexamethylenetetramine	SML(T) = 15 mg/kg ([21]) (expressed as Formaldehyde)
178A	68078	027253–31–2	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 Directive 85/572/EEC
182A	69920	000144–62–7	Oxalic acid	SML(T) = 6 mg/kg [(28)]
195D	76866	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C_{12}–C_{18} or n-octanol and / or n-decanol	SML = 30 mg/kg
240ZA	85601	—	Silicates, natural (with the exception of asbestos)	
280B	95000	028931–67–1	Trimethylolpropane trimethacrylatemethyl	

Item	“1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
			methacrylate copolymer”	

SCHEDULE 4

Regulation 11(b)

(ENTRIES TO BE SUBSTITUTED FOR ENTRIES IN PART I OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS)

Item	“1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
60A	45450	068610–51–5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 5 mg/kg
198A	77895	068439–49–6	Polyethyleneglycol (EO = 2–6) monoalkyl (C_{16}–C_{18}) ether	SML = 0.05 mg/kg and in compliance with the specifications laid down in Schedule 2B”

SCHEDULE 5

Regulation 12(a)

(ENTRIES TO BE INSERTED IN PART II OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS

Item	“1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
4A	34650	151841–65–5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phospate	SML = 5 mg/kg
7A	38000	000553–54–8	Benzoic acid, lithium salt	SML(T) = 0.6 mg/kg [8] (expressed as Lithium)

Item	"1 *PM/REF No.*	2 *CAS No.*	3 *Name*	4 *Restrictions and specifications*
18A	40720	025013–16–5	tert-Butyl-4-hydroxyanisole (= BHA)	SML = 30 mg/kg
27B	46640	000128–37–0	2,6-Di-tert-butyl-p-cresol (= BHT)	SML = 3.0 mg/kg
54A	54880	000050–00–0	Formaldehyde	SML(T) = 15 mg/kg ([21])
54B	55200	001166–52–5	Gallic acid, dodecyl ester	SML(T) = 30 mg/kg [33]
54C	55280	001034–01–1	Gallic acid, octyl ester	SML(T) = 30 mg/kg [33]
54D	55360	000121–79–9	Gallic acid, propyl ester	SML(T) = 30 mg/kg [33]
79A	67896	020336–96–3	Myristic acid, lithium salt	SML(T) = 0.6 mg/kg [8] (expressed as Lithium)
83A	71935	007601–89–0	Perchloric acid, sodium salt monohydrate	SML 0.0 5 mg/kg [30]
88A	76680	068132–00–3	Polycyclopentadiene, hydrogenated	SML = 5 mg/kg [1]
100A	86480	007631–90–5	Sodium bisulphite	SML(T) = 10 mg/kg [29] (expressed as $S0_2$)
102A	86920	007632–00–0	Sodium nitrite	SML = 0.6 mg/kg
102B	86960	007757–83–7	Sodium sulphite	SML(T) = 10 mg/kg [29] (expressed as $S0_2$)
102C	87120	007772–98–7	Sodium thiosulphate	SML(T) = 10 mg/kg [29] (expressed as $S0_2$)
110A	94400	036443–68–2	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	SML = 9 mg/kg"

SCHEDULE 6 Regulation 15

(SUBSTITUTE FOR SCHEDULE 2B TO THE PRINCIPAL REGULATIONS)

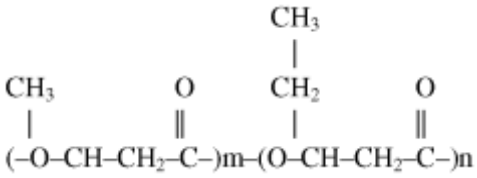
"SCHEDULE 2B Regulation 7A

SPECIFICATIONS

Item	1 *PM/REF No.*	2 *Specifications*	
1	11530	Acrylic acid, 2-hydroxypropyl ester. It may contain up to 25% (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No. 002918–23–2)	
2	16690	Divinylbenzene It may contain up to 45% (m/m) of Ethylvinylbenzene	
3	18888	3-Hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	
		Definition	The 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

Note:–

(*) Quantity of substance used/quantity of formulation.

Item	1 *PM/REF No.*	2 *Specifications*	
			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-hydroxybutanoate-co–3-D-hydroxypentanoate)
		CAS number	080181–31–3
		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-

Note:–

(*) Quantity of substance used/quantity of formulation.

Item	1 *PM/REF No.*	2 *Specifications*	
			hydroxybutanoate-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 a chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water
		Restriction	QMA for crotonic acid is 0.05 mg/6 dm^2
		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
4	23547	Polydimethylsiloxane (Mw > 6800)	

Note:–

(*) Quantity of substance used/quantity of formulation.

Item	1 *PM/REF No.*	2 *Specifications*
		Minimum viscosity 100×10^{-6} m^2/s (= 100 centistokes) at 25°C
5	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.
6	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)
7	43680	Chlorodifluoromethane Content of chlorofluoromethane less than 1 mg/kg of the substance
8	47210	Dibutylthiostannoic acid polymer Molecular unit = $(C_8H_{18}S_3Sn_2)n$ (n = 1.5–2)
9	76721	Polydimethylsiloxane (Mw > 6800) Minimum viscosity 100×10^{-6} m^2/s (= 100 centistokes) at 25°C
10	77895	Polyethyleneglycol (EO = 2–6) monoalkyl (C_{16}–C_{18}) ether The composition of this mixture is as follows: — polyethyleneglycol (EO = 2–6) monoalkyl (C_{16}–C_{18}) ether (approximately 28%) — fatty alcohols (C_{16}–C_{18}) (approximately 48%) — ethyleneglycol monoalkyl (C_{16}–C_{18}) ether (approximately 24%)
11	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 (*))

Note:–

(*) Quantity of substance used/quantity of formulation.

Item	1 *PM/REF No.*	2 *Specifications*
		— 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 (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. 112949–97-0) (<5% w/w (*)) **Other specifications** — Phosphor content of minimum 5.4% to maximum 5.9% — Acid value of maximum 10 mg KOH per gram — Melt range of 85–110°C
12	88640	Soyabean oil, epoxidized Oxirane < 8%, iodine number < 6
13	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
14	95883	White mineral oils, paraffinic derived from petroleum 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)

Note:–

(*) Quantity of substance used/quantity of formulation.

Item	1 *PM/REF No.*	2 *Specifications*
		— Viscosity not less than 8.5×10^{-6} m^2/s (= 8.5 centistokes) at 100°C — Average molecular weight not less than 480”

Note:–

(*) Quantity of substance used/quantity of formulation.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, further amend 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, in Scotland, Commission Directive 2004/19/EC (O.J. No. L 71, 10.3.04, p.8) amending Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (O.J. No. L 220, 15.8.02, p.18), (“the Directive”).

The Regulations amend the 1998 Regulations by–

(a) substituting the definition of “additive” used in the Directive, for consistency (regulation 3(a));

(b) removing references to lists of substances whose authorisations are now spent (regulation 4(a));

(c) extending to articles the provisions of regulation 4(5) of the 1998 Regulations that formerly only applied to materials (regulation 4(b));

(d) adding a restriction on the use of additives in the manufacture of plastic materials and articles which relates to substances also used as food additives or flavourings (regulation 5(a));

(e) extending to articles the provisions of regulation 5(4) of the 1998 Regulations that formerly only applied to materials (regulation 5(b));

(f) making provision for the procedure to be followed and the time limits to be observed by any person wishing to have an additive included in the Community list of authorised additives (regulation 6);

(g) imposing additional labelling requirements for plastic materials and articles at the pre-retail stage so as to make additional information available to users (regulation 7);

(h) making a consequential amendment to regulation 10 (offences) brought about by the amendment to the labelling requirements (regulation 8(a));

(i) providing a defence to breach the 1998 Regulations as last amended by these Regulations in respect of plastic materials or articles manufactured or imported into the European Community before 1st March 2006 (regulation 8(b)).

They also amend the Schedules to the 1998 Regulations by–

(a) inserting new entries, and amending or deleting some existing ones, in the list of monomers authorised without time limit in Section A of Part I of Schedule 1 (regulation 9(a) and Schedules 1 & 2);

(b) removing the list of entries for monomers authorised with a time limit that has now expired (regulation 9(b));

(c) adding further supplementary specifications in Part II of Schedule 1 (regulation 10);

(d) inserting new entries and amending or deleting some existing entries in the list of additives used in the manufacture of plastic materials and articles in Part I of Schedule 2 (regulation 11 and Schedules 3 & 4);

(e) inserting new entries and deleting some existing entries in the list of additives used in the manufacture of plastic materials and articles set out I Part II of Schedule 2 (regulation 12 and Schedule 5);

(f) adding further supplementary specifications to Part III of Schedule 2, and extending the time limit applicable to substances listed in Part II of that Schedule (regulation 13);

(g) amending the restrictions and specifications in the entry in Schedule 2A relating to products obtained by bacterial fermentation (regulation 14);

(h) inserting new entries and amending or deleting some existing ones in the specifications set out in Schedule 2B (regulation 15 and Schedule 6);adding a provision to the basic rules for overall and specific migration testing using food simulants set out in Part I of Schedule 4, to allow for migration testing to be omitted in the specific circumstances provided for in the Directive (regulation 16).

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