
OFFERYNNAU STATUDOL CYMRU

2001 Rhif 1263 (Cy.70)

BWYD, CYMRU

**Rheoliadau Deunyddiau ac Eitemau Plastig mewn
Cysylltiad â Bwyd (Diwygio) (Cymru) 2001**

Wedi'u gwneud - - - *20 Mawrth 2001*

Yn dod i rym - - - *1 Ebrill 2001*

Drwy arfer y pwerau a roddir gan adrannau 16(2), 17(1), 26(1)(a) a 48(1) o Ddeddf Diogelwch Bwyd 1990(1) ac sydd bellach wedi'u breinio yng Nghynulliad Cenedlaethol Cymru(2), mae Cynulliad Cenedlaethol Cymru, ar ôl rhoi sylw yn unol ag adran 48(4A) o'r Ddeddf honno i gyngor perthnasol a roddwyd gan yr Asiantaeth Safonau Bwyd ac ar ôl ymgynghori yn unol ag adran 48(4) a (4B) o'r Ddeddf honno, yn gwneud y Rheoliadau canlynol:

Enwi, cychwyn a chymhwyso

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Deunyddiau Plastig ac Eitemau mewn Cysylltiad â Bwyd (Diwygio) (Cymru) 2001 a deuant i rym ar 1 Ebrill 2001.

(2) Mae'r Rheoliadau hyn yn gymwys i Gymru yn unig.

Diwygio Rheoliadau

2. Diwygir Rheoliadau Deunyddiau Plastig ac Eitemau sy'n Dod i Gysylltiad â Bwyd 1998(3) (“y prif Reoliadau”) (i'r graddau y maent yn gymwys i Gymru) fel a ganlyn.

3. Yn rheoliad 2 (dehongli), yn y diffiniad o “the Directive” yn lle'r geiriau “and 96/11/EC(4)” rhoddir “, 96/11/EC and 1999/91/EC(5) as corrected (6)”.

4. Yn lle paragraff (4)(a) o reoliad 3 (cyfyngu ar ddefnyddio, gwerthu neu fewnforio deunyddiau ac eitemau plastig) rhoddir—

“(a) if—

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

(1) 1990 p. 16.

(2) Gorchymyn Cynulliad Cenedlaethol Cymru (Trosglwyddo Swyddogaethau) 1999 (OS 1999/672)

(3) O.S. 1998/1376.

(4) OJ Rhif L161, 12.3.96, t.26.

(5) OJ Rhif L310, 4.12.99, t.41.(dd) OJ Rhif L249, 4.10.2000, t.26

(6) OJ Rhif L249, 4.10.2000, t.26.

- (ii) it has been manufactured with a prohibited additive as described in regulation 5(1);
 - (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. Yn rheoliad 4 (cyfyngu ar weithgynhyrchu â monomerau)—
- (a) ym mharagraff (1)(c), yn lle'r geiriau “restrictions (if any) specified” rhoddir y geiriau “restrictions and specifications (if any) set out”; a
 - (b) dilëir paragraff (3)(d).
6. Yn rheoliad 5 (cyfyngu ar weithgynhyrchu ag ychwanegion)—
- (a) yn lle paragraff (1) rhoddir—
 - “(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 I 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.”; a
 - (b) ychwanegir y paragraffau canlynol ar y diwedd—
 - “(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 subparagraph (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. Ar ôl rheoliad 5 mewnosodir y rheoliad canlynol—

“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. Ar ôl rheoliad 7 (trosglwyddo cyfansoddion) mewnosodir y rheoliad canlynol—

“Specifications

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

9. Yn rheoliad 10 (tramgwyddo) ychwanegir y paragraff canlynol ar y diwedd—

“(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) (Wales) Regulations 2001 came into force.”.

10. Yn Atodlen 1 (monomerau)—

- (a) yn Rhan I, yn adran A yng ngholofn 4, yn lle'r pennawd “Restrictions” rhoddir “Restrictions and/or specifications”;
- (b) mewnosodir rhif a llythyren yr eitem, Rhif PM/REF, Rhif CAS, enw, cyfyngiad a manyleb (os oes un) ar gyfer pob monomer a enwir yn Rhan I o Atodlen 1 i'r Rheoliadau hyn yn Adran A o Ran I o Atodlen 1 i'r prif Rheoliadau yn y lle sy'n cyfateb i'r rhif a'r llythyren (os oes un) a bennir ar gyfer y monomer hwnnw yn y golofn o dan y pennawd “item” yn y Rhan honno o'r Atodlen honno i'r Rheoliadau hyn;
- (c) yn Rhan I, yn Adran A yn lle'r cofnodion yng ngholofn 4 (cyfyngiadau a manylebau), gyferbyn â'r eitemau ac yn cyfateb i'r eitemau a restrir yn Rhan II o Atodlen 1 i'r Rheoliadau hyn mewnosodir y cofnodion cyfatebol a bennir yn y Rhan II a enwyd;
- (ch) yn Rhan I, yn Adran A, yn eitem 196 dilëir y cofnod yng ngholofn 4 (cyfyngiadau a manylebau);
- (d) yn Rhan I, yn Adran B, dilëir eitem 67 a'r cofnodion ar ei chyfer;
- (dd) yn Rhan I, yn Adran B, yn lle'r cofnodion yng ngholofn 4 (cyfyngiadau), gyferbyn â'r eitemau ac yn cyfateb i'r eitemau a restrir yn Rhan III o Atodlen 1 i'r Rheoliadau hyn rhoddir y cofnodion cyfatebol a bennir yn Rhan III o Atodlen 1 i'r Rheoliadau hyn;

- (e) yn Rhan I, yn Adran B, ar ôl y cofnodion sy'n ymwneud ag eitem 77 mewnosodir rhif a llythyren yr eitem, Rhif PM/REF, Rhif CAS, enw a chyfyngiad ar gyfer y monomer a enwir yn Rhan IV o Atodlen 1 i'r Rheoliadau hyn;
- (f) yn Rhan I, dilëir yr eitemau a restrir yn Rhan V o Atodlen 1 i'r Rheoliadau hyn, a'r cofnodion ar gyfer yr eitemau hynny yn yr Adran honno, a mewnosodir yn Adran A yn y lle sy'n cyfateb i'r rhif hwnnw a'r llythyren honno yn y golofn o dan y pennawd "Item No. for Section A" yn Rhan V o Atodlen 1 i'r Rheoliadau hyn y cofnodion sy'n ymwneud â'r eitem honno yn y Rhan V a enwyd; ac
- (ff) yn Rhan II mewnosodir y paragraff canlynol ar y diwedd—

“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.H₂O
- (d) Badge.HCl
- (e) Badge.2HCl
- (f) Badge.H₂O.HCl

However in aqueous food simulants, the SML (T) should also include Badge.2H₂O(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. Yn Atodlen 2 (ychwanegion)—

- (a) yn Rhan I ychwanegir colofn ychwanegol, yn dwyn y rhif “4” a'r pennawd “Restrictions and specifications”;
- (b) mewnosodir rhif a llythyren yr eitem, Rhif PM/REF, Rhif CAS, enw, cyfyngiad a manyleb (os oes un) ar gyfer pob ychwanegyn a enwir yn Atodlen 2 i'r Rheoliadau hyn yn Rhan I o Atodlen 2 i'r prif Rheoliadau yn y lle sy'n cyfateb i'r rhif a'r llythyren a bennir ar gyfer yr ychwanegyn hwnnw yn y golofn o dan y pennawd “Item” yn Atodlen 2 i'r Rheoliadau hyn;
- (c) yn Rhan I, yn lle'r cofnodion yng ngholofn 2 (Rhif CAS) a cholofn 3 (enw) ar gyfer eitem 38 rhoddir y canlynol—

087826- 41-3	Bis(methylbenzylidene) sorbitol
069158- 41-1	Bis(methylbenzylidene) sorbitol
054686- 97-4	Bis(methylbenzylidene) sorbitol
081541- 12-0	Bis(methylbenzylidene) sorbitol

(ch) yn Rhan I, yn lle'r cofnod yng ngholofn 2 (Rhif CAS) ar gyfer eitem 179 rhoddir y cofnod "037244-96-5";

(d) yn Rhan I, dilëir eitem 195 a'r cofnodion ar ei chyfer; ac

(dd) yn Rhan II, mewnosodir y paragraff canlynol ar y diwedd—

“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(7).”.

12. Ar ôl Atodlen 2 ychwanegir cynnwys Atodlenni 3 a 4 i'r Rheoliadau hyn fel Atodlenni 2A a 2B.

13. Yn Atodlen 3 (darpariaethau sy'n gymwys wrth brofi a ydy yn cydymffurfio â'r terfynau ymfudo)—

(a) ym mharagraff 4(3) a (4), yn lle “regulation 7 or Schedule 1” ym mhob achos mewnosodir “regulation 7, Schedule 1 or Schedule 2”; a

(b) ym mharagraff 7(2)(c) yn lle “M1 and M2” rhoddir “M2 and M3”.

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(8).

20 Mawrth 2001

D.Elis Thomas
Llywydd y Cynulliad Cenedlaethol

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	00176-71-3	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 0.05 mg/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 quantity 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

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ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
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/6 dm 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, triethylester	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

ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
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 (9).

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) = 6 mg/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 1 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)

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

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ITEM	PM/REF No.	CAS No.	Name	Restrictions and specifications
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 quantity 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

ITEM	PM/REF No	CAS/No.	Name	Restrictions
				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 0.01mg/kg, analytical tolerance included)

PART IV

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

Items	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

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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	05976-02-8	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 dodecyl ester	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg. For use only as a 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/6dm ² (measured as 1,3,5 — benzenetricarboxylic
16	49A	13780	002425-79-8	1,4-Butanediol bis(2,3-	The quantity of this substance in

Item No. in Section B	Item No. For Section A	PM/REF No.	CAS No.	NAME	Restrictions and specifications
				epoxypropyl) ether	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 0.05 mg/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-Heptylaminoacetic 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

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Item No. in Section B	Item No. For Section A	PM/REF No.	CAS No.	NAME	Restrictions and specifications
42	121A	19060	000109-53-5	Isobutyl vinyl ether	exceed 3 mg/kg The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
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

Item No. in Section B	Item No. For Section A	PM/REF No.	CAS No.	NAME	Restrictions and specifications
					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	Styrenesulphonid acid	The specific migration of this substance shall not exceed 0.05 mg/kg
83	224	26170	003195-78-6	N-Vinyl-N-methylacetamid	The quantity of this substance in the finished plastic material or article shall

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Item No. in Section B	Item No. For Section A	PM/REF No.	CAS No.	NAME	Restrictions and specifications
					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	
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 migration 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

ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
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 1 January 2002.
27A	36640	000123-77-3	Azodicarbonamide	For use only as blowing agent.
31A	37360	000100-52-7	Benzaldehyde	(10)
36A	38320	005242-49-6	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

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ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
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) specific hydroxymethylphosphonate	The specific migration of this substance shall not exceed 0.6 mg/kg. Authorised only until 1 January 2002
44A	41680	000076-22-2	Camphor	(10)
47A	42320	007492-68-4	Carbonic acid, copper salt	SML (T) = 30 mg/kg (7)
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 2	3,5-Di-tert-butyl-4-hydroxybenzyl	The specific migration of this substance shall

ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
			phosphonic acid, monoethyl ester, calcium salt	not exceed 6 mg/kg
73A	47680	000111-46-3	Diethyleneglycol	SML (T) = 30 mg/kg (3)
73B	48460	000075-37-6	1,1-Difluoroethane	
73C	49485	134701-20-2	2,4-Dimethyl-6-(1-methylpentadecyl)phosphine	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	54453-03-1	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-butylphenyl) fluorophosphonite	The specific migration of this substance shall not exceed 6 mg/kg
92A	54930	025359-91-5	Formaldehyde-1-naphthol, copolymer [poly (1-hydroxynaphthylmethane)]	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-Chlorobenzo Chlorobenzotriazole	The specific migration of this substance shall not exceed 30 mg/kg
169A	66560	004066-02-8	2,2'-Methylenebis(4-	SML (T) = 3 mg/kg

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ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
169B	66580	000077-62-3	methyl-6-cyclohexylphenol) 2,2'-Methylenebis [4-methyl-6-(1-methylcyclohexyl) 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-dimethylphenyl)-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-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

ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
				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 (10) .
191A	73720	000115-96-6	Phosphoric acid, trichloroethyl ester	The specific migration of this substance shall not be 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 mentioned 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	The specific migration of this substance shall not exceed 30 mg/kg

(10) OJ No. L372, 31.12.85, p.14.

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ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
			with acetic acid or fatty acids C10-C18 or n-octanol and/or n-decanol	
198A	77895	068439-49-6	Polyethyleneglycol (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 1	Poly(zinc glycerolate)	
210A	81760		Powders, flakes and fibres of 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 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 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)

ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
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 0	Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-Carboxylate- dine	The specific migration of this substance shall not exceed 6 mg/kg
280A	94960	000077-99-6 6	1,1,1-Trimethylolpropanem	The specific migration of this substance shall not exceed 6 mg/kg
281A	95725	110638-71-6 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 (i)(11).
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	In compliance with the specifications laid down in Schedule 2B

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

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ITEM	PM/REF No.	CAS No.	NAME	Restrictions and specifications
			hydrocarbon feedstocks	

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 croton acid (as impurity) and in compliance with the specifications laid down in Schedule 2B”

SCHEDULE 4

Regulations 8, 13

“SCHEDULE 2B

Regulation 7A

SPECIFICATIONS

ITEM	PM REF No	OTHER SPECIFICATIONS
1	18888	<p>3-HYDROXYBUTANOIC ACID-3-HYDROXYPENTANOIC ACID, COPOLYMER</p> <p>Definition</p> <p>These copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from</p>

ITEM	PM REF No	OTHER SPECIFICATIONS
		<p>a single wild-type organism <i>Alcaligenes eutrophus</i> 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.</p>
		<p>Chemical name Poly (3-D-hydroxybutanoato-co-3-D-hydroxypentanoate).</p>
		<p>CAS number 80181-31-3.</p>
		<p>Structural formula</p> $ \begin{array}{ccccccc} & & & \text{CH}_3 & & & \\ & & & & & & \\ \text{CH}_3 & & \text{O} & & \text{CH}_2 & & \text{O} \\ & & & & & & \\ (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_m & - & & & & & (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_n \end{array} $

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ITEM	PM REF No	OTHER SPECIFICATIONS
		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.
		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

ITEM	PM REF No	OTHER SPECIFICATIONS
		—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 x 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 should have the following specifications: <ul style="list-style-type: none"> — Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w) — Viscosity not less than 11 x 10⁻⁶ m²/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 should have the following specifications: <ul style="list-style-type: none"> — Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w) — Viscosity not less than 8.5 x 10⁻⁶ m²/s (=8.5 centistokes) at 100°C — Average molecular weight not less than 480"

EXPLANATORY NOTE

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

1. Mae'r Rheoliadau hyn yn diwygio, mewn perthynas â Chymru, Reoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998 (“Rheoliadau 1998”), sy'n gymwys i Brydain Fawr. Mae'r Rheoliadau hyn yn gweithredu Cyfarwyddeb y Comisiwn 1999/91/EC sy'n diwygio Cyfarwyddeb 90/128/EEC ynghylch deunyddiau ac eitemau plastig y bwriedir iddynt ddod i gysylltiad â bwydydd.

2. Mae'r Rheoliadau hyn—

- (a) yn diweddarar'r rhestr o fonomerau ac ychwanegion a all gael eu defnyddio wrth weithgynhyrchu deunyddiau ac eitemau plastig i ddod i gysylltiad â bwyd (rheoliadau 10 ac 11 ac Atodlenni 1 a 2);
- (b) yn gosod cyfyngiadau a manylebau mewn perthynas â rhai o'r monomerau a'r ychwanegion hyn (rheoliadau 5(a), 6, 8, 10, 11 a 12 ac Atodlenni 1, 2 a 4); yn benodol, mae math newydd o gyfyngiad yn cael ei gyflwyno (y swm mwyaf o'r sylwedd a ganiateir yn y deunydd neu'r eitem orffenedig wedi'i fynegi mewn miligramau am bob 6 decimetr sgwâr o'r arwynebedd sydd mewn cysylltiad â'r bwyd);
- (c) yn dod â chynhyrchion a geir drwy epleu â bacteria o fewn cwmpas Rheoliadau 1998 ac yn gosod cyfyngiadau a manylebau ar gyfer cynhyrchion o'r fath (rheoliadau 4, 5(b), 7 a 12 ac Atodlen 3);
- (ch) yn cynnwys darpariaeth drosiannol (rheoliad 9); a
- (d) yn gwneud rhai diwygiadau canlyniadol (rheoliadau 3 a 13(a)) ac yn cywiro dau wall yn Rheoliadau 1998 (rheoliadau 10(ch) a 13(b)).

3. Mae arfarniad rheoleiddiol ar gyfer y Rheoliadau hyn wedi'i baratoi yn unol ag adran 65 o Ddeddf Llywodraeth Cymru 1998 ac wedi'i osod yn llyfrgell Cynulliad Cenedlaethol Cymru. Gellir cael copïau oddi wrth yr Asiantaeth Safonau Bwyd, Llawr 1, Southgate House, Caerdydd CF10 1EN.