



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2001 Rhif 1263 (Cy.70)

2001 No. 1263 (W.70)

BWYD, CYMRU

FOOD, WALES

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

**The Plastic Materials and Articles
in Contact with Food
(Amendment) (Wales) Regulations
2001**

NODYN ESBONIADOL

EXPLANATORY NOTE

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

(This note does not form part of the Regulations)

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.

1. These Regulations amend, in relation to Wales, 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. Mae'r Rheoliadau hyn -

2. These Regulations -

- (a) yn diweddarau'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 eplesu 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);

- (a) update the list 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 milligrammes per 6 square decimetres of the surface in contact with the 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);

- (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.

- (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 appraisal for these Regulations has been prepared pursuant to section 65 of the Government of Wales Act 1998 and placed in the library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, 1st Floor, Southgate House, Cardiff CF10 1EN.

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*Wedi'u gwneud**20 Mawrth 2001**Made**20th March 2001**Yn dod i rym**1 Ebrill 2001**Coming into force**1st April 2001*

Drwy arfer y pwerau a roddir gan adrannau 16(2), 17(1), 26(1)(a) a 48(1) o Ddeddf Diogelwch Bwyd 1990(a) ac sydd bellach wedi'u breinio yng Nghynulliad Cenedlaethol Cymru(b), 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:

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 now vested in the National Assembly for Wales(b), the National Assembly for Wales, 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, makes the following Regulations:

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.

Title, commencement and application

1.-(1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2001 and shall come into force on 1st April 2001.

(2) These Regulations apply to Wales only.

Diwygio Rheoliadau

2. Diwygir Rheoliadau Deunyddiau Plastig ac Eitemau sy'n Dod i Gysylltiad â Bwyd 1998(c) ("y prif Rheoliadau") (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(ch)" rhoddir "96/11/EC and 1999/91/EC(d) as corrected (dd)".

Amendment of Regulations

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

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

(a) 1990 p. 16.

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

(c) O.S. 1998/1376.

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

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

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

(a) 1990 c. 16.

(b) The National Assembly for Wales (Transfer of Functions) Order 1999 (SI 1999/672)

(c) S.I. 1998/1376.

(d) OJ No. L161, 12.3.96, p.26.

(e) OJ No. L310, 4.12.99, p.41.(f) OJ No. L249, 4.10.2000, p.26.

(f) OJ No. L249, 4.10.2000, p.26.

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);
- (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 sub-paragraph (b) below; and

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);
- (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 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.”;
- and

- (b) there shall be added 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. 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) 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 Schedules 1, 2 and 2A.”.

9. In regulation 10 (offences) the following paragraph shall be added 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) (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

(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. In Schedule 1 (monomers) –

(a) in Part I, in section A in column 4, for the heading “Restrictions” there shall be substituted “Restrictions and/or 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 Schedule 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.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) mewnosdir 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 Reoliadau 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;

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. In Schedule 2 (additives) –

- (a) in Part I there shall be added 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) yn Rhan I, yn lle'r cofnodion yng ngholofn 2 (Rhif CAS) a cholofn 3 (enw) ar gyfer eitem 38 rhoddir y canlynol –

(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 | | 087826-41-3 | Bis(methylbenzylidene) sorbitol |
| 069158-41-4 | Bis(methylbenzylidene) sorbitol | | 069158-41-1 | Bis(methylbenzylidene) sorbitol |
| 054686-97-4 | Bis(methylbenzylidene) sorbitol | | 054686-97-4 | Bis(methylbenzylidene) sorbitol |
| 081541-12-0 | 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) in Part I, for the entry in column 2 (CAS No.) for item 179 there shall be substituted the entry "037244-96-5";

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

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

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

(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:

"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.

(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.

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(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.

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(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.

(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.

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(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)."

(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)."

(a) OS 1987/1523, y ceir diwygiadau iddo nad ydynt yn berthnasol l'r Rheoliadau hyn.

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

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(a).

12. After Schedule 2 there shall be added 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 “M1 and M2” there shall be substituted “M2 and M3”.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(a)

D.Elis Thomas

20 Mawrth 2001

Llywydd y Cynulliad Cenedlaethol

20th March 2001

The Presiding Officer of the National Assembly

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 |
| 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, 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 | 009016-006 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) = 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) |
| 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 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 | CAS No. 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 | 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-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 |
| 19 | 52A | 14020 | 000098-54-4 | 4-tert-Butylphenol | equal to 43) The specific migration of this substance shall not |
| 22 | 73A | 15130 | 000872-05-9 | 1-Decene | exceed 0.05 mg/kg The specific migration of this substance shall not |
| 30 | 88A | 16360 | 000576-26-1 | 2,6-Dimethylphenol | exceed 0.05 mg/kg The specific migration of this substance shall not |
| 32 | 88B | 16450 | 000646-06-0 | 1,3-Dioxolane | exceed 0.05 mg/kg The specific migration of this substance shall not |
| 37 | 111A | 18220 | 068564-88-5 | N-Heptylaminoundecanoic acid | exceed 0.05 mg/kg 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 |

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|----|------|-------|-------------|---|---|
| 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 | |
| 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 |
| 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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|------|-------|-------------|--|--|
| 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 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 | 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 | 000111-46-3 | 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)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 | 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-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-Chlorobenzo 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 |
| 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 not be 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). |
| 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 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 |

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

| | | | | |
|------|-------|-------------|---|--|
| 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 | 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 | 000109-43-33 | 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 | 008013-07-88 | Soybean oil, epoxidized | In compliance with the specifications laid down in Schedule 2B |
| 263A | 89200 | 007617-31-44 | 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 | 010124-44-44 | Sulphuric acid, copper salt | SML (T) = 30 mg/kg (7) (expressed as copper) |
| 276A | 92700 | 078301-43-66 | 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 | 120218-34-00 | 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 | 000077-99-66 | 1,1,1-Trimethylolpropane | The specific migration of this substance shall not exceed 6 mg/kg |
| 281A | 95725 | 110638-71-66 | Vermiculite, reaction product with citric acid, lithium salt | SML (T) = 0.6 mg/kg (8) (expressed as lithium) |
| 281B | 95855 | 007732-18-55 | Water | In compliance with Directive 98/83/EC (i)(a). |
| 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
"SCHEDULE 2A

Regulation 12
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><u>Definition</u></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 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 CAS number Structural formula</p> <p>Poly (3-D-hydroxybutanoato-co-3-D-hydroxypentanoate). 80181-31-3.</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} $ <p>where n/(m+n) greater than 0 and less or equal to 0.25</p> <p>Average molecular weight Assay</p> <p>Not less than 150,000 Daltons (measured by gel permeation chromatography). Not less than 98% poly (3-D-hydroxybutanoato-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-</p> |

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| | | | hydroxybutanoic and 3-D-hydroxypentanoic acids. |
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| | | <p><u>Description</u></p> <p>White to off-white powder after isolation.</p> <p><u>Characteristics</u></p> <p>Identification tests:</p> <p>Solubility</p> <p>Migration</p> <p>Purity</p> <ul style="list-style-type: none"> - Nitrogen - Zinc - Copper - Lead - Arsenic - Chromium | <p>Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water.</p> <p>The migration of crotonic acid should not exceed 0.05 mg/kg food.</p> <p>Prior to granulation the raw material copolymer powder must contain:</p> <p>Not more than 2,500 mg/kg of plastic</p> <p>Not more than 100 mg/kg of plastic</p> <p>Not more than 5 mg/kg of plastic</p> <p>Not more than 2 mg/kg of plastic</p> <p>Not more than 1 mg/kg of plastic</p> <p>Not more than 1 mg/kg of plastic</p> |
| 2 | 23547 | <p>POLYDIMETHYLSILOXANE (MW> 6800)</p> <p>Minimum viscosity 100 centistokes at 25°C</p> | |
| 3 | 25385 | <p>TRIALLYLAMINE</p> <p>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.</p> | |
| 4 | 38320 | <p>4-(2-BENZOXAZOLYL) -4'-(5-METHYL-2-BENZOXAZOLYL) STILBENE</p> <p>Not more than 0.05% w/w (quantity of substance used/quantity of the formulation)</p> | |
| 5 | 76721 | <p>POLYDIMETHYLSILOXANE (Mw>6800)</p> <p>Minimum viscosity 100 x 10⁻⁶ m²/s (=100 centistokes) at 25°C</p> | |
| 6 | 88640 | <p>SOYBEAN OIL, EPOXIDIZED</p> <p>Oxirane <8%, iodine number < 6</p> | |
| 7 | 95859 | <p>WAXES, REFINED DERIVED FROM PETROLEUM BASED OR SYNTHETIC HYDROCARBON FEEDSTOCKS</p> <p>The product should have the following specifications:</p> <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 | <p>WHITE MINERAL OILS, PARAFFINIC DERIVED FROM PETROLEUM BASED HYDROCARBON FEEDSTOCKS</p> <p>The product should have the following specifications:</p> <ul style="list-style-type: none"> - Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w) | |

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| | | - | Viscosity not less than $8.5 \times 10^{-6} \text{ m}^2/\text{s}$ (=8.5 centistokes) at 100°C |
| | | - | Average molecular weight not less than 480 |

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2001 Rhif 1263 (Cy.70)

BWYD, CYMRU

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Bwyd (Diwygio) (Cymru)
2001

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FOOD, WALES

The Plastic Materials and Articles
in Contact with Food
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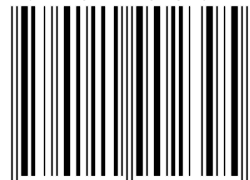
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