



CYNULLIAD CENEDLAETHOL CYMRU

NATIONAL ASSEMBLY FOR WALES

OFFERYNNAU STATUDOL

STATUTORY INSTRUMENTS

2002 Rhif 2834 (Cy.272)

2002 No. 2834 (W.272)

BWYD, CYMRU

FOOD, WALES

**Rheoliadau Deunyddiau ac
Eitemau Plastig mewn Cysylltiad â
Bwyd (Diwygio) (Cymru)
2002**

**The Plastic Materials and Articles
in Contact with Food
(Amendment) (Wales) Regulations
2002**

NODYN ESBONIADOL

EXPLANATORY NOTE

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

(This note is not part of the Regulations)

1. Mae'r Rheoliadau hyn yn diwygio, mewn perthynas â Chymru, Rheoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998, er mwyn rhoi ar waith -
 - (a) Cyfarwyddeb y Comisiwn 2001/62/EC sy'n diwygio Cyfarwyddeb 90/128/EEC ynghylch deunyddiau ac eitemau plastig y bwriedir iddynt ddod i gysylltiad â bwydydd (OJ Rhif. L221, 17.8.2001, t.18);
 - (b) Cyfarwyddeb y Comisiwn 2002/16/EC ar ddefnyddio deilliadau epoksi penodol mewn deunyddiau y bwriedir iddynt ddod i gysylltiad â bwydydd (OJ Rhif. L51, 22.2.2002, t.27); a
 - (c) (mewn mân agweddau) Cyfarwyddeb y Comisiwn 2002/17/EC sy'n diwygio Cyfarwyddeb 90/128/EEC ynghylch deunyddiau ac eitemau plastig y bwriedir iddynt ddod i gysylltiad â bwydydd (OJ Rhif. L58, 28.2.2002, t.19).
2. Mae'r Rheoliadau hefyd yn adlewyrchu, yn effeithiol o 4 Medi 2002, ddiddymiad Cyfarwyddeb 90/128/EEC ynghylch deunyddiau ac eitemau plastig y bwriedir iddynt ddod i gysylltiad â bwydydd (OJ Rhif. L75, 21.3.1990) fel y'i diwygiwyd a'i hailddeddfiad mewn ffurf gyd-grynhoi gan Gyfarwyddeb y Comisiwn 2002/72/EC ynghylch deunyddiau ac eitemau plastig y bwriedir iddynt ddod i gysylltiad â bwydydd (OJ Rhif. L220 15.8.2002, t.18).

1. These Regulations amend, in relation to Wales, the Plastic Materials and Articles in Contact with Food Regulations 1998, so as to implement -
 - (a) Commission Directive 2001/62/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (OJ No. L221, 17.8.2001, p.18);
 - (b) Commission Directive 2002/16/EC on the use of certain epoxy derivatives in materials intended to come into contact with foodstuffs (OJ No. L51, 22.2.2002, p.27); and
 - (c) (in minor respects) Commission Directive 2002/17/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (OJ No. L58, 28.2.2002, p.19).
2. The Regulations also reflect the revocation, with effect from 4th September 2002, of Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (OJ No. L75, 21.3.1990) as amended and its re-enactment in consolidated form by Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs (OJ No. L220, 15.8.2002, p.18).

3. Mae'r Rheoliadau yn diwygio Rheoliadau 1998 drwy wneud y canlynol -

- (a) ychwanegu darpariaeth yn datgan bod Rheoliadau 1998, yn ychwanegol at reoleiddio (fel cynt) gysylltiad mathau penodol o ddeunyddiau ac eitemau plastig â bwyd, bellach hefyd yn cynnwys darpariaethau sy'n rheoleiddio cysylltiad â bwyd ar fathau penodol o ddeunyddiau eraill sy'n dod i gysylltiad â bwyd, sef gludyddion a deunyddiau neu eitemau orchuddiwyd â haenau arwyneb (*rheoliad 3*);
- (b) darparu bod y diffiniad o "plastic material or article" i gael ystyr estynedig pan ddefnyddir y term hwnnw yng nghydedstun darpariaethau a ychwanegwyd at Rheoliadau 1998 wrth weithredu Cyfarwyddeb y Comisiwn 2002/16/EC (*rheoliad 4(a)(vii) a (c)*);
- (c) estyn, er mwyn cymhwyso i ludyddion a deunyddiau ac eitemau a orchuddiwyd â haenau arwyneb, y darpariaethau yn Rheoliadau 1998 sydd yn gwneud y canlynol -
 - (i) rhoi i'r term "sale" ystyr estynedig at ddibenion y Rheoliadau hynny,
 - (ii) gwahardd defnyddio, gwerthu neu fewnforio deunyddiau ac eitemau plastig nad ydynt yn bodloni'r safonau penodedig,
 - (iii) peri bod yr amddiffyniad o "due diligence" ar gael yn achos tramgwyddau sy'n ymwneud â deunyddiau ac eitemau plastig,
 - (iv) creu rhagdybiaeth ynghylch cywirdeb unrhyw fanylion a ddangosir mewn perthynas â deunyddiau neu eitemau plastig a all ddod i gysylltiad â bwyd, a
 - (v) cymhwyso at ddibenion y Rheoliadau hynny, mewn perthynas â deunyddiau ac eitemau plastig, ddarpariaethau amrywiol o Ddeddf Diogelwch Bwyd 1990 (*rheoliadau 4(b), 5, 12(b), 13 a 14 yn ôl eu trefn*);
- (ch) ychwanegu at y darpariaethau sy'n cyfyngu ar ddefnyddio sylweddau fel monomerau neu ychwanegion wrth weithgynhyrchu deunyddiau neu eitemau plastig, darpariaethau sy'n cyfyngu ar ddefnyddio 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether, ("BADGE"), bis(hydroxyphenyl) methane bis(2,3-epoxypropyl) ethers ("BFDGE") a novolac glycidyl ethers ("NOGE") fel monomerau neu ychwanegion mewn gweithgynhyrchu o'r fath (*rheoliadau 6(a) ac 8(a)*);

3. The Regulations amend the 1998 Regulations by -

- (a) adding a provision declaring that, in addition to regulating (as previously) the contact with food of certain types of plastic materials and articles, the 1998 Regulations now also include provisions which regulate the contact with food of certain other types of food contact materials, namely adhesives and materials or articles covered by surface coatings (*regulation 3*);
- (b) providing for the definition of "plastic material or article" to have an extended meaning where that term is used in the context of provisions added to the 1998 Regulations in implementation of Commission Directive 2002/16/EC (*regulation 4(a)(vii) and (c)*);
- (c) extending, so as to apply to adhesives and materials and articles covered by surface coatings, the provisions in the 1998 Regulations which -
 - (i) give to the term "sale" an extended meaning for the purposes of those Regulations,
 - (ii) prohibit the use, sale or importation of plastic materials and articles not meeting specified standards,
 - (iii) make available the defence of "due diligence" in the case of offences relating to plastic materials and articles,
 - (iv) create a presumption as to the accuracy of any particulars shown in relation to a plastic material or article which may come into contact with food, and
 - (v) apply for the purposes of those Regulations, in relation to plastic materials and articles, various provisions of the Food Safety Act 1990 (*regulations 4(b), 5, 12(b), 13 and 14 respectively*);
- (d) adding to the provisions restricting the use of certain substances as monomers or additives in the manufacture of plastic materials or articles, provisions restricting the use of 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether, ("BADGE"), bis(hydroxyphenyl) methane bis(2,3-epoxypropyl) ethers ("BFDGE") and novolac glycidyl ethers ("NOGE") as monomers or additives in such manufacture (*regulations 6(a) and 8(a)*);

- (d) newid y dyddiad (o 31 Rhagfyr 2001 i 31 Rhagfyr 2004) pan na cheir wedyn ddefnyddio'r monomerau a restrir yn Adran B o Atodlen 1 i Reoliadau 1998 wrth weithgynhyrchu deunyddiau neu eitemau plastig ac addasu'r rhestr o'r mathau o ddeunyddiau ac eitemau plastig nad yw'r cyfyngiadau ar ddefnyddio monomerau wrth eu gweithgynhyrchu yn gymwys iddynt (*rheoliad 6(b) ac (c)*);
- (dd) cyflwyno cyfyngiadau newydd wrth weithgynhyrchu deunyddiau ac eitemau plastig sy'n defnyddio BADGE, BFDGE neu NOGE heblaw fel monomerau neu ychwanegion (*rheoliad 7*);
- (e) diwygio'r darpariaethau sy'n llywodraethu profi gallu deunyddiau ac eitemau plastig i drosglwyddo eu hansoddion i fwyd, yn benodol drwy ychwanegu darpariaethau sy'n llywodraethu profi'r gallu hwnnw yn achos BADGE, BFDGE a NOGE (*rheoliadau 9 a 18*);
- (f) ychwanegu darpariaeth yn cyfyngu ar faint y caniateir i ddeunyddiau neu eitemau plastig penodol drosglwyddo sylweddau penodol i fwyd (*rheoliad 10*);
- (ff) cyflwyno cyfyngiadau newydd ar weithgynhyrchu gludyddion neu ddeunyddiau ac eitemau a orchuddir â haenau arwyneb sy'n defnyddio BADGE, BFDGE neu NOGE a darpariaethau newydd sy'n llywodraethu profi gallu gludyddion neu ddeunyddiau ac eitemau o'r fath i drosglwyddo'r sylweddau hynny i fwyd (*rheoliad 11*);
- (g) ei gwneud yn dramgwydd i dorri unrhyw un o'r cyfyngiadau y cyfeirir atynt yn is-baragraffau (ch), (dd) neu (ff) uchod gan gynnwys darpariaethau trosiannol (*rheoliad 12 (a) ac (c)*);
- (ng) ychwanegu sylweddau newydd at y rhestr o fonomerau y gellir eu defnyddio wrth weithgynhyrchu deunyddiau neu eitemau plastig a diwygio'r defnydd o fonomerau penodol a ddefnyddir mewn gweithgynhyrchu o'r fath (*rheoliad 15*);
- (h) ychwanegu sylweddau newydd at y rhestr anghyflawn o ychwanegion a ddefnyddir wrth weithgynhyrchu deunyddiau neu eitemau plastig, diwygio amodau defnyddio ychwanegion penodol a ddefnyddir mewn gweithgynhyrchu o'r fath a dileu un ychwanegyn o'r rhestr honno (*rheoliadau 8(a) ac 16*);
- (i) ychwanegu sylweddau penodol at y rhestr o sylweddau y nodir manylebau amdanynt yn Atodlen 2B i Reoliadau 1998 (*rheoliad 17*); a
- (e) changing (from 31st December 2001 to 31st December 2004) the date beyond which the monomers listed in Section B of Schedule 1 to the 1998 Regulations may no longer be used in the manufacture of plastic materials or articles and modifying the list of the types of plastic materials and articles to which the restrictions on the use of monomers in their manufacture do not apply (*regulation 6(b) and (c)*);
- (f) introducing new restrictions on the manufacture of plastic materials and articles using BADGE, BFDGE or NOGE other than as monomers or additives (*regulation 7*);
- (g) amending the provisions governing the testing of the capability of plastic materials and articles to transfer their constituents to food, in particular by adding provisions governing the testing of that capability in the case of BADGE, BFDGE and NOGE (*regulations 9 and 18*);
- (h) adding a provision restricting the extent to which certain plastic materials or articles are allowed to transfer certain substances to food (*regulation 10*);
- (i) introducing new restrictions on the manufacture of adhesives or materials and articles covered by surface coatings using BADGE, BFDGE or NOGE and new provisions governing the testing of the capability of such adhesives, materials or articles to transfer those substances to food (*regulation 11*);
- (j) making it an offence to contravene any of the restrictions referred to in subparagraphs (d), (f) or (i) above and including transitional provisions (*regulation 12 (a) and (c)*);
- (k) adding new substances to the list of monomers which may be used in the manufacture of plastic materials or articles and amending the conditions of use of certain monomers used in such manufacture (*regulation 15*);
- (l) adding new substances to the non-exhaustive list of additives used in the manufacture of plastic materials or articles, amending the conditions of use of certain additives used in such manufacture and deleting one additive from that list (*regulations 8(a) and 16*);
- (m) adding certain substances to the list of substances whose specifications are set out in Schedule 2B to the 1998 Regulations (*regulation 17*); and

- (j) gwneud diwygiad canlyniadol i Reoliadau Diogelwch Bwyd (Samplio a Chymwysterau) 1990 (*rheoliad 19*).
- 4. Mae arfarniad rheoliadol, sydd yn cynnwys asesiad cost cydymffurfedd o'r effaith y maent yn debygol o gael ar gostau busnes, wedi cael ei baratoi ar gyfer y Rheoliadau hyn.
- (n) making a consequential amendment to the Food Safety (Sampling and Qualifications) Regulations 1990 (*regulation 19*).
- 4. A regulatory appraisal, which includes a compliance cost assessment of the effect that they are likely to have on business costs, has been prepared for these Regulations.

2002 Rhif 2834 (Cy.272)**2002 No. 2834 (W.272)****BWYD, CYMRU****FOOD, WALES****Rheoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd (Diwygio) (Cymru) 2002****The Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2002**

Wedi'u gwneud 7 Tachwedd 2002
Yn dod i rym 30 Tachwedd 2002

Made 7th November 2002
Coming into force 30th November 2002

Drwy arfer y pwerau a roddwyd gan adrannau 16(2), 17(1), 26(1)(a), 31 a 48(1) o Ddeddf Diogelwch Bwyd 1990(a), ac sydd bellach yn arferadwy mewn perthynas â Chymru gan Gynulliad Cenedlaethol Cymru(b) 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 â gofynion Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor sy'n pennu egwyddorion cyffredinol a gofynion cyfraith bwyd, sy'n sefydlu Awdurdod Diogelwch Bwyd Ewrop ac sy'n pennu gweithdrefnau mewn materion diogelwch bwyd(c), 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), 31 and 48(1) of the Food Safety Act 1990(a), which are now exercisable in relation to Wales by the National Assembly for Wales(b) having regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), and after consultation in accordance with section 48(4) and 4(B) of that Act, makes the following Regulations:

Enwi, cychwyn a chymhwyso

1.-(1) Enw'r rheoliadau hyn yw Rheoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd (Diwygio) (Cymru) 2002 a daw i rym ar 30 Tachwedd 2002.

(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 2002 and shall come into force on 30th November 2002.

(2) These Regulations apply to Wales only.

Diwygiadau i Reoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998

2. Diwygir Rheoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998(ch) ("y prif Reoliadau"), i'r graddau y maent yn gymwys i Gymru, yn unol â rheoliadau 3 i 18.

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

2. The Plastic Materials and Articles in Contact with Food Regulations 1998(d) ("the principal Regulations") shall be amended, in so far as they apply to Wales, in accordance with regulations 3 to 18.

(a) 1990 p.16.

(b) Trosglwyddwyd swyddogaethau'r "Ysgrifennydd Gwladol" i'r graddau y maent yn arferadwy mewn perthynas â Chymru i Gynulliad Cenedlaethol Cymru gan O.S. 1999/672, fel y'i diwygiwyd gan a.40(3) o Ddeddf Safonau Bwyd 1999 (1999 p.28).

(c) OJ Rhif L31, 1.2.2002, t.1.

(ch) O.S. 1998/1376, a ddiwygiwyd gan O.S. 2001/1263.

(a) 1990 c.16.

(b) Functions of "the Secretary of State" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by S.I. 1999/672, as amended by s.40(3) of the Food Standards Act 1999 (1999 c.28).

(c) OJ No. L31, 1.2.2002, p1.

(d) S.I. 1998/1376, amended by S.I. 2001/1263.

3. Yn union ar ôl rheoliad 1 mewnosoder y rheoliad canlynol -

"Scope of these Regulations

1A. Notwithstanding the title to these Regulations -

- (a) regulations 3 and 9 to 12 apply also in relation to adhesives and to materials or articles covered by surface coatings; and
- (b) regulation 8A and regulation 8B apply only in relation to adhesives and to materials or articles covered by surface coatings."

4. Yn rheoliad 2 (dehongli) -

(a) ym mharagraff (1) -

- (i) yn union ar ôl y diffiniad o "additive" mewnosoder y diffiniadau canlynol -

""adhesive" means anything which, for the purposes of Commission Directive 2002/16, is included among the adhesives to which that Directive applies;

"BADGE" means 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether;

"BFDGE" means bis(hydroxyphenyl) methane bis(2,3-epoxypropyl) ethers;"

- (ii) yn lle'r diffiniad o "capable" rhodder y diffiniad canlynol -

""capable" means capable as established -

- (a) in relation to any plastic material or article, under regulation 6; and
- (b) in relation to any adhesive or material or article covered by a surface coating, under regulation 8B;"

- (iii) yn union ar ôl y diffiniad o "capable" mewnosoder y diffiniadau canlynol -

""Commission Directive 2001/62" means Commission Directive 2001/62/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs(a);

"Commission Directive 2002/16" means Commission Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs(b);"

- (iv) yn lle'r diffiniad o "the Directive" rhodder y diffiniad canlynol - ""the Directive" means Commission Directive 2002/72/EC

3. Immediately after regulation 1 there shall be added the following regulation -

"Scope of these Regulations

1A. Notwithstanding the title to these Regulations -

- (a) regulations 3 and 9 to 12 apply also in relation to adhesives and to materials or articles covered by surface coatings; and
- (b) regulation 8A and regulation 8B apply only in relation to adhesives and to materials or articles covered by surface coatings."

4. In regulation 2 (interpretation) -

(a) in paragraph (1) -

- (i) immediately after the definitions of "additive" there shall be inserted the following definitions -

""adhesive" means anything which, for the purposes of Commission Directive 2002/16, is included among the adhesives to which that Directive applies;

"BADGE" means 2,2-bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether;

"BFDGE" means bis(hydroxyphenyl) methane bis(2,3-epoxypropyl) ethers;"

- (ii) for the definition of "capable" there shall be substituted the following definition -

""capable" means capable as established -

- (a) in relation to any plastic material or article, under regulation 6; and
- (b) in relation to any adhesive or material or article covered by a surface coating, under regulation 8B;"

- (iii) immediately after the definition of "capable" there shall be inserted the following definitions -

""Commission Directive 2001/62" means Commission Directive 2001/62/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs(a);

"Commission Directive 2002/16" means Commission Directive 2002/16/EC on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs(b);"

- (iv) For the definition of "the Directive" there shall be substituted the following definition - ""the Directive" means Commission Directive 2002/72/EC

(a) OJ Rhif L221, 17.8.2001, t.18.

(b) OJ Rhif L215, 9.8.2001, t.26.

(a) OJ No. L221, 17.8.2001, p.18.

(b) OJ No. L215, 9.8.2001, p.26.

relating to plastic materials and articles intended to come into contact with foodstuffs (a);",

- (v) yn union ar ôl y diffiniad o "import" mewnosoder y diffiniad canlynol -

""material or article covered by a surface coating" means anything which, for the purposes of Commission Directive 2002/16, is included among the materials and articles covered by surface coatings to which that Directive applies;"

- (vi) yn union ar ôl y diffiniad o "monomer" mewnosoder y diffiniad canlynol -

""NOGE" means novolac glycidyl ethers not covered by Article 1(a) or (b) of Commission Directive 2002/16;"

- (vii) ar ddiwedd y diffiniad o "plastic material or article" ychwaneger y geiriau canlynol ", except that, where it is used in any provisions referred to in paragraph (5) below, to the extent that they implement or relate to the enforcement of Commission Directive 2002/16, it means any material or article made of any type of plastic"; a

- (viii) ar ôl y diffiniad o "sell" ychwaneger y diffiniad canlynol -

""QMA" has the same meaning as it bears in the first sentence of the subparagraph relating to that term in paragraph 8 of Annex II to the Directive;"

- (b) yn lle paragraff (2) rhodder y ddarpariaeth ganlynol -

"(2) For the purposes of these Regulations, the supply in the course of a business, otherwise than on sale, of any plastic material or article, adhesive or material or article covered by a surface coating, shall be deemed to be a sale of the plastic material or article, adhesive or material or article covered by a surface coating concerned."; ac

- (c) yn union ar ôl paragraff (4) mewnosoder y paragraff canlynol -

"(5) The provisions referred to in the definition of "plastic material or article" in paragraph (1) of this regulation are regulations 3, 4, 4A, 5, 6, 10, 11 and 12 and Schedules 3 and 4."

5. Yn rheoliad 3 (cyfyngu ar ddefnyddio, gwerthu neu fewnforio deunyddiau ac eitemau plastig) -

- (a) yn lle'r pennawd rhodder y pennawd canlynol -

relating to plastic materials and articles intended to come into contact with foodstuffs (a);",

- (v) immediately after the definition of "import" there shall be inserted the following definition -

""material or article covered by a surface coating" means anything which, for the purposes of Commission Directive 2002/16, is included among the materials and articles covered by surface coatings to which that Directive applies;"

- (vi) immediately after the definition of "monomer" there shall be inserted the following definition -

""NOGE" means novolac glycidyl ethers not covered by Article 1(a) or (b) of Commission Directive 2002/16;"

- (vii) at the end of the definition of "plastic material or article" there shall be added the following words ", except that, where it is used in any provisions referred to in paragraph (5) below, to the extent that they implement or relate to the enforcement of Commission Directive 2002/16, it means any material or article made of any type of plastic"; and

- (viii) after the definition of "sell" there shall be added the following definition -

""QMA" has the same meaning as it bears in the first sentence of the subparagraph relating to that term in paragraph 8 of Annex II to the Directive;"

- (b) for paragraff (2) there shall be substituted the following provision -

"(2) For the purposes of these Regulations, the supply in the course of a business, otherwise than on sale, of any plastic material or article, adhesive or material or article covered by a surface coating, shall be deemed to be a sale of the plastic material or article, adhesive or material or article covered by a surface coating concerned."; and

- (c) immediately after paragraff (4) there shall be inserted the following paragraph -

"(5) The provisions referred to in the definition of "plastic material or article" in paragraph (1) of this regulation are regulations 3, 4, 4A, 5, 6, 10, 11 and 12 and Schedules 3 and 4."

5. In regulation 3 (restriction on the use, sale or importation of plastic materials and articles) -

- (a) for the heading there shall be substituted the following heading -

(a) OJ Rhif L220, 15.8.2002, t.18.

(a) OJ No. L220, 15.8.2002, p.18.

"Restriction on the use, sale or importation of plastic materials and articles, adhesives and materials and articles covered by surface coatings";

- (b) ym mharagraffau (1) a (2), yn union ar ôl y cyfeiriadau at "plastic material or article", lle bynnag y maent yn ymddangos, mewnosoder cyfeiriadau at ", adhesive or material or article covered by a surface coating";
- (c) yn is-baragraff (4)(a)(iii) dileir y gair "or";
- (ch) yn lle is-baragraff (4)(a)(iv) rhodder yr is-baragraff canlynol -
- "(iv) it does not comply with regulation 4(5), (5A) or (5B), 4A(4), (5) or (6), 5(4), (4A), (4B) or (4C), 7 or 7A(1) or 8A(4), (5) or (6); or"; ac
- (d) yn union ar ôl is-baragraff (4)(a)(iv) ychwaneger yr is-baragraff canlynol -
- "(v) it has been manufactured in contravention of a prohibition contained in regulation 4A(1), (2) or (3)."
- (dd) ychwaneger y paragraff canlynol ar y diwedd -
- "(5) For the purposes of this regulation, an adhesive or a material or article covered by a surface coating fails to meet the requisite standards if -
- (i) it has been manufactured in contravention of a prohibition contained in regulation 8A(1), (2) or (3), or
- (ii) it does not comply with regulation 8A(4), (5) or (6)."

6. Yn rheoliad 4 (cyfyngu ar weithgynhyrchu â monomerau) -

- (a) yn lle'r pennawd a pharagraff (1) rhodder y darpariaethau canlynol -

"Restriction on manufacture with monomers of plastic materials and articles

(1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of any plastic material or article any prohibited monomer, that is to say -

- (a) any monomer (not being one to which sub-paragraph (b) or (c) below relates) which is not -
- (i) of good technical quality;
- (ii) identified by PM/REF No., CAS No. (if any) and name in columns 1, 2 and 3 respectively of the relevant section of Part I of Schedule 1, and

"Restriction on the use, sale or importation of plastic materials and articles, adhesives and materials and articles covered by surface coatings";

- (b) in paragraphs (1) and (2), immediately after the references to "plastic material or article", wherever they appear, there shall be inserted references to ", adhesive or material or article covered by a surface coating";
- (c) in sub-paragraph (4)(a)(iii) the word "or" shall be deleted;
- (d) for sub-paragraph (4)(a)(iv) there shall be substituted the following sub-paragraph -
- "(iv) it does not comply with regulation 4(5), (5A) or (5B), 4A(4), (5) or (6), 5(4), (4A), (4B) or (4C), 7 or 7A(1) or 8A(4), (5) or (6); or"; and
- (e) immediately after sub-paragraph (4)(a)(iv) there shall be added the following sub-paragraph -
- "(v) it has been manufactured in contravention of a prohibition contained in regulation 4A(1), (2) or (3)."
- (f) there shall be added at the end the following paragraph -
- "(5) For the purposes of this regulation, an adhesive or a material or article covered by a surface coating fails to meet the requisite standards if -
- (i) it has been manufactured in contravention of a prohibition contained in regulation 8A(1), (2) or (3), or
- (ii) it does not comply with regulation 8A(4), (5) or (6)."

6. In regulation 4 (restriction on manufacture with monomers) -

- (a) for the heading and paragraph (1) there shall be substituted the following provisions -

"Restriction on manufacture with monomers of plastic materials and articles

(1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of any plastic material or article any prohibited monomer, that is to say -

- (a) any monomer (not being one to which sub-paragraph (b) or (c) below relates) which is not -
- (i) of good technical quality;
- (ii) identified by PM/REF No., CAS No. (if any) and name in columns 1, 2 and 3 respectively of the relevant section of Part I of Schedule 1, and

- (iii) used in accordance with the restrictions and specifications (if any) for that monomer set out or referred to in the corresponding entry in column 4 of that section;
- (b) BFDGE to the extent that they are used in such manufacture -
 - (i) on or after 1st January 2005, or
 - (ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex; or
- (c) NOGE to the extent that it is used in such manufacture -
 - (i) on or after 1st January 2005, or
 - (ii) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.";
- (b) ym mharagraff (2) -
 - (i) yn is-baragraff (b) rhodder y darpariaethau canlynol - " in the case of a plastic material or article manufactured on or after 30th November 2002 and before 1st January 2005, Section A or B", a
 - (ii) yn is-baragraff (c), rhodder y darpariaethau canlynol " in the case of a plastic material or article manufactured on or after 1st January 2005, Section A.";
- (c) yn lle paragraff (3) rhodder y paragraff canlynol -

"(3) Paragraph (1)(a) of this regulation does not apply to the use of a monomer in the manufacture of any -

 - (a) surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, including, but not limited to, varnishes, lacquers and paints;
 - (b) epoxy resins;
 - (c) adhesives and adhesion promoters; or
 - (d) printing inks.";
 - (ch) ym mharagraff (4), yn lle'r ymadrodd "Paragraph (1)" rhodder yr ymadrodd "Paragraph (1)(a)";
- (d) yn union ar ôl paragraff (5) mewnosoder y paragraffau canlynol -

"(5A) No plastic material or article manufactured using BFDGE as a monomer shall be capable of transferring constituents of that monomer to food
- (iii) used in accordance with the restrictions and specifications (if any) for that monomer set out or referred to in the corresponding entry in column 4 of that section;
- (b) BFDGE to the extent that they are used in such manufacture -
 - (i) on or after 1st January 2005, or
 - (ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex; or
- (c) NOGE to the extent that it is used in such manufacture -
 - (i) on or after 1st January 2005, or
 - (ii) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.";
- (b) in paragraph (2) -
 - (i) for sub-paragraph (b) there shall be substituted the following provisions - " in the case of a plastic material or article manufactured on or after 30th November 2002 and before 1st January 2005, Section A or B", and
 - (ii) for sub-paragraph (c), there shall be substituted the following provisions " in the case of a plastic material or article manufactured on or after 1st January 2005, Section A.";
- (c) for paragraph (3) there shall be substituted the following paragraph -

"(3) Paragraph (1)(a) of this regulation does not apply to the use of a monomer in the manufacture of any -

 - (a) surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, including, but not limited to, varnishes, lacquers and paints;
 - (b) epoxy resins;
 - (c) adhesives and adhesion promoters; or
 - (d) printing inks.";
 - (d) in paragraph (4), for the expression "Paragraph (1)" there shall be substituted the expression "Paragraph (1)(a)";
 - (e) immediately after paragraph (5) there shall be inserted the following paragraphs -

"(5A) No plastic material or article manufactured using BFDGE as a monomer shall be capable of transferring constituents of that monomer to food

with which that plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(5B) On or after 1st March 2003, no plastic material or article manufactured using NOGE as a monomer shall fail to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."; and

(dd) ym mharagraff (7) -

- (i) yn lle'r ymadrodd "paragraph (1)" rhodder yr ymadrodd "paragraph (1)(a)", a
- (ii) ar ôl y geiriau "Part I of Schedule 1" mewnosoder y geiriau "or to which sub-paragraph (b) or (c) of that paragraph relates".

7. Yn union ar ôl rheoliad 4 (cyfyngu ar weithgynhyrchu â monomerau) mewnosoder y rheoliad canlynol -

"Restriction on manufacture of plastic materials and articles using certain substances other than as monomers or additives"

4A.-(1) No person shall use BADGE in the manufacture of any plastic material or article, where the use is not as a monomer or an additive -

- (a) on or after 1st January 2005; or
- (b) prior to that date in contravention of the restriction specified in paragraph 1 of Annex 1 to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(2) No person shall use BFDGE in the manufacture of any plastic material or article, where the use is not as a monomer or an additive -

- (a) on or after 1st January 2005; or
- (b) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(3) No person shall use NOGE in the manufacture of any plastic material or article, where the use is not as a monomer or additive -

- (a) on or after 1st January 2005; or
- (b) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.

(4) No plastic material or article manufactured using BADGE other than as a monomer or an additive shall be capable of transferring constituents of BADGE to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified

with which that plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(5B) On or after 1st March 2003, no plastic material or article manufactured using NOGE as a monomer shall fail to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."; and

(f) in paragraph (7) -

- (i) for the expression "paragraph (1)" there shall be substituted the expression "paragraph (1)(a)", and
- (ii) after the words "Part I of Schedule 1" there shall be inserted the words "or to which sub-paragraph (b) or (c) of that paragraph relates".

7. Immediately after regulation 4 (restriction on manufacture with monomers) there shall be inserted the following regulation -

"Restriction on manufacture of plastic materials and articles using certain substances other than as monomers or additives"

4A.-(1) No person shall use BADGE in the manufacture of any plastic material or article, where the use is not as a monomer or an additive -

- (a) on or after 1st January 2005; or
- (b) prior to that date in contravention of the restriction specified in paragraph 1 of Annex 1 to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(2) No person shall use BFDGE in the manufacture of any plastic material or article, where the use is not as a monomer or an additive -

- (a) on or after 1st January 2005; or
- (b) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(3) No person shall use NOGE in the manufacture of any plastic material or article, where the use is not as a monomer or additive -

- (a) on or after 1st January 2005; or
- (b) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.

(4) No plastic material or article manufactured using BADGE other than as a monomer or an additive shall be capable of transferring constituents of BADGE to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified

in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(5) No plastic material or article manufactured using BFDGE other than as a monomer or an additive shall be capable of transferring constituents of BFDGE to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(6) On and after 1st March 2003, no plastic material or article manufactured using NOGE other than as a monomer or an additive shall fail to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."

8. Yn rheoliad 5 (cyfyngu ar weithgynhyrchu ag ychwanegion) -

(a) yn lle'r pennawd a pharagraff (1) rhodder y darpariaethau canlynol -

"Restriction on manufacture of plastic materials and articles with additives

(1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of plastic material or article any prohibited additive, that is to say -

(a) any additive identified by PM/REF No., CAS No. (if any) and name in columns 1, 2 and 3 respectively of Part I of Schedule 2 or columns 1, 2 and 3 respectively of Part II of that Schedule, which is not -

- (i) of good technical quality, and
- (ii) used in accordance with the restrictions and specifications (if any) for that additive set out in the corresponding entry in column 4 of Part I or Part II, as appropriate;

(b) BADGE to the extent that it is used in such manufacture -

- (i) on or after 1st January 2005, or
- (ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex;

(c) BFDGE which is used in such manufacture -

- (i) on or after 1st January 2005, or
- (ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex; or

in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(5) No plastic material or article manufactured using BFDGE other than as a monomer or an additive shall be capable of transferring constituents of BFDGE to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(6) On and after 1st March 2003, no plastic material or article manufactured using NOGE other than as a monomer or an additive shall fail to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."

8. In regulation 5 (restriction on manufacture with additives) -

(a) for the heading and paragraph (1) there shall be substituted the following provisions -

"Restriction on manufacture of plastic materials and articles with additives

(1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of plastic material or article any prohibited additive, that is to say -

(a) any additive identified by PM/REF No., CAS No. (if any) and name in columns 1, 2 and 3 respectively of Part I of Schedule 2 or columns 1, 2 and 3 respectively of Part II of that Schedule, which is not -

- (i) of good technical quality, and
- (ii) used in accordance with the restrictions and specifications (if any) for that additive set out in the corresponding entry in column 4 of Part I or Part II, as appropriate;

(b) BADGE to the extent that it is used in such manufacture -

- (i) on or after 1st January 2005, or
- (ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex;

(c) BFDGE which is used in such manufacture -

- (i) on or after 1st January 2005, or
- (ii) prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex; or

- (d) NOGE not otherwise covered by this paragraph and which is used in such manufacture -
- (i) on or after 1st January 2005, or
 - (ii) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.";
- (b) ym mharagraff (2), yn union ar ôl yr ymadrodd "Part I" ychwaneger yr ymadrodd "or Part II";
- (c) yn lle paragraff (3), rhodder y paragraff canlynol -
- "(3) Part III of Schedule 2 shall have effect to supplement this regulation and Parts I and II of that Schedule.";
- (ch) ym mharagraff (4) -
- (i) yn lle'r ymadrodd "Part I of Schedule 2" rhodder yr ymadrodd "Part I or Part II of Schedule 2," a
 - (ii) yn is-baragraffau (a) a (b), yn lle'r gair "therein" rhodder yr ymadrodd "that column".
- (d) rhwng paragraffau 4 a 5 mewnosoder y paragraffau canlynol -
- "(4A) No plastic material or article manufactured using BADGE as an additive shall be capable of transferring constituents of that additive to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.
- (4B) No plastic material or article manufactured using BFDGE as an additive shall be capable of transferring constituents of that additive to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.
- (4C) On and after 1st March 2003, no plastic material or article manufactured using NOGE as an additive shall fall to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."; and
- (dd) ym mharagraff (5), yn lle'r ymadrodd "Part I of Schedule 2" rhodder yr ymadrodd "Part I or Part II of Schedule 2,".
- 9. Yn rheoliad 6 (dull profi'r gallu i drosglwyddo ansoddion) -**
- (a) yn lle'r pennawd, y geiriau rhagarweiniol a pharagraff (1)(a) rhodder y pennawd canlynol -

- (d) NOGE not otherwise covered by this paragraph and which is used in such manufacture -
- (i) on or after 1st January 2005, or
 - (ii) prior to that date but on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.";
- (b) in paragraph (2), immediately after the expression "Part I" there shall be added the expression "or Part II";
- (c) for paragraph (3), there shall be substituted the following paragraph -
- "(3) Part III of Schedule 2 shall have effect to supplement this regulation and Parts I and II of that Schedule.";
- (d) in paragraph (4) -
- (i) for the expression "Part I of Schedule 2" there shall be substituted the expression "Part I or Part II of Schedule 2," and
 - (ii) in each of sub-paragraphs (a) and (b), for the word "therein" there shall be substituted the expression "that column".
- (e) between paragraphs 4 and 5 there shall be inserted the following paragraphs -
- "(4A) No plastic material or article manufactured using BADGE as an additive shall be capable of transferring constituents of that additive to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex I to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.
- (4B) No plastic material or article manufactured using BFDGE as an additive shall be capable of transferring constituents of that additive to food with which the plastic material or article may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.
- (4C) On and after 1st March 2003, no plastic material or article manufactured using NOGE as an additive shall fall to comply with the requirements of the first sentence of Article 4 of Commission Directive 2002/16."; and
- (f) in paragraph (5), for the expression "Part I of Schedule 2" there shall be substituted the expression "Part I or Part II of Schedule 2,".
- 9. In regulation 6 (method of testing capability of transferring constituents) -**
- (a) for the heading, the introductory words and paragraph (1)(a) there shall be substituted the following heading -

"Method of testing the capability of plastic materials or articles of transferring constituents and methods of analysis;

(1) For the purposes of these Regulations, a plastic material or article shall be treated as being capable of transferring constituents other than NOGE to food with which it may come into contact to the extent that such capability is established -

(a) in any case other than one to which subparagraph (b) below relates, and subject to Article 8.4 of Commission Directive 2001/62 (which may be applied on compliance with the conditions stated therein) by the verification methods specified in Schedules 3 and 4;" a

(b) ar ôl paragraff (3) ychwaneger y darpariaethau canlynol -

"(4) The specific migration from a plastic material or article shall, where applicable, be determined in the manner specified in the relevant sub-division of paragraph 8 of the Annex to the Directive.

(5) The specific migration from a plastic material or article of the substances listed in paragraph 1 of Annex I to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(6) The specific migration from a plastic material or article of the substances listed in paragraph 1 of Annex II to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(7) Whether or not the detection requirement specified in Article 4 of Commission Directive 2002/16 is complied with in relation to a plastic material or article shall be determined in the manner specified in the second sentence of that Article.

(8) The quantity of a constituent in a plastic material or article shall, where applicable, be determined in the manner specified in the subparagraph of paragraph 8 of Annex II to the Directive relating to the term "QM(T)" or, as the case may be, the sub-paragraph of that paragraph relating to the term "QMA".

10. Yn lle rheoliad 7A (manylebau) rhodder y rheoliad canlynol -

"Specifications

7A.-(1) Subject to paragraph (3), no plastic material or article manufactured using isocyanates or colourants prepared by diazo-coupling shall be capable of transferring primary aromatic amines (expressed as aniline), not being primary aromatic amines listed in these Regulations, to food with which that plastic material or article may come into contact.

"Method of testing the capability of plastic materials or articles of transferring constituents and methods of analysis;

(1) For the purposes of these Regulations, a plastic material or article shall be treated as being capable of transferring constituents other than NOGE to food with which it may come into contact to the extent that such capability is established -

(a) in any case other than one to which subparagraph (b) below relates, and subject to Article 8.4 of Commission Directive 2001/62 (which may be applied on compliance with the conditions stated therein) by the verification methods specified in Schedules 3 and 4;" and

(b) after paragraph (3) there shall be added the following provisions -

"(4) The specific migration from a plastic material or article shall, where applicable, be determined in the manner specified in the relevant sub-division of paragraph 8 of the Annex to the Directive.

(5) The specific migration from a plastic material or article of the substances listed in paragraph 1 of Annex I to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(6) The specific migration from a plastic material or article of the substances listed in paragraph 1 of Annex II to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(7) Whether or not the detection requirement specified in Article 4 of Commission Directive 2002/16 is complied with in relation to a plastic material or article shall be determined in the manner specified in the second sentence of that Article.

(8) The quantity of a constituent in a plastic material or article shall, where applicable, be determined in the manner specified in the subparagraph of paragraph 8 of Annex II to the Directive relating to the term "QM(T)" or, as the case may be, the sub-paragraph of that paragraph relating to the term "QMA".

10. For regulation 7A (specifications) there shall be substituted the following regulation -

"Specifications

7A.-(1) Subject to paragraph (3), no plastic material or article manufactured using isocyanates or colourants prepared by diazo-coupling shall be capable of transferring primary aromatic amines (expressed as aniline), not being primary aromatic amines listed in these Regulations, to food with which that plastic material or article may come into contact.

(2) Schedule 2B shall have effect for the purpose of prescribing, for certain items listed in Part I of Schedule 1, Part I or II of Schedule 2 or Schedule 2A, the specifications for those items which are referred to in column 4 of the Part or, as the case may be, Schedule concerned.

(3) For the purposes of paragraph (1), "detectable quantity" means a quantity of at least DLO.02 milligrams per kilogram of food or food simulant (analytical tolerance included)."

11. Yn union ar ôl rheoliad 8 (labelu) mewnosoder y rheoliadau canlynol -

"Restriction on manufacture with certain substances of adhesives materials and articles covered by surface coatings and adhesives

8A.-(1) No person shall (in any case not covered by Article 1(2) of Commission Directive 2002/16) use BADGE in the manufacture of any -

- (a) adhesive; or
- (b) material or article covered by a surface coating.

on or after 1st January 2005, or prior to that date, in contravention of the restriction specified in paragraph 1 of Annex 1 to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(2) No person shall (in any case not covered by Article 1.2 of Commission Directive 2002/16) use BFDGE in the manufacture of any -

- (a) adhesive; or
- (b) material or article covered by a surface coating

on or after 1st January 2005, or prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(3) No person shall (in any case not covered by Article 1(2) of Commission Directive 2002/16) use NOGE in the manufacture of any -

- (a) adhesive; or
- (b) material or article covered by a surface coating

on or after 1st January 2005, or prior to that date but, on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.

(4) No adhesive, or material or article covered by a surface coating, manufactured using BADGE and not covered by Article 1(2) of Commission Directive 2002/16, shall be capable of transferring constituents of BADGE to food with which the adhesive or, as the case may be, material or article, may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex 1 to that Directive, as read with the second sentence of paragraph 2 of that Annex.

(2) Schedule 2B shall have effect for the purpose of prescribing, for certain items listed in Part I of Schedule 1, Part I or II of Schedule 2 or Schedule 2A, the specifications for those items which are referred to in column 4 of the Part or, as the case may be, Schedule concerned.

(3) For the purposes of paragraph (1), "detectable quantity" means a quantity of at least DLO.02 milligrams per kilogram of food or food simulant (analytical tolerance included)."

11. Immediately after regulation 8 (labelling) there shall be inserted the following regulations -

"Restriction on manufacture with certain substances of adhesives materials and articles covered by surface coatings and adhesives

8A.-(1) No person shall (in any case not covered by Article 1(2) of Commission Directive 2002/16) use BADGE in the manufacture of any -

- (a) adhesive; or
- (b) material or article covered by a surface coating.

on or after 1st January 2005, or prior to that date, in contravention of the restriction specified in paragraph 1 of Annex 1 to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(2) No person shall (in any case not covered by Article 1.2 of Commission Directive 2002/16) use BFDGE in the manufacture of any -

- (a) adhesive; or
- (b) material or article covered by a surface coating

on or after 1st January 2005, or prior to that date in contravention of the restriction specified in paragraph 1 of Annex II to Commission Directive 2002/16, as read with the second sentence of paragraph 2 of that Annex.

(3) No person shall (in any case not covered by Article 1(2) of Commission Directive 2002/16) use NOGE in the manufacture of any -

- (a) adhesive; or
- (b) material or article covered by a surface coating

on or after 1st January 2005, or prior to that date but, on or after 1st March 2003, in contravention of the restriction specified in the first sentence of Article 4 of Commission Directive 2002/16.

(4) No adhesive, or material or article covered by a surface coating, manufactured using BADGE and not covered by Article 1(2) of Commission Directive 2002/16, shall be capable of transferring constituents of BADGE to food with which the adhesive or, as the case may be, material or article, may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex 1 to that Directive, as read with the second sentence of paragraph 2 of that Annex.

(5) No adhesive, or material or article covered by a surface coating, manufactured using BFDGE and not covered by Article 1(2) of Commission Directive 2002/16, shall be capable of transferring constituents of BFDGE to food with which that adhesive or, as the case may be, material or article, may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to that Directive, as read with the second sentence of paragraph 2 of that Annex.

(6) On and after 1st March 2003, no adhesive, or material or article covered by a surface coating, manufactured using NOGE and not covered by Article 1(2) of Commission Directive 2002/16, shall fail to comply with the requirements of the first sentence of Article 4 of that Directive.

Method of testing the capability of materials or articles covered by surface coatings and adhesives of transferring constituents and methods of analysis

8B.-(1) Subject to paragraphs (2) and (3) of this regulation, for the purposes of regulation 8A(1), (2), (4) and (5) an adhesive or a material or article covered by a surface coating shall be treated as being capable of transferring BADGE or, as the case may be, BFDGE to food with which it may come into contact to the extent that it is established for those purposes by the verification methods specified in Section A or Schedule 3 and in Schedule 4.

(2) Subject to paragraph (3) of this regulation, in Section A of Schedule 3 and in Schedule 4, references to migration or release of a substance shall be construed as references to the transfer of constituents to the simulant representing the food or, as the case may be, the food with which the substance may come into contact.

(3) For the purposes of paragraphs (1) and (2) of this regulation, Schedules 3 and 4 shall have effect as if -

- (a) the references in Section A of Schedule 3 and in Schedule 4 to "a plastic material or article" were references to "an adhesive or a material or article covered by a surface coating"; and
- (b) the references in paragraph 4(3) and (4) of Section A of Schedule 3 to "regulation 7, Schedule 1 or Schedule 2" were references to "a migration limited referred to in regulation 8A(4) or (5)"; and
- (c) the reference in paragraph 5 of Part II of Schedule 4 and paragraph 2(1)(b) of Part III of that Schedule to "regulation 7 or Schedule 1" were a reference to "regulation 8A(4) or (5)".

(4) The specific migration from an additive or a material or article covered by a surface coating of

(5) No adhesive, or material or article covered by a surface coating, manufactured using BFDGE and not covered by Article 1(2) of Commission Directive 2002/16, shall be capable of transferring constituents of BFDGE to food with which that adhesive or, as the case may be, material or article, may come into contact, in quantities exceeding the appropriate limit specified in paragraph 1 of Annex II to that Directive, as read with the second sentence of paragraph 2 of that Annex.

(6) On and after 1st March 2003, no adhesive, or material or article covered by a surface coating, manufactured using NOGE and not covered by Article 1(2) of Commission Directive 2002/16, shall fail to comply with the requirements of the first sentence of Article 4 of that Directive.

Method of testing the capability of materials or articles covered by surface coatings and adhesives of transferring constituents and methods of analysis

8B.-(1) Subject to paragraphs (2) and (3) of this regulation, for the purposes of regulation 8A(1), (2), (4) and (5) an adhesive or a material or article covered by a surface coating shall be treated as being capable of transferring BADGE or, as the case may be, BFDGE to food with which it may come into contact to the extent that it is established for those purposes by the verification methods specified in Section A or Schedule 3 and in Schedule 4.

(2) Subject to paragraph (3) of this regulation, in Section A of Schedule 3 and in Schedule 4, references to migration or release of a substance shall be construed as references to the transfer of constituents to the simulant representing the food or, as the case may be, the food with which the substance may come into contact.

(3) For the purposes of paragraphs (1) and (2) of this regulation, Schedules 3 and 4 shall have effect as if -

- (a) the references in Section A of Schedule 3 and in Schedule 4 to "a plastic material or article" were references to "an adhesive or a material or article covered by a surface coating"; and
- (b) the references in paragraph 4(3) and (4) of Section A of Schedule 3 to "regulation 7, Schedule 1 or Schedule 2" were references to "a migration limited referred to in regulation 8A(4) or (5)"; and
- (c) the reference in paragraph 5 of Part II of Schedule 4 and paragraph 2(1)(b) of Part III of that Schedule to "regulation 7 or Schedule 1" were a reference to "regulation 8A(4) or (5)".

(4) The specific migration from an additive or a material or article covered by a surface coating of

the substances listed in paragraph 1 of Annex I to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(5) The specific migration from an adhesive or a material or article covered by a surface coating of the substances listed in paragraph 1 of Annex II to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(6) Whether or not the detection limit specified in Article 4 of Commission Directive 2002/16 is complied with in relation to an adhesive or a material or article covered by a surface coating shall be determined in the manner specified in the second and third sentences of that Article."

12. Yn rheoliad 10 (tramgwyddau) -

- (a) ym mharagraff (1), yn lle'r ymadrodd "regulation 3, 4(1), 5(1) or 8" rhodder yr ymadrodd "3, 4(1), 4A(1), (2) or (3), 5(1), 8 or 8A(1), (2) or (3)";
- (b) ym mharagraffau (9) a (10), yn union ar ôl y geiriau "plastic material or article" mewnosoder y geiriau "or, as the case may be, adhesive or material or article covered by a surface coating,"; ac
- (c) yn union ar ôl paragraff (15) ychwaneger y paragraffau canlynol -

"(16) Subject to paragraph (18) of this regulation, in any proceedings for an offence under these Regulations, it shall be a defence to prove that -

- (a) the act constituting the offence was committed in relation to a plastic material or article which was put into circulation in the European Community before 30th November 2002; and
- (b) the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by the provisions referred to in paragraph (17) below had not been in force at the time that matter occurred.

(17) The provisions referred to in paragraph (16) of this regulation are regulations 5(d), 6(b), 8(a), (b) and (d), 10, 12(a) and 15 to 17 of the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2002 which implement or provide for the enforcement of the requirements of Commission Directive 2001/62 to which Article 2 of that Directive applies.

(18) For the purposes of paragraph (16) of this regulation, "free circulation" shall have the same meaning as in Article 2 of Commission Directive 2001/62.

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

the substances listed in paragraph 1 of Annex I to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(5) The specific migration from an adhesive or a material or article covered by a surface coating of the substances listed in paragraph 1 of Annex II to Commission Directive 2002/16 shall be determined in the manner specified in paragraph 3 of that Annex.

(6) Whether or not the detection limit specified in Article 4 of Commission Directive 2002/16 is complied with in relation to an adhesive or a material or article covered by a surface coating shall be determined in the manner specified in the second and third sentences of that Article."

12. In regulation 10 (offences) -

- (a) in paragraph (1), for the expression "regulation 3, 4(1), 5(1) or 8" there shall be substituted the expression "3, 4(1), 4A(1), (2) or (3), 5(1), 8 or 8A(1), (2) or (3)";
- (b) in each of paragraphs (9) and (10), immediately after the words "plastic material or article" there shall be inserted the words "or, as the case may be, adhesive or material or article covered by a surface coating,"; and
- (c) immediately after paragraph (15) there shall be added the following paragraphs -

"(16) Subject to paragraph (18) of this regulation, in any proceedings for an offence under these Regulations, it shall be a defence to prove that -

- (a) the act constituting the offence was committed in relation to a plastic material or article which was put into circulation in the European Community before 30th November 2002; and
- (b) the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by the provisions referred to in paragraph (17) below had not been in force at the time that matter occurred.

(17) The provisions referred to in paragraph (16) of this regulation are regulations 5(d), 6(b), 8(a), (b) and (d), 10, 12(a) and 15 to 17 of the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2002 which implement or provide for the enforcement of the requirements of Commission Directive 2001/62 to which Article 2 of that Directive applies.

(18) For the purposes of paragraph (16) of this regulation, "free circulation" shall have the same meaning as in Article 2 of Commission Directive 2001/62.

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

- (a) the act constituting the offence consisted was the sale of an adhesive or a material or article covered by a surface coating -
 - (i) which was brought into contact with food before 28th February 2003,
 - (ii) on which (in the case of a material or article covered by a surface coating) the date of filling appeared at the time of sale; and
 - (iii) the labelling or marking of which at the time of sale (in the case of a material or article covered by a surface coating) complied with the requirement as regards labelling relating to durability contained in Article 2.1(a) of Directive 2000/13/EC of the European Parliament and the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs(a);
- (b) the sale would not have constituted an offence under these Regulations if the amendments made to them by the provisions referred to in paragraph (20) below had not been in force at the time of sale.

(20) The provisions referred to in paragraph (18) above are regulations 5(b) and (f), 8A and 12(a) of those provisions of the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2002".

13. Yn rheoliad 11 (rhagdybiaeth ynghylch bwyd y mae deunydd neu eitem blastig i ddod i gysylltiad ag ef) a'r pennawd iddo, yn union ar ôl y geiriau "plastic material or article", lle bynnag y maent yn ymddangos, mewnosoder y geiriau ", adhesive or material or article covered by a surface coating".

14. Yn rheoliad 12 (cymhwysio darpariaethau eraill) -

- (a) ym mharagraff (1), ar ôl y geiriau "plastic materials or articles" ychwaneger y geiriau ", adhesives and materials or articles covered by a surface coating"; a
- (b) ym mharagraff (3), yn lle'r geiriau "relate to plastic materials or articles" rhodder y geiriau "apply to plastic materials or articles, adhesives or materials or articles covered by a surface coating".

15 Yn Atodlen 1 (monomerau a awdurdodwyd heb derfyn amser, monomerau a awdurdodwyd tan ddiwedd 2001, monomerau a awdurdodwyd tan ddiwedd 1998 ac ategolion) -

- (a) yn Adran A o Ran I -
 - (i) yn achos pob monomer a restrir yn Rhan I o Atodlen 1 i'r Rheoliadau hyn,

- (a) the act constituting the offence consisted was the sale of an adhesive or a material or article covered by a surface coating -
 - (i) which was brought into contact with food before 28th February 2003,
 - (ii) on which (in the case of a material or article covered by a surface coating) the date of filling appeared at the time of sale; and
 - (iii) the labelling or marking of which at the time of sale (in the case of a material or article covered by a surface coating) complied with the requirement as regards labelling relating to durability contained in Article 2.1(a) of Directive 2000/13/EC of the European Parliament and the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs(a);
- (b) the sale would not have constituted an offence under these Regulations if the amendments made to them by the provisions referred to in paragraph (20) below had not been in force at the time of sale.

(20) The provisions referred to in paragraph (18) above are regulations 5(b) and (f), 8A and 12(a) of those provisions of the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2002".

13. In regulation 11 (presumption as to food with which a plastic material or article is to come into contact) and the heading thereto, immediately after the words "plastic material or article", wherever they appear, there shall be inserted the words ", adhesive or material or article covered by a surface coating".

14. In regulation 12 (application of other provisions) -

- (a) in paragraph (1), after the words "plastic materials or articles" there shall be added the words ", adhesives and materials or articles covered by a surface coating"; and
- (b) in paragraph (3), for the words "relate to plastic materials or articles" there shall be substituted the words "apply to plastic materials or articles, adhesives or materials or articles covered by a surface coating".

15. In Schedule 1 (monomers authorised without time limit, monomers authorised up to the end of 2001, monomers authorised up to the end of 1998 and supplementary) -

- (a) in Section A of Part I -
 - (i) in the case of each monomer listed in Part I of Schedule 1 to these Regulations, the

(a) OJ Rhif L109, 6.5.2000, t.29.

(a) OJ No. L109, 6.5.2000, p.29.

mewnosodir rhif a llythyren yr eitem, PM/REF No, CAS No. (os o gwbl), yr enw a'r cyfyngiad neu'r fanyleb a bennir ar gyfer y monomer hwnnw yn y Rhan honno yn y safle rhifiadol priodol ar gyfer rhif a llythyren yr eitem hwnnw,

- (ii) yn achos pob monomer a enwir yn ail golofn Rhan II o Atodlen 1 i'r Rheoliadau hyn, yn lle rhif a llythyren y monomer a bennir gyferbyn ag ef yn y golofn gyntaf (item) rhodder rhif a llythyren yr eitem ar ei gyfer a bennir yn y golofn gyntaf (item) o'r Rhan honno, a
- (iii) yn achos pob monomer a enwir yng ngholofn gyntaf Rhan III o Atodlen 1 i'r Rheoliadau hyn, yn lle'r cofnod i'r monomer hwnnw a bennir gyferbyn ag ef yng ngholofn 4 (cyfyngiadau a manylebau) rhodder y cofnod iddo a bennir yn ail golofn y Rhan honno (cyfyngiadau a manylebau);

(b) yn lle Adran B o Ran I rhodder cynnwys Rhan IV o Atodlen 1 i'r Rheoliadau hyn; ac

(c) yn Rhan II, yn lle paragraff 4 rhodder y paragraff canlynol -

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

- (1) Warning: there is a risk that the specific migration limit could be exceeded in fatty food simulants.
- (2) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.
- (3) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.
- (4) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.
- (5) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.
- (14) SML(T) in this case means that the restriction shall not be exceeded by the

item number and letter, PM/REF No. CAS No. (if any), name and restriction or specification specified for that monomer in that Part shall be inserted in the appropriate numerical position for that item number and letter,

- (ii) in the case of each monomer named in the second column of Part II of Schedule 1 to these Regulations, for the item number and letter for that monomer specified opposite to it in the first column (item) there shall be substituted the item number and letter for it specified in the first column (item) of that Part, and
- (iii) in the case of each monomer named in the first column of Part III of Schedule 1 to these Regulations, for the entry for that monomer specified opposite to it in column 4 (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of that Part;

(b) for Section B of Part I there shall be substituted the contents of Part IV of Schedule 1 to these Regulations; and

(c) in Part II, for paragraph 4 there shall be substituted the following paragraph -

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

- (1) Warning: there is a risk that the specific migration limit could be exceeded in fatty food simulants.
- (2) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.
- (3) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.
- (4) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.
- (5) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.
- (14) SML(T) in this case means that the restriction shall not be exceeded by the

sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(21) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260 and 18670."

16. Yn Atodlen 2 (ychwanegion ac ategolion) -

(a) Yn Rhan I -

- (i) yn lle'r pennawd "Part I Additives" rhodder y pennawd "Part I : Incomplete list of additives used in the manufacture of plastic materials and articles (not being additives to which paragraph 5 of Part III of this Schedule applies)",
- (ii) yn achos pob ychwanegyn a restrir yn Rhan I o Atodlen 1 i'r Rheoliadau hyn, mewnosodir rhif a llythyren yr eitem, PM/REF No, CAS No. (os o gwbl), yr enw a'r cyfyngiad neu'r fanyleb a bennir ar gyfer yr ychwanegyn hwnnw yn y Rhan honno yn y safle rhifiadol priodol ar gyfer rhif a llythyren yr eitem hwnnw,
- (iii) yn achos pob ychwanegyn a enwir yn ail golofn Rhan II o Atodlen 1 i'r Rheoliadau hyn, yn lle rhif a llythyren yr ychwanegyn a bennir gyferbyn ag ef yn y golofn gyntaf gyda'r pennawd "Item" rhodder rhif a llythyren yr eitem ar ei gyfer a bennir yn y golofn gyntaf (item) o'r Rhan honno, a
- (iv) yn achos pob ychwanegyn a enwir yng ngholofn gyntaf Rhan III o Atodlen 1 i'r Rheoliadau hyn, yn lle'r cofnod i'r ychwanegyn hwnnw a bennir gyferbyn ag ef yng ngholofn 4 (cyfyngiadau a manylebau) rhodder y cofnod iddo a bennir yn ail golofn y Rhan honno (cyfyngiadau a manylebau); a

(v) dileir pob cofnod am yr ychwanegyn Sicilic acid, salts, (eitem 241);

(b) yn union ar ôl Rhan I mewnosoder cynnwys Rhan IV o Atodlen 2 i'r Rheoliadau hyn (hwy fydd Rhan II o Atodlen 2 i'r prif Rheoliadau pan ddaw'r Rheoliadau hyn i rym);

(c) yn Rhan II -

- (i) yn y pennawd, yn lle'r ymadrodd "Part II" rhodder yr ymadrodd "Part III";
- (ii) ym mharagraff 1, yn lle'r ymadrodd "Part I" rhodder yr ymadrodd "Parts I and II";
- (iii) ym mhob un o baragraffau 2, 3 a 4, yn

sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(21) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260 and 18670."

16. In Schedule 2 (additives and supplementary) -

(a) In Part I -

- (i) for the heading "Part I Additives" there shall be substituted the heading "Part I: Incomplete list of additives used in the manufacture of plastic materials and articles (not being additives to which paragraph 5 of Part III of this Schedule applies)",
- (ii) in the case of each additive listed in Part I of Schedule 2 to these Regulations, the item number and letter, PM/REF No., CAS No. (if any), name and restriction or specification (if any) specified for that additive in that Part shall be inserted in the appropriate numerical position for that item number and letter,
- (iii) in the case of each additive named in the second column of Part II of Schedule 2 to these Regulations, for the item number for that additive specified opposite to it in the column headed "Item" there shall be substituted the item number for it specified in the first column (item) of that Part,
- (iv) in the case of each additive named in the first column of Part III of Schedule 2 to these Regulations, for the entry for that additive specified opposite to it in column 4 (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of that Part, and

(v) all the entries for the additive Silicic acid, salts, (item 241) shall be deleted;

(b) immediately after Part I there shall be inserted the contents of Part IV of Schedule 2 to these Regulations (which shall become Part II of Schedule 2 to the principal Regulations on the coming into force of these Regulations);

(c) in Part II -

- (i) in the heading, for the expression "Part II" there shall be substituted the expression "Part III";
- (ii) in paragraph 1, for the expression "Part I" there shall be substituted the expression "Parts I and II";
- (iii) in each of paragraphs 2, 3 and 4, immediately after the expression "Part I"

union ar ôl yr ymadrodd "Part I" ychwaneger yr ymadrodd "or Part II"; a

- (iv) yn lle paragraff 4 rhodder y paragraff canlynol -

"4. Where an entry in column 4 of Part I or in column 4 of Part II of this Schedule (in each case restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in those Parts:

- (1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.
- (2) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.
- (3) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.
- (4) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.
- (5) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.
- (6) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 66560 and 66580.
- (7) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.
- (8) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 42400, 64320, 73040, 85760, 85840, 85920 and 95725.
- (9) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.
- (10) SML(T) in this case means that the restriction shall not be exceeded by the

there shall be added the expression "or Part II"; and

- (iv) for paragraph 4 there shall be substituted the following paragraph -

"4. Where an entry in column 4 of Part I or in column 4 of Part II of this Schedule (in each case restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in those Parts:

- (1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.
- (2) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.
- (3) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.
- (4) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.
- (5) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.
- (6) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 66560 and 66580.
- (7) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.
- (8) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 42400, 64320, 73040, 85760, 85840, 85920 and 95725.
- (9) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.
- (10) SML(T) in this case means that the restriction shall not be exceeded by the

sum of the migration levels of the substances having PM/REF Nos. 45200, 64320, 81680 and 86800.

- (11) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 36720, 36800 and 92000.
- (12) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 39090 and 39120.
- (13) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 44960, 68078, 82020 and 89170.
- (14) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.
- (15) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 49600, 67520 and 83599.
- (16) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.
- (17) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 67600, 67680 and 67760.
- (18) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 60400, 60480 and 61440.
- (19) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 66400 and 66480.
- (20) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 93120 and 93280.
- (21) SML(T) in this case means that the restriction shall not be exceeded by the

sum of the migration levels of the substances having PM/REF Nos. 45200, 64320, 81680 and 86800.

- (11) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 36720, 36800 and 92000.
- (12) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 39090 and 39120.
- (13) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 44960, 68078, 82020 and 89170.
- (14) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.
- (15) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 49600, 67520 and 83599.
- (16) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.
- (17) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 67600, 67680 and 67760.
- (18) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 60400, 60480 and 61440.
- (19) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 66400 and 66480.
- (20) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 93120 and 93280.
- (21) SML(T) in this case means that the restriction shall not be exceeded by the

sum of the migration levels of the substances having PM/REF Nos. 17260 and 18670."; and

(ch) yn union ar ôl paragraff 4 ychwaneger y paragraff canlynol -

"5. In the case of the substances listed in Part II of this Schedule, the specific migration limits specified in column 4 of that Part (restrictions and specifications) shall have effect from 1st January 2004 where the verification of compliance is carried out in simulant D or in test media of substitute tests as prescribed in Council Directive 82/711/EEC(a) and Council Directive 85/572/EEC(b)."

17. Yn Atodlen 2B (manylebau) yn achos pob sylwedd a restrir yn Atodlen 3 i'r Rheoliadau hyn, mewnsodir rhif a llythyren yr eitem, PM/REF No. a'r fanyleb a nodir ar gyfer y sylwedd hwnnw yn yr Atodlen honno yn y safle rhifiadol priodol ar gyfer rhif a llythyren yr eitem hwnnw.

18. Yn Atodlen 3 (y darpariaethau cymwys wrth brofi cydymffurfedd â therfynau mudo) -

(a) yn is-baragraffau (3) a (4) o baragraff 4, ar ôl y geiriau "specified in regulation" mewnosoder yr ymadrodd "4(5A), 4A(4) or (5), 5(4A) or (4B), or"; a

(b) yn lle is-baragraff (2)(b) o baragraff 8 rhodder yr is-baragraff canlynol -

"(b) 12 mg/kg or, as the case may be, 2 milligrams per square decimeter in migration tests using other simulants referred to in Schedule 4."

Diwygio Rheoliadau Diogelwch Bwyd (Samplu a Chymwysterau) 1990

19. Yn Atodlen 1 i Reoliadau Diogelwch Bwyd (Samplu a Chymwysterau) 1990(c) (darpariaethau nad yw'r Rheoliadau hyn yn gwymlwys iddynt) diwygir y cyfeiriad yn yr ail golofn, gyferbyn â'r cyfeiriad yn y golofn gyntaf at Reoliadau Deunyddiau ac Eitemau Plastig mewn cysylltiad â Bwyd 1998, mewn perthynas â Chymru i ddarllen "S.I. 1998/1376 as amended by S.I. 2000/3162 and S.I. 2002/2834.

(a) OJ Rhif L297, 23.10.82, t.26, a ddiwygiwyd ddiwethaf gan Ggyfarwydddeb y Comisiwn 97/48/EC (OJ Rhif L222, 12.8.97, t.10).

(b) OJ Rhif L372, 31.12.85, t.14.

(c) O.S. 1990/2463; y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

sum of the migration levels of the substances having PM/REF Nos. 17260 and 18670."; and

(d) immediately after paragraph 4 there shall be added the following paragraph -

"5. In the case of the substances listed in Part II of this Schedule, the specific migration limits specified in column 4 of that Part (restrictions and specifications) shall have effect from 1st January 2004 where the verification of compliance is carried out in simulant D or in test media of substitute tests as prescribed in Council Directive 82/711/EEC(a) and Council Directive 85/572/EEC(b)."

17. In Schedule 2B (specifications) in the case of each substance listed in Schedule 3 to these Regulations, the item number and letter, PM/REF No. and specification set out for that substance in that Schedule shall be inserted in the appropriate numerical position for that item number and letter.

18. In Schedule 3 (provisions applicable when testing compliance with the migration limits) -

(a) in each of sub-paragraphs (3) and (4) of paragraph 4, after the words "specified in regulation" there shall be inserted the expression "4(5A), 4A(4) or (5), 5(4A) or (4B), or"; and

(b) for sub-paragraph (2)(b) of paragraph 8 there shall be substituted the following sub-paragraph -

"(b) 12 mg/kg or, as the case may be, 2 milligrams per square decimeter in migration tests using other simulants referred to in Schedule 4."

Amendment of the Food Safety (Sampling and Qualifications) Regulations 1990

19. In Schedule 1 to the Food Safety (Sampling and Qualifications) Regulations 1990(c) (provisions to which those Regulations do not apply) the reference in the second column, opposite the reference in the first column to the Plastic Materials and Articles in Contact with Food Regulations 1998, shall be amended in relation to Wales so as to read "S.I. 1998/1376 as amended by S.I. 2000/3162 and S.I. 2002/2834.

(a) OJ No. L297, 23.10.82, p.26, last amended by Commission Directive 97/48/EC (OJ No. L222, 12.8.97, p.10).

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

(c) S.I. 1990/2463; to which there are amendments not relevant to these Regulations.

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

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

7 Tachwedd 2002

7th November 2002

Rhodri Morgan

Prif Weinidog y Cynulliad Cenedlaethol

The First Minister of the National Assembly

ATODLEN 1

Rheoliad 15(a) a (b)

RHAN I

**RHESTR O FONOMERAU I'W
HYCHWANEGU AT ADRAN A O RAN I O
ATODLEN 1 I'R PRIF REOLIADAU**

SCHEDULE 1

Regulation 15(a) and (b)

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
15A	11530	00999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0.05 mg/6 dm ²
28B	12763	00141-43-5	2-Aminoethanol	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
28C	12765	84434-12-8	N-(2-aminoethyl)- beta-alanine, sodium salt	SML = 0.05 mg/kg
38A	13395	04767-03-7	2,2-Bis(hydroxymethyl) propionic acid	QMA = 0.05 mg/6 dm ²
47A	13617	00080-09-1	Bisphenol S	As item 86A
49B	13810	00505-65-7	1,4-Butanediol formal	QMA = 0.05 mg/6 dm ²
52A	13932	00598-32-3	3-Buten-2-ol	QMA = ND (DL = 0.02 mg/6 dm ²). To be used only as a co-monomer for the preparation of polymeric additive
70A	15030	00931-88-4	Cyclooctene	SML = 0.05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Council Directive 85/572/EEC
76A	15370	03236-53-1	1,6-Diamino-2,2, 4-trimethylhexane	QMA = 5 mg/6 dm ²
76B	15400	03236-54-2	1,6-Diamino-2,4, 4-trimethylhexane	QMA = 5 mg/6 dm ²
77A	15610	00080-07-9	4,4'-Dichlorodiphenyl sulphone	SML = 0.05 mg/kg
86A	16090	00080-09-01	4,4'-Dihydroxydiphenyl sulphone	SML = 0.05 mg/kg
88B	16390	00126-30-7	2,2-Dimethyl-1, 3-propanediol	SML = 0.05 mg/kg
121B	19110	04098-71-9	1-Isocyanato -3-isocyanatomethyl-3,5, 5-trimethylcyclohexane	QM(T) = 1 mg/kg in FP (as NCO)
122A	19243	00078-79-5	Isoprene	As item 145A
126A	19490	00947-04-6	Lauro lactam	SML = 5 mg/kg

135A	20260	00101-43-9	Methacrylic acid, cyclohexyl ester	SML = 0.05 mg/kg
135B	20410	02082-81-7	Methacrylic acid, diester with 1, 4-butanediol	SML = 0.05 mg/kg
135D	20590	00106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QMA=0.02mg/6dm ²
144A	21520	01561-92-8	Methallylsulphonic acid, sodium salt	SML = 5 mg/kg
145A	21640	00078-79-5	2-Methyl-1,3-butadiene	QM = 1 mg/kg in FP or SML = ND (DL = 0.02 mg/kg, analytical tolerance included)
145C	21765	106246-33-7	4,4'-Methylenebis (3-chloro-2, 6-diethylaniline)	QMA = 0.05 mg/6 dm ²
145D	21821	00505-65-7	1,4-(Methylenedioxy) butane	As item 49B
148A	22360	01141-38-4	2,6-Naphthalenedi carboxylic acid	SML = 5 mg/kg
150A	22437	00126-30-7	Neopentylglycol	As item 88B
156A	22778	07456-68-0	4,4'-Oxybis (benzenesulphonyl azide)	QMA = 0.05 mg/6 dm ²
159A	22900	00109-67-1	1-Pentene	SML = 5 mg/kg
184A	24073	000101-90-6	Resorcinol diglycidyl	QMA = 0.005 mg/g dm ² . Not for ether use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
214A	25380		Trialkyl acetic acid (C7-C17), vinyl esters (= vinyl versatate)	QMA = 0.05 mg/g dm ²
215A	25450	26896-48-0	Tricyclodecanedimethanol	SML = 0.05 mg/kg
217A	25900	00110-88-3	Trioxane	SML = 0.05 mg/kg

RHAN II

**RHESTR O FONOMERAU Y MAE'R
COFNOD AMDANYNT A GYNHWYSIR YNG
NGHOLOFN GYNTAF (ITEM) ADRAN A O
RAN I O ATODLEN 1 I'R PRIF REOLIADAU
I'W DIWYGIO**

PART II

**LIST OF MONOMERS FOR WHICH THE
ENTRY CONTAINED IN THE FIRST COLUMN
(ITEM) OF SECTION A OF PART I OF
SCHEDULE 1 TO THE PRINCIPAL
REGULATIONS IS TO BE AMENDED**

Item	Name
52B	4-tert-Butylphenol
88C	1,3 Dioxolane
121C	Isophthalic acid
135C	Methacrylic acid, 2-(dimethylamino) ethyl ester
145B	3-Methyl-1-butene
159B	Perfluoropropyl perfluorovinyl ether
214B	Triallylamine

RHAN III

**RHESTR O FONOMERAU Y MAE'R
COFNOD AMDANYNT A GYNHWYSIR YNG
NGHOLOFN 4 (CYFYNGIADAU A
MANYLEBAU) O ADRAN A O RAN I O
ATODLEN 1 I'R PRIF REOLIADAU I'W
DIWYGIO**

PART III

**LIST OF MONOMERS FOR WHICH THE
ENTRY CONTAINED IN COLUMN 4
(RESTRICTIONS AND SPECIFICATIONS) OF
SECTION A OF PART I OF SCHEDULE 1 TO
THE PRINCIPAL REGULATIONS IS TO BE
AMENDED**

Name	Restrictions and specifications
2,2-Bis(4-hydroxyphenyl) propane bis(2,3-epoxypropyl) ether (= BADGE)	In any case not covered by article 1.2 of Commission Directive [2002/16], use must be before 1st January 2005 and be as specified in paragraph 1 of Annex I to that Directive
4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
Formaldehyde	SML(T) = 15 mg/kg (21)
Hexamethylenetetramine	SML(T) = 15 mg/kg (expressed as formaldehyde) (21)
1,3-Phenylenediamine	SML = ND (DL = 0.02 mg/kg, analytical tolerance included)

RHAN IV

**DARPARIAETHAU A AMNEWIDIR AM
ADRAN B O RAN I O ATODLEN 1 I'R PRIF
REOLIADAU**

**"SECTION B: MONOMERS AUTHORISED
UP TO THE END OF 2004**

PART IV

**PROVISIONS SUBSTITUTED FOR SECTION
B OF PART I OF SCHEDULE 1 TO THE
PRINCIPAL REGULATIONS**

**"SECTION B: MONOMERS AUTHORISED
UP TO THE END OF 2004**

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
1	10599/90A	61788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	
2	10599/91	61788-89-4	Acids, fatty, unsaturated (C18), dimers, non-distilled	
3	10599/92A	68783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled	
4	10599/93	68783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non-distilled	
5	11500	00103-11-7	Acrylic acid, 2-ethylhexyl ester	
6	13050	00528-44-9	1,2,4-Benzenetricarboxylic acid	As item 23
7	13075	00091-76-9	Benzoguanamine	
8	13720	00110-63-4	1,4-Butanediol	
9	14260	00502-44-3	Caprolactone	
10	14800	03724-65-0	Crotonic acid	
11	15310	00091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	
12	15730	00077-73-6	Dicyclopentadiene	
13	16210	06864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexylmethane	
14	16690	01321-74-0	Divinylbenzene	
15	16697	00693-23-2	Dodecanedioic acid	
16	17110	16219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	
17	18370	00592-45-0	1,4-Hexadiene	
18	18700	00629-11-8	1,6-Hexanediol	
19	21370	10595-80-9	Methacrylic acid, 2-sulphoethyl ester	
20	21400	54276-35-6	Methacrylic acid, sulphopropyl ester	

21	21970	00923-02-4	N-methylolmethacrylamide	
22	22210	00098-83-9	Alpha-methylstyrene	
23	25540	00528-44-9	Trimellitic acid	QM(T) = 5 mg/kg in FP
24	25550	00552-30-7	Trimellitic anhydride	QM(T) = 5 mg/kg in FP (expressed as trimellitic acid)
25	25840	03290-92-4	1,1,1-Trimethylopropane trimethacrylate	
26	26230	00088-12-0	Vinylpyrrolidone	

"

ATODLEN 2

Rheoliad 16(a) a (b)

RHAN I

**RHESTR O YCHWANEGION I'W
HYCHWANEGU AT RAN I O ATODLEN 2 I'R
PRIF REOLIADAU**

SCHEDULE 2

Regulation 16(a) and (b)

PART I

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

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
19A	35160	06642-31-5	6-Amino-1,3-dimethyluracil	SML = 5 mg/kg
19B	35170	00141-43-5	2-Aminoethanol	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
19C	35284	00111-41-1	N-(2-aminoethyl) ethanolamine	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
36E	38840	154862-43-8	Bis(-2,4-dicumylphenyl) pentaerythritoldiphosphite	SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl) pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol))
38A	39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethyl hexane	SML = 0.05 mg/kg
41A	41120	10043-52-4	Calcium chloride	
45A	41840	00105-60-2	Caprolactam	SML(T) = 15 mg/kg (6)
72B	47210	26427-07-6	Dibutylthiostannoic acid polymer [= thiobis(butyl-tin sulphide), polymer]	In compliance with the specifications laid down in Schedule 2B
73A	47540	27458-90-8	Di-tert-dodecyl disulfide	SML = 0.05 mg/kg
73D	48620	00123-31-9	1,4-Dihydroxybenzene	SML = 0.6 mg/kg
73E	48720	00611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
77A	52645	10436-08-5	Cis-11-eicosenamide	
164A	64800	00110-16-7	Maleic acid	SML(T) = 30 mg/kg (4)
167A	65920	66822-60-4	[N-methacryloyloxyethyl-N,N-dimethyl-N-carboxymethyl-ammonium chloride, sodium salt-octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers	

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
191A	73160		Phosphoric acid, mono- and di-n-alkyl (C16 and C18) esters	SML = 0.05 mg/kg
195B	76730		Polydimethylsiloxane, gamma-hydroxypropylated	SML = 6 mg/kg
240B	85680	01343-98-2	Silicic acid	
271A	92150	01401-55-4	Tannic acids	According to the JECFA specifications
279A	93270	00108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
281A	95270	161717-32-4	2,4,6-Tris(tert-butyl) phenyl 2-butyl-2-ethyl-1,3-propanediol phosphite	SML = 2 mg/kg (as sum of phosphite, phosphate and the hydrolysis product = TTBP)

RHAN II

**RHESTR O YCHWANEGION Y MAE'R
COFNOD AMDANYNT A GYNHWYSIR YNG
NGHOLOFN GYNTAF (ITEM) RHAN I O
ATODLEN 1 I'R PRIF REOLIADAU I'W
DIWYGIO**

PART II

**LIST OF ADDITIVES FOR WHICH THE
ENTRY CONTAINED IN THE FIRST COLUMN
(ITEM) OF PART I OF SCHEDULE 1 TO THE
PRINCIPAL REGULATIONS IS TO BE
AMENDED**

Item	Name
36F	Bis(3-4-dimethylbenzylidene)sorbitol
38B	Bis(polyethyleneglycol)hydroxymethyl-phosphonate
73B	Diethyleneglycol
73C	1,1-Difluoroethane
73F	2,4-Dimethyl-6-(1-methylpentadecyl)phenol
191B	Phosphoric acid, trichloroethyl ester
195C	Polyesters of 1,2-propanediol and/or 1,3-and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and/or n-decanol
208B	Poly (zinc glycerolate)
240C	Silicic acid, lithium, magnesium, sodium salt
281B	Vermiculite, reaction product with citric acid, lithium salt
281C	Water
281D	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feed stocks
281E	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feed stocks

RHAN III**PART III****RHESTR O YCHWANEGION Y MAE'R
COFNOD AMDANYNT A GYNHWYSIR YNG
NGHOLOFN 4 (CYFYNGIADAU A
MANYLEBAU) O RAN I O ATODLEN 2 I'R
PRIF REOLIADAU I'W DIWYGIO****LIST OF ADDITIVES FOR WHICH THE
ENTRY CONTAINED IN COLUMN 4
(RESTRICTIONS AND SPECIFICATIONS) OF
PART I OF SCHEDULE 2 TO THE PRINCIPAL
REGULATIONS IS TO BE AMENDED**

Name	Restrictions and specifications
Bis(polyethylenelycol)hydroxymethyl-phosphonate	SML = 0.6 mg/kg. Authorised until 1st January 2004
Copper iodide	SML(T) = 30 mg/kg ⁽⁷⁾ (expressed as copper) and the specific migration of this substance shall not exceed 1 mg/kg ⁽¹⁰⁾ (expressed as iodine)
2'-(2-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg ⁽¹⁸⁾

RHAN IV

PART IV

DARPARIAETHAU A FEWNOSODIR AR ÔL
RHAN I O ATODLEN 2 I'R PRIF
REOLIADAU

PROVISIONS INSERTED AFTER PART I OF
SCHEDULE 2 TO THE PRINCIPAL
REGULATIONS

"PART II: INCOMPLETE LIST OF
ADDITIVES USED IN THE MANUFACTURE
OF PLASTIC MATERIALS AND ARTICLES
(BEING ADDITIVES TO WHICH PARAGRAPH
5 OF PART III OF THIS SCHEDULE APPLIES)

"PART II: INCOMPLETE LIST OF
ADDITIVES USED IN THE MANUFACTURE
OF PLASTIC MATERIALS AND ARTICLES
(BEING ADDITIVES TO WHICH PARAGRAPH
5 OF PART III OF THIS SCHEDULE APPLIES)

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
1	30180	02180-18-9	Acetic acid, manganese salt	SML(T) = 0.6 mg/kg (⁹) (expressed as manganese)
2	31520	61167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	SML = 6 mg/kg
3	31920	00103-23-1	Adipic acid, bis(2-ethylhexyl) ester	SML = 18 mg/kg (¹)
4	34230		Alkyl(C8-C22)sulphonic acids	SML = 6 mg/kg
5	35760	01309-64-4	Antimony trioxide	SML = 0.02 mg/kg (expressed as antimonium and analytical tolerance included)
6	36720	17194-00-2	Barium hydroxide	SML(T) = 1 mg/kg (¹¹) (expressed as barium)
7	36800	10022-31-8	Barium nitrate	SML(T) = 1 mg/kg (¹¹) (expressed as barium)
8	38240	00119-61-9	Benzophenone	SML = 0.6 mg/kg
9	38560	07128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML = 0.6 mg/kg
10	38700	63397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctylmercaptoacetate)	SML = 18 mg/kg
11	38800	32687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	SML = 15 mg/kg
12	38820	26741-53-7	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	SML = 0.6 mg/kg
13	39060	35958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	SML = 5 mg/kg
14	39090		N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	SML(T) = 1.2 mg/kg (¹²)
15	39120		N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides	SML(T) = 1.2 mg/kg (¹²) (expressed as N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine)
16	40000	00991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	SML = 30 mg/kg
17	40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	SML = 6 mg/kg

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
18	40160	61269-61-2	N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	SML = 2.4 mg/kg
19	40800	13003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	SML = 6 mg/kg
20	40980	19664-95-0	Butyric acid, manganese salt	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
21	42000	63438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctylmercaptoacetate)	SML = 30 mg/kg
22	42400	10377-37-4	Carbonic acid, lithium salt	SML(T) = 0.6 mg/kg ⁽⁸⁾ (expressed as lithium)
23	42480	00584-09-8	Carbonic acid, rubidium salt	SML = 12 mg/kg
24	43600	04080-31-3	1-(3-Chloroallyl)-3,5,7-triazol-1-azoniaadamantane chloride	SML = 0.3 mg/kg
25	43680	00075-45-6	Chlorodifluoromethane	SML = 6 mg/kg and in compliance with the specifications laid down in Schedule 2B
26	44960	11104-61-3	Cobalt oxide	SML(T) = 0.05 mg/kg ⁽¹³⁾ (expressed as cobalt)
27	45440	-	Cresols, butylated, styrenated	SML = 12 mg/kg
28	46720	04130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4.8 mg/6 dm ²
29	47600	84030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML = 12 mg/kg
30	48640	00131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁴⁾
31	48800	00097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	SML = 12 mg/kg
32	48880	00131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁴⁾
33	49600	26636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	SML(T) 0.18 mg/kg ⁽¹⁵⁾ (expressed as tin)
34	49840	02500-88-1	Diocetadecyl disulphide	SML = 3 mg/kg
35	50160		Di-n-octyltin bis(n-alkyl(C10-C16) mercapto acetate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
36	50240	10039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
37	50320	15571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
38	50360		Di-n-octyltin bis(ethyl maleate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
39	50400	33568-99-9	Di-n-octyltin bis(isooctyl maleate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
40	50480	26401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
41	50560		Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
42	50640	03648-18-8	Di-n-octyltin dilaurate	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
43	50720	15571-60-5	Di-n-octyltin dimaleate	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
46	50960	69226-44-4	Di-n-octyltin ethyleneglycol bis (mercaptoacetate)	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
47	51040	15535-79-2	Di-n-octyltin mercaptoacetate	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
48	51120		Di-n-octyltin thiobenzoate 2-ethyl-hexyl mercaptoacetate	SML(T) = 0.04 mg/kg ⁽¹⁶⁾ (expressed as tin)
49	51570	00127-63-9	Diphenyl sulphone	SML = 3 mg/kg
50	51680	00102-08-9	N,N'-diphenylthiourea	SML = 3 mg/kg
51	52000	27176-87-0	Dodecylbenzenesulphonic acid	SML = 30 mg/kg
52	52320	52047-59-3	2-(4-Dodecylphenyl)indole	SML = 0.06 mg/kg
53	52880	23676-09-7	4-Ethoxybenzoic acid, ethyl ester	SML = 3.6 mg/kg
54	53200	23949-66-8	2-Ethoxy-2'-ethyloxanilide	SML = 30 mg/kg
55	58960	00057-09-0	Hexadecyltrimethylammonium bromide	SML = 6 mg/kg
56	59120	23128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionamide)	SML = 45 mg/kg
57	59200	35074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate)	SML = 6 mg/kg
58	60320	70321-86-7	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl) benzotriazole	SML = 1.5 mg/kg
59	60400	03896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg ⁽¹⁸⁾
60	60800	65447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl, piperidine-succinic acid, dimethyl ester, copolymer	SML = 30 mg/kg
61	61280	03293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁴⁾
62	61360	00131-57-7	2-Hydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁴⁾
63	61440	02440-22-4	2-(2-Hydroxy-5-methylphenyl) benzotriazole	SML(T) = 30 mg/kg ⁽¹⁸⁾
64	61600	01843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	SML(T) = 6 mg/kg ⁽¹⁴⁾
65	63200	51877-53-3	Lactic acid, manganese salt	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
66	64320	10377-51-2	Lithium iodide	SML(T) = 1 mg/kg ⁽¹⁰⁾ (expressed as iodine) and SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as lithium)

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
67	65120	07773-01-5	Manganese chloride	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
68	65200	12626-88-9	Manganese hydroxide	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
69	65280	10043-84-2	Manganese hypophosphite	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
70	65360	11129-60-5	Manganese oxide	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
71	65440		Manganese pyrophosphite	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
72	66360	85209-91-2	2-2'-Methylene bis(4,6-di-tert-butylphenyl)sodium phosphate	SML = 5 mg/kg
73	66400	00088-24-4	2-2'-Methylenebis(4-ethyl-6-tert-butylphenol)	SML(T) = 1.5 mg/kg ⁽¹⁹⁾
74	66480	00119-47-1	2-2'-Methylenebis(4-methyl-6-tert-butylphenol)	SML(T) = 1.5 mg/kg ⁽¹⁹⁾
75	67360	67649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML = 24 mg/kg
76	67520	54849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	SML(T) = 0.18 mg/kg ⁽¹⁵⁾ (expressed as tin)
77	67600		Mono-n-octyltin tris(alkyl(C10-C16)-mercaptoacetate)	SML(T) = 1.2 mg/kg ⁽¹⁷⁾ (expressed as tin)
78	67680	27107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	SML(T) = 1.2 mg/kg ⁽¹⁷⁾ (expressed as tin)
79	67760	26401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	SML(T) = 1.2 mg/kg ⁽¹⁷⁾ (expressed as tin)
80	68078	27253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0.05 mg/kg (expressed as neodecanoic acid) and SML(T) = 0.05 mg/kg ⁽¹³⁾ (expressed as cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC
81	68320	02082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6 mg/kg
82	68400	10094-45-8	Octadecylceramide	SML = 5 mg/kg
83	69840	16260-09-6	Olelypalmitamide	SML = 5 mg/kg
84	72160	00948-65-2	2-Phenylindole	SML = 15 mg/kg
85	72800	01241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	SML = 2.4 mg/kg
86	73040	13763-32-1	Phosphoric acid, lithium salts	SML(T) = 0.6 mg/kg ⁽⁸⁾ (expressed as lithium)
87	73120	10124-54-6	Phosphoric acid, manganese salt	SML(T) = 0.6 mg/kg ⁽⁹⁾ (expressed as manganese)
88	74400		Phosphorous acid, tris(nonyl- and/or dimonylphenyl) ester	SML = 30 mg/kg

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
89	77440		Polyethyleneglycol diricinoleate	SML = 42 mg/kg
90	77520	61791-12-6	Polyethyleneglycol ester of castor oil	SML = 42 mg/kg
91	78320	09004-97-1	Polyethyleneglycol monoricinoleate	SML = 42 mg/kg
92	81200	71878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]	SML = 3 mg/kg
93	81680	07681-11-0	Potassium iodide	SML(T) = 1 mg/kg ⁽¹⁰⁾ (expressed as iodium)
94	82020	19019-51-3	Propionic acid, cobalt salt	SML(T) = 0.05 mg/kg ⁽¹³⁾ (expressed as cobalt)
95	83595	119345-01-6	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with friedel craft reaction product of phosphorus trichloride and biphenyl	SML = 18 mg/kg and in compliance with the specifications in Schedule 2B
96	83700	00141-22-0	Ricinoleic acid	SML = 42 mg/kg
97	84800	00087-18-3	Salicylic acid, 4-tert-butylphenyl ester	SML = 12 mg/kg
98	84880	00119-36-8	Salicylic acid, methyl ester	SML = 30 mg/kg
99	85760	12068-40-5	Silicic acid, lithium aluminium salt (2:1:1)	SML(T) = 0.6 mg/kg ⁽⁸⁾ (expressed as lithium)
100	85920	12627-14-4	Silicic acid, lithium salt	SML(T) = 0.6 mg/kg ⁽⁸⁾ (expressed as lithium)
101	86800	07681-82-5	Sodium iodide	SML(T) = 1 mg/kg ⁽¹⁰⁾ (expressed as iodium)
102	86880		Sodium monoalkyl dialkylphenoxybenzenedi-sulphonate	SML = 9 mg/kg
103	89170	13586-84-0	Stearic acid, cobalt salt	SML(T) = 0.05 mg/kg ⁽¹³⁾ (expressed as cobalt)
104	92000	07727-43-7	Sulphuric acid, barium salt	SML(T) = 1 mg/kg ⁽¹¹⁾ (expressed as barium)
105	92320		Tetradecyl-polyethyleneglycol (EO = 3-8) ether of glycolic acid	SML = 15 mg/kg
106	92560	38613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	SML = 18 mg/kg
107	92800	00096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	SML = 0.48 mg/kg
108	92880	41484-35-9	Thiodiethanol bis(3-(3-5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 2.4 mg/kg
109	93120	00123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5 mg/kg ⁽²⁰⁾
110	93280	00693-36-7	Thiodipropionic acid, dioctadecyl ester	SML(T) = 5 mg/kg ⁽²⁰⁾

Item	PM/REF No.	CAS No.	Name	Restrictions and specifications
111	94560	00122-20-3	Triisopropanolamine	SML = 5 mg/kg
112	95280	40601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML = 6 mg/kg
114	95600	01843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	SML = 5 mg/kg"

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**LIST OF SUBSTANCES TO BE ADDED TO
SCHEDULE 2B TO THE PRINCIPAL
REGULATIONS**

Item	PM/REF No.	Specifications
4A	43680- -	CHLORODIFLUOROMETHANE Content of chlorofluoromethane less than 1 mg/kg of the substance
4B	47210- -	DIBUTYLTHIOSTANNOIC ACID POLYMER Molecular unit = (C ₈ H ₁₈ S ₃ Sn ₂) _n (n = 1,5-2)
5A	83595	REACTION PRODUCT OF DI-TERT-BUTYLPHOSPHONITE WITH BIPHENYL, OBTAINED BY CONDENSATION OF 2,4-DI-TERT-BUTYLPHENOL WITH FRIEDEL CRAFT REACTION PRODUCT OF PHOSPHORUS TRICHLORIDE AND BIPHENYL Composition <ul style="list-style-type: none"> - 4,4'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No. 38613-77-3) (36-46% w/w (1)) - 4,3'- Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No. 118421-00-4) (17-23% w/w) - 3,3'- Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No. 118421-01-5) (1-5% w/w) - 4-Biphenylene-0,0-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No. 91362-37-7) (11-19% w/w) - Tris(2,4-di-tert-butylphenyl)phosphite (CAS No. 31570-04-4) (9-18% w/w) - 4,4'-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No. 112949-970) (5% w/w) Other specifications <ul style="list-style-type: none"> - Phosphor content of minimum 5.4% to 5.9% - Acid value of maximum 10 mg KOH per gram - Melt range of 85-110°C