

OFFERYNNAU STATUDOL CYMRU

2002 Rhif 2834 (Cy.272)

BWYD, CYMRU

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

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|----------------------|-----|-------------------------|
| <i>Wedi'u gwneud</i> | - - | <i>7 Tachwedd 2002</i> |
| <i>Yn dod i rym</i> | - - | <i>30 Tachwedd 2002</i> |

Drwy arfer y pwerau a roddwyd gan adrannau 16(2), 17(1), 26(1)(a), 31 a 48(1) o Ddeddf Diogelwch Bwyd 1990(1), ac sydd bellach yn arferadwy mewn perthynas â Chymru gan Gynulliad Cenedlaethol Cymru(2) 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(3), ac ar ôl ymgynghori yn unol ag adran 48(4) a (4B) o'r Ddeddf honno, yn gwneud y Rheoliadau canlynol:

Enwi, cychwyn a chymhwyso

1.—(1) Enw'r rheoliadau hyn yw Rheoliadau Deunyddiau 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.

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

2. Diwygir Rheoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998(4) (“y prif Reoliadau”), i'r graddau y maent yn gymwys i Gymru, yn unol â rheoliadau 3 i 18.

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

“Scope of these Regulations

1A. Notwithstanding the title to these Regulations—

(1) 1990 p.16.

(2) 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).

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

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

- (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(5);

“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(6);”,

(iv) yn lle'r diffiniad o “the Directive” rhodder y diffiniad canlynol - ““the Directive” means Commission Directive [2002/72/EC](#) relating to plastic materials and articles intended to come into contact with foodstuffs(7);”,

(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;”,

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

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

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

(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—

“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”;

(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

- (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 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 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
- (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—

“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 sub-paragraph (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 sub-paragraph 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.

(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.

(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—

- (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⁽⁸⁾;
- (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 2002⁷.

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 (cymhwyso 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, 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

⁽⁸⁾ OJ Rhif L109, 6.5.2000, t.29.

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 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 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\(9\)](#) and Council Directive [85/572/EEC\(10\)](#).”.

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”;

(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 (Samplo a Chymwysterau) 1990

19. Yn Atodlen 1 i Reoliadau Diogelwch Bwyd (Samplo a Chymwysterau) 1990(11) (darpariaethau nad yw'r Rheoliadau hyn yn gwymwys iddynt) diwygir y cyfeiriad yn yr ail golofn, gyferbyn â'r cyfeiriad yn y golofn gyntaf at Reoliadau Deunyddiau ac Eitemau Plastig mewn

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

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

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

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](#).

Llofnodwyd ar ran Cynulliad Cenedlaethol Cymru o dan adran 66(1) o Ddeddf Llywodraeth Cymru 1998(12)

7 Tachwedd 2002

Rhodri Morgan
Prif Weinidog y Cynulliad Cenedlaethol

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**

| 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 |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|-------------|--|---|
| | | | | 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-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 |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|-------------|---|--|
| 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 | Tricyclodecanedimethine | 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 NGHLOFN GYNTAF (ITEM) ADRAN A O RAN I O ATODLEN 1 I'R PRIF REOLIADAU I'W DIWYGIO

| Item | Name |
|------|--------------------|
| 52B | 4-tert-Butylphenol |
| 88C | 1.3 Dioxolane |

Statws This is the original version (as it was originally made).

| Item | Name |
|------|---|
| 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 NGHOLFN 4 (CYFYNGIADAU A MANYLEBAU) O ADRAN A O RAN I O ATODLEN 1 I'R PRIF REOLIADAU I'W DIWYGIO

| 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

| 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 | |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|------------|--|---------------------------------|
| 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 | |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|------------|--|---|
| 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-Trimethylpropane 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

| 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 |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|-------------|--|--|
| | | | | 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) pentaerythritoldiphosphate | SML = 5 mg/kg (as sum of 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 ⁽⁵⁾ |
| 72B | 47210 | 26427-07-6 | Dibutylthiostannic 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 ⁽⁴⁾ |
| 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- | |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|-------------|--|--|
| | | | ammonium chloride, sodium salt-octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers | |
| 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 NGHLOFN GYNTAF (ITEM) RHAN I O ATODLEN I I'R PRIF REOLIADAU I'W DIWYGIO

| Item | Name |
|------|--|
| 36F | Bis(3-4-dimethylbenzylidene)sorbitol |
| 38B | Bis(polyethyleneglycol)hydroxymethyl-phosphonate |
| 73B | Diethyleneglycol |
| 73C | 1,1-Difluoroethane |

| Item | Name |
|------|---|
| 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

RHESTR O YCHWANEGION Y MAE'R COFNOD AMDANYNT A GYNHWYSIR YNG NGHOLFN 4 (CYFYNGIADAU A MANYLEBAU) O RAN I O ATODLEN 2 I'R PRIF REOLIADAU I'W DIWYGIO

| 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⁾ |

Statws This is the original version (as it was originally made).

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

“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 anti-monium 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 |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|-------------|--|---|
| 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 |
| 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⁾ |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications (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-triaza-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 (isooctylmercaptoacetate) | SML = 12 mg/kg |
| 30 | 48640 | 00131-56-6 | 2,4-Dihydroxybenzophenone | SML(T) = 6 mg/kg ⁽⁴⁾ |
| 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⁾ |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|------------|---|--|
| 33 | 49600 | 26636-01-1 | Dimethyltin bis(isooctyl mercaptoacetate) | SML(T) 0.18 mg/kg ⁽¹⁵⁾ (expressed as tin) |
| 34 | 49840 | 02500-88-1 | Diocadecyl disulphide | SML = 3 mg/kg |
| 35 | 50160 | | Di-n-octyltin bis(n-alkyl(C10-C16) mercaptoacetate) | 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) |
| 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) |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|------------|--|--|
| 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 = 10 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- | SML = 30 mg/kg |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|------------|--|---|
| | | | succinic acid, dimethyl ester, copolymer | |
| 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 ⁽⁸⁾ (expressed as lithium) |
| 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⁾ |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications (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 |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|------------|---|--|
| 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 | Oleylpalmitamide | 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 |
| 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)limino] | 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⁾ |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications (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) |

| Item | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|------|------------|------------|---|----------------------------------|
| 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⁾ |
| 111 | 94560 | 00122-20-3 | Triisopropanolamin | 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 ^{''} |

ATODLEN 3

Rheoliad 17

**RHESTR O SYLWEDDAU I'W HYCHWANEGU
AT ATODLEN 2B I'R PRIF REOLIADAU**

| Item | PM/REF No. | Specifications |
|------|------------|-----------------------|
| 4A | 43680— | CHLORODIFLUOROMETHANE |

Statws This is the original version (as it was originally made).

| Item | PM/REF No. | Specifications |
|------|-------------|---|
| 4B | 47210— — | Content of chlorofluoromethane less than 1 mg/kg of the substance 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 — 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) |

| Item | PM/REF No. | Specifications |
|------|------------|---|
| | | <p>— 4,4'-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite</p> <p>(CAS No. 112949-970) (5% w/w)</p> <p>Other specifications</p> <p>— Phosphor content of minimum 5.4% to 5.9%</p> <p>— Acid value of maximum 10 mg KOH per gram</p> <p>— Melt range of 85—110°C</p> |

EXPLANATORY NOTE

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

1. Mae'r Rheoliadau hyn yn diwygio, mewn perthynas â Chymru, Reoliadau Deunyddiau ac Eitemau Plastig mewn Cysylltiad â Bwyd 1998, er mwyn rhoi ar waith—

- 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);
- Cyfarwyddeb y Comisiwn [2002/16/EC](#) ar ddefnyddio deilliadau epocsi penodol mewn deunyddiau y bwriedir iddynt ddod i gysylltiad â bwydydd (OJ Rhif. L51, 22.2.2002, t.27);
a
- (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 haildeddfiad 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).

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

- 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 nghyd-destun darpariaethau a ychwanegwyd at Reoliadau 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)*);
- (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
- (j) gwneud diwygiad canlyniadol i Reoliadau Diogelwch Bwyd (Samplo 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.