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COMMISSION DIRECTIVE 1999/91/EC
of 23 November 1999
amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact
with foodstuffs
(Text with EEA relevance)
(OJ L 310, 4.12.1999, p. 41)

Corrected by:

► C1 Corrigendum, OJ L 249, 4.10.2000, p. 26 (1999/91)



COMMISSION DIRECTIVE 1999/91/EC

of 23 November 1999

amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs⁽¹⁾ and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) Commission Directive 90/128/EEC⁽²⁾, as last amended by Directive 96/11/EC⁽³⁾, provides in Article 3(2) for the revision of Annex II thereto.
- (2) On the basis of the information available, certain monomers provisionally admitted at national level may be included in the Community list.
- (3) Other monomers have been requested for use following the adoption of Directive 90/128/EEC: the technical data supplied permit their inclusion in the Community list.
- (4) Annex III to Directive 90/128/EEC includes a list of additives, which should be amended so as to include other additives fully evaluated by the Scientific Committee on Food.
- (5) For certain substances, the restrictions already set out should be amended according to the information available.
- (6) The current total list of additives is an incomplete list inasmuch as it does not contain all the substances which are currently accepted in one or more Member States; accordingly, these substances continue to be regulated by national laws pending a decision on inclusion in the Community list.
- (7) This Directive establishes purity criteria for only a few substances, and therefore the other substances which may require purity criteria remain regulated in this respect by national laws pending a decision at Community level.
- (8) The measures contained in this Directive do not go beyond what is necessary to achieve the objectives already provided for in Directive 89/109/EEC.
- (9) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/128/EEC is amended as follows:

1. the fourth indent of Article 3(5) is deleted;

⁽¹⁾ OJ L 40, 11.2.1989, p. 38.

⁽²⁾ OJ L 75, 21.3.1990, p. 19.

⁽³⁾ OJ L 61, 12.3.1996, p. 26.

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2. Article 3a is replaced by the following:

‘Article 3a

An incomplete list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions on their use, is set out in Annex III’;

3. the following Articles 3b and 3c are inserted:

‘Article 3b

Only the products obtained by means of bacterial fermentation listed in Annex IV may be used in contact with foodstuffs.

Article 3c

1. The specifications relating to some substances appearing in Annexes II, III and IV are laid down in Annex V.
2. The meaning of the numbers between brackets appearing in the Column ‘Restrictions and/or specifications’ is explained in Annex VI’;
4. Annex II is amended as shown in Annex I to this Directive;
5. Annex III is amended as shown in Annex II to this Directive;
6. the texts set out in Annex III to this Directive are added as Annexes IV, V and VI.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 2000. They shall immediately inform the Commission thereof.

Member States shall permit, as from 1 January 2002, the trade in and use of plastic materials and articles intended to come into contact with foodstuffs and complying with this Directive.

They shall prohibit, as from 1 January 2003, the manufacture and importation into the Community of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

*ANNEX I*

Annex II is amended as follows:

1. The fourth indent of paragraph 5 is replaced by the following:
 - Column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically mentioned,
 - any type of specifications related to the substance or to the polymer;
2. The title of column 4 is modified to 'Restrictions and/or specifications';
3. Sections A and B are amended as shown in Appendices 1 to 5.



Appendix I

List of monomers and other starting substances inserted in Section A of Annex II to Directive 90/128/EEC

| PM/REF No | CAS No | Name | Restrictions and/or specifications |
|-----------|----------------------------|--|--|
| (1) | (2) | (3) | (4) |
| 12761 | 000693-57-2 | 12-Aminododecanoic acid | SML = 0,05 mg/kg |
| 13180 | 000498-66-8 | Bicyclo[2.2.1]hept-2-ene (= norbornene) | SML = 0,05 mg/kg |
| 13210 | 001761-71-3 | Bis(4-aminocyclohexyl)methane | SML = 0,05 mg/kg |
| 14650 | 000079-38-9 | Chlorotrifluoroethylene | QMA = 0,05 mg/6 dm ² |
| 14841 | 000599-64-4 | 4-Cumylphenol | SML = 0,05 mg/kg |
| 16694 | 013811-50-2 | N,N'-Divinyl-2-imidazolidinone | QM = 5 mg/kg in FP |
| 16704 | 000112-41-4 | 1-Dodecene | SML = 0,05 mg/kg |
| 22331 | 025513-64-8 | Mixture of (40 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (60 % w/w) 1,6-diamino-2,4,4-trimethylhexane | QMA = 5 mg/6 dm ² |
| 22550 | 000498-66-8 | Norbornene | See "Bicyclo[2.2.1]hept-2-ene" |
| 23175 | 000122-52-1 | Phosphorous acid, triethyl ester | QM = ND (DL = 1 mg/kg in FP) |
| 23547 | 009016-00-6 063148-62-9 | Polydimethylsiloxane (MW > 6800) | In compliance with the specifications laid down in Annex V |
| 25080 | 001120-36-1 | 1-Tetradecene | SML = 0,05 mg/kg |
| 25385 | 000102-70-5 | Triallylamine | In compliance with the specifications laid down in Annex V |
| 25927 | 027955-94-8 | 1,1,1-Tris(4-hydroxyphenyl)ethane | QM = 0,5 mg/kg in FP. For use only in polycarbonates |
| 26155 | 001072-63-5 | 1-Vinylimidazole | QM = 5 mg/kg in FP |
| 26320 | 002768-02-7 | Vinyltrimethoxysilane | QM = 5 mg/kg in FP |
| 26360 | 007732-18-5 | Water | In compliance with Directive 98/83/EC |



Appendix 2

List of monomers and other starting substances in Section A of Annex II to Directive 90/128/EEC for which the content of the column “Restriction and/or specifications” is modified

| PM/Ref No | CAS No | Name | Restrictions and/or specifications |
|-----------|-------------|--|--|
| (1) | (2) | (3) | (4) |
| 10060 | 000075-07-0 | Acetaldehyde | SML(T) = 6 mg/kg (2) |
| 13510 | 001675-54-3 | 2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (= BADGE) | SML(T) = 1 mg/kg (9) Authorised until 1 January 2005 |
| 14200 | 000105-60-2 | Caprolactam | SML(T) = 15 mg/kg (5) |
| 14230 | 002123-24-2 | Caprolactam, sodium salt | SML(T) = 15 mg/kg (5) (expressed as caprolactam) |
| 15760 | 000111-46-6 | Diethyleneglycol | SML(T) = 30 mg/kg (3) |
| 16990 | 000107-21-1 | Ethyleneglycol | SML(T) = 30 mg/kg (3) |
| 17160 | 000097-53-0 | Eugenol | SML = ND (DL = 0,02 mg/kg, analytical tolerance included) |
| 19540 | 000110-16-7 | Maleic acid | SML(T) = 30 mg/kg (4) |
| 19960 | 000108-31-6 | Maleic anhydride | SML(T) = 30 mg/kg (4) (expressed as maleic acid) |
| 25360 | — | Trialkyl(C5-C15) acetic acid, 2,3-epoxypropyl ester | QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43) |

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Appendix 3

List of monomers and others starting substances deleted from Section B of Annex II to Directive 90/128/EEC

| PM/Ref No | CAS No | Name | Restrictions and/or specifications |
|-----------|-------------|-------------------------------|------------------------------------|
| (1) | (2) | (3) | (4) |
| 22428 | 051000-52-3 | Neodecanoic acid, vinyl ester | |

Appendix 4

List of monomers and other starting substances in Section B of Annex II to Directive 90/128/EEC for which the content of the column 'Restrictions and/or specifications' is modified

| PM/Ref No | CAS No | Name | Restrictions and/or specifications |
|-----------|-------------|---|---|
| (1) | (2) | (3) | (4) |
| 16690 | 001321-74-0 | Divinylbenzene | QM = 1 mg/kg in FP or SML = ND (DL = 0,02 mg/kg, analytical tolerance included) |
| 20590 | 000106-91-2 | Methacrylic acid, 2,3-epoxypropyl ester | QM(T) = 5 mg/kg in FP (expressed as epoxy group, molecular weight = 43) |
| 22720 | 000140-66-9 | 4-tert-Octylphenol | See "4-(1,1,3,3-Tetramethylbutyl)phenol" |
| 25185 | 000140-66-9 | 4-(1,1,3,3-Tetramethylbutyl)phenol (= 4-tert-Octylphenol) | SML = ND (DL = 0,01 mg/kg, analytical tolerance included) |



Appendix 5

List of monomers and other starting substances transferred from Section B to Section A of Annex II to Directive 90/128/EEC

| PM/Ref No | CAS No | Name | Restrictions and/or specifications |
|-----------|-------------|--|---|
| (1) | (2) | (3) | (4) |
| 11000 | 050976-02-8 | Acrylic acid, dicyclopentadienyl ester | QMA = 0,05 mg/6 dm ² |
| 11245 | 002156-97-0 | Acrylic acid, dodecyl ester | SML = 0,05 mg/kg (1) |
| 12265 | 004074-90-2 | Adipic acid, divinyl ester | QM = 5 mg/kg in FP. For use only as comonomer |
| 13060 | 004422-95-1 | 1,3,5-Benzenetricarboxylic acid trichloride | QMA = 0,05 mg/6 dm ² (measured as 1,3,5-benzenetricarboxylic acid) |
| 13780 | 002425-79-8 | 1,4-Butanediol bis(2,3-epoxypropyl) ether | QM = 1 mg/kg in FP (expressed as epoxy group, molecular weight = 43) |
| 14020 | 000098-54-4 | 4-tert-Butylphenol | SML = 0,05 mg/kg |
| 15130 | 000872-05-9 | 1-Decene | SML = 0,05 mg/kg |
| 16360 | 000576-26-1 | 2,6-Dimethylphenol | SML = 0,05 mg/kg |
| 16450 | 000646-06-0 | 1,3-Dioxolane | SML = 0,05 mg/kg |
| 18220 | 068564-88-5 | N-Heptylaminoundecanoic acid | SML = 0,05 mg/kg (1) |
| 18820 | 000592-41-6 | 1-Hexene | SML = 3 mg/kg |
| 19060 | 000109-53-5 | Isobutyl vinyl ether | QM = 5 mg/kg in FP |
| 19150 | 000121-91-5 | Isophthalic acid | SML = 5 mg/kg |
| 19990 | 000079-39-0 | Methacrylamide | SML = ND (DL = 0,02 mg/kg, analytical tolerance included) |
| 20050 | 000096-05-9 | Methacrylic acid, allyl ester | SML = 0,05 mg/kg |
| 20530 | 002867-47-2 | Methacrylic acid, 2-(dimethylamino)ethyl ester | SML = ND (DL = 0,02 mg/kg, analytical tolerance included) |
| 21730 | 000563-45-1 | 3-Methyl-1-butene | QMA = 0,006 mg/6 dm ² . For use only in polypropylene. |
| 22937 | 001623-05-8 | Perfluoropropyl perfluorovinyl ether | SML = 0,05 mg/kg |
| 23770 | 000504-63-2 | 1,3-Propanediol | SML = 0,05 mg/kg |
| 23920 | 000105-38-4 | Propionic acid, vinyl ester | SML(T) = 6 mg/kg (2) (expressed as acetaldehyde) |
| 24760 | 026914-43-2 | Styrenesulphonic acid | SML = 0,05 mg/kg |
| 26170 | 003195-78-6 | N-Vinyl-N-methylacetamide | QM = 2 mg/kg in FP' |

*ANNEX II*

Annex III is amended as follows:

1. The fourth indent of paragraph 5 is replaced by the following:
 - Column 4 (Restrictions and/or specifications). These may include:
 - specific migration limit (SML),
 - maximum permitted quantity of the substance in the finished material or article (QM),
 - maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs (QMA),
 - any other restriction specifically laid down,
 - any type of specification related to the substance or to the polymer;
2. The title of the column 4 is modified into 'Restrictions and/or specifications';
3. 'Incomplete list of additives' is amended as shown in Appendices 1, 2 and 3.

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Appendix I

List of additives inserted in Annex III to Directive 90/128/EEC

| PM/REF No | CAS No | Name | Restrictions and/or specifications |
|-------------|-------------|--|--|
| (1) | (2) | (3) | (4) |
| 30080 | 004180-12-5 | Acetic acid, copper salt | SML(T) = 30 mg/kg (7) (expressed as copper) |
| 30610 | — | Acids, C2-C24, aliphatic, linear, mono-carboxylic, from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included) | |
| 30612 | — | Acids, C2-C24, aliphatic, linear, mono-carboxylic, synthetic, and their mono-, di- and triglycerol esters | |
| 31530 | 123968-25-2 | Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl]-phenyl ester | SML = 5 mg/kg |
| 33801 | — | n-Alkyl(C10-C13)benzenesulphonic acid | SML = 30 mg/kg |
| 34240 | — | Alkyl(C10-C20)sulphonic acid, | SML = 6 mg/kg. Authorised until 1 January 2002 |
| 36640 | 000123-77-3 | Azodicarbonamide | For use only as a blowing agent |
| 37360 | 000100-52-7 | Benzaldehyde | In compliance with note 10 in Annex VI |
| 38320 | 005242-49-9 | 4-(2-Benzoxazolyl)-4'-(5-methyl-2-benzoxazolyl)stilbene | In compliance with the specifications laid down in Annex V |
| 38510 | 136504-96-6 | 1,2-Bis(3-aminopropyl)ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine | SML = 5 mg/kg |
| ▼ C1 | | | |
| 38515 | 001533-45-5 | 4,4'-Bis(2-benzoxazolyl)stilbene | SML = 0,05 mg/kg (1) |
| ▼ B | | | |
| 38810 | 080693-00-1 | Bis(2,6-di-tert-butyl-4-methylphenyl)-pentaerythritol diphosphite | SML = 5 mg/kg (sum of phosphite and phosphate) |
| 38879 | 135861-56-2 | Bis(3,4-dimethylbenzylidene)sorbitol | |
| 39200 | 006200-40-4 | Bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride | SML = 1,8 mg/kg |
| ▼ C1 | | | |
| 39815 | 182121-12-6 | 9,9-Bis(methoxymethyl)fluorene | QMA = 0,05 mg/6 dm ² |
| ▼ B | | | |
| 40120 | — | Bis(polyethyleneglycol)hydroxymethylphosphonate | SML = 0,6 mg/kg. Authorised until 1 January 2002 |
| 41680 | 000076-22-2 | Camphor | In compliance with note 10 in Annex VI |
| ▼ C1 | | | |
| 42320 | 007492-68-4 | Carbonic acid, copper salt | SML(T) = 30 mg/kg (7) (expressed as copper) |
| ▼ B | | | |
| 43515 | — | Chlorides of choline esters of coconut oil fatty acids | QMA = 0,9 mg/6 dm ² |
| 45195 | 007787-70-4 | Copper bromide | SML(T) = 30 mg/kg (7) (expressed as copper) |

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| PM/REF No | CAS No | Name | Restrictions and/or specifications | |
|-------------|-------------|--|---|---|
| (1) | (2) | (3) | (4) | |
| 45200 | 001335-23-5 | Copper iodide | SML(T) = 30 mg/kg (7) (expressed as copper) and SML = 1 mg/kg (expressed as iodine) | |
| 45450 | 068610-51-5 | p-Cresol-dicyclopentadiene-isobutylene, copolymer | SML = 0,05 mg/kg (1) | |
| 46880 | 065140-91-2 | 3,5-Di-tert-butyl-4-hydroxybenzyl phosphonic acid, monoethyl ester, calcium salt | SML = 6 mg/kg | |
| ▼ <u>C1</u> | 47680 | 000111-46-6 | Diethyleneglycol | SML(T) = 30 mg/kg (3) |
| ▼ <u>B</u> | 48460 | 000075-37-6 | 1,1-Difluoroethane | |
| | 49485 | 134701-20-5 | 2,4-Dimethyl-6-(1-methylpentadecyl)-phenol | SML = 1 mg/kg |
| ▼ <u>C1</u> | 51700 | 147315-50-2 | 2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol | SML = 0,05 mg/kg |
| | 53610 | 054453-03-1 | Ethylenediaminetetraacetic acid, copper salt | SML(T) = 30 mg/kg (7) (expressed as copper) |
| ▼ <u>B</u> | 53650 | 000107-21-1 | Ethyleneglycol | SML(T) = 30 mg/kg (3) |
| | 54300 | 118337-09-0 | 2,2'Ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite | SML = 6 mg/kg |
| | 54930 | 025359-91-5 | Formaldehyde-1-naphthol, copolymer [=Poly(1-hydroxynaphthyl-methane)] | SML = 0,05 mg/kg |
| | 57800 | 018641-57-1 | Glycerol tribehenate | |
| ▼ <u>C1</u> | 60480 | 003864-99-1 | 2-(2-Hydroxy-3,5-di-tert-butyl-phenyl)-5-chlorobenzotriazole | SML = 30 mg/kg |
| ▼ <u>B</u> | 66560 | 004066-02-8 | 2,2'Methylenebis(4-methyl-6-cyclohexylphenol) | SML(T) = 3 mg/kg (6) |
| | 66580 | 000077-62-3 | 2,2'Methylenebis[4-methyl-6-(1-methylcyclo-hexyl)phenol] | SML(T) = 3 mg/kg (6) |
| ▼ <u>C1</u> | 66755 | 002682-20-4 | 2-Methyl-4-isothiazolin-3-one | SML = ND (DL = 0,02 mg/kg, analytical tolerance included) |
| ▼ <u>B</u> | 67170 | — | Mixture of (80 to 100 % w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and (0 to 20 %w/w)5,7-di-tert-butyl-3-(2,3-di-methylphenyl)-2(3H)-benzofuranone | SML = 5 mg/kg |
| | 67180 | — | Mixture of (50 % w/w) phthalic acid, n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-decyl ester, and (25 % w/w) phthalic acid di-n-octyl ester | SML = 5 mg/kg (1) |
| | 68145 | 080410-33-9 | 2,2',2''-Nitrilo[triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite] | SML = 5 mg/kg (sum of phosphite and phosphate) |

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| PM/REF No | CAS No | Name | Restrictions and/or specifications |
|-----------|-------------|--------------------------|--|
| (1) | (2) | (3) | (4) |
| 71635 | 025151-96-6 | Pentaerythritol dioleate | SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC |

▼C1

| | | | |
|-------|--------------|---------------------------------------|---|
| 73720 | 0000115-96-8 | Phosphoric acid, trichloroethyl ester | SML = ND (DL = 0,02 mg/kg, analytical tolerance included) |
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|-------|-------------|--|--|
| 74010 | 145650-60-8 | Phosphorous acid, bis (2,4-di-tert-butyl-6-methylphenyl) ethyl ester | SML = 5 mg/kg (sum of phosphite and phosphate) |
|-------|-------------|--|--|

| | | | |
|-------|----------------------------|----------------------------------|--|
| 76721 | 009016-00-6 063148-62-9 | Polydimethylsiloxane (MW > 6800) | In compliance with the specifications laid down in Annex V |
|-------|----------------------------|----------------------------------|--|

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| | | | |
|-------|---|--|----------------|
| 76865 | — | Polyesters of 1,2-propanediol and/or 1,3- and 1,4-butanediol and/or polypropylene-glycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and/or n-decanol | SML = 30 mg/kg |
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|-------|-------------|---|------------------|
| 77895 | 068439-49-6 | Polyethyleneglycol (EO = 2-6) mono-alkyl(C16-C18) ether | SML = 0,05 mg/kg |
|-------|-------------|---|------------------|

| | | | |
|-------|-------------|------------------------|--|
| 81515 | 087189-25-1 | Poly(zinc glycerolate) | |
|-------|-------------|------------------------|--|

| | | | |
|-------|---|--|---|
| 81760 | — | Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron | SML(T) = 30 mg/kg (7) (expressed as copper); SML = 48 mg/kg (expressed as iron) |
|-------|---|--|---|

| | | | |
|-------|-------------|-----------------------------|--|
| 85360 | 000109-43-3 | Sebacic acid, dibutyl ester | |
|-------|-------------|-----------------------------|--|

| | | | |
|-------|---|--|--|
| 85610 | — | Silicates, natural, silanated (with the exception of asbestos) | |
|-------|---|--|--|

| | | | |
|-------|-------------|---|---|
| 85840 | 053320-86-8 | Silicic acid, lithium magnesium sodium salt | SML(T) = 0,6 mg/kg (8) (expressed as lithium) |
|-------|-------------|---|---|

| | | | |
|-------|---|----------------------------|--|
| 86285 | — | Silicon dioxide, silanated | |
|-------|---|----------------------------|--|

| | | | |
|-------|-------------|-------------------------|--|
| 88640 | 008013-07-8 | Soybean oil, epoxidised | In compliance with the specifications laid down in Annex V |
|-------|-------------|-------------------------|--|

| | | | |
|-------|-------------|---------------------------|---|
| 89200 | 007617-31-4 | Stearic acid, copper salt | SML(T) = 30 mg/kg (7) (expressed as copper) |
|-------|-------------|---------------------------|---|

| | | | |
|-------|---|--|-----------------------|
| 89440 | — | Stearic acid, esters with ethyleneglycol | SML(T) = 30 mg/kg (3) |
|-------|---|--|-----------------------|

| | | | |
|-------|-------------|-----------------------------|---|
| 92030 | 010124-44-4 | Sulphuric acid, copper salt | SML(T) = 30 mg/kg (7) (expressed as copper) |
|-------|-------------|-----------------------------|---|

| | | | |
|-------|-------------|---|---------------|
| 92700 | 078301-43-6 | 2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro[5.1.11.2]-heneicosan-21-one, polymer | SML = 5 mg/kg |
|-------|-------------|---|---------------|

| | | | |
|-------|-------------|--|---------------|
| 92930 | 120218-34-0 | Thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate) | SML = 6 mg/kg |
|-------|-------------|--|---------------|

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| | | | |
|-------|-------------|--------------------------|---------------|
| 94960 | 000077-99-6 | 1,1,1-Trimethylolpropane | SML = 6 mg/kg |
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| | | | |
|-------|-------------|--|---|
| 95725 | 110638-71-6 | Vermiculite, reaction product with citric acid, lithium salt | SML(T) = 0,6 mg/kg (8) (expressed as lithium) |
|-------|-------------|--|---|

| | | | |
|-------|-------------|-------|---------------------------------------|
| 95855 | 007732-18-5 | Water | In compliance with Directive 98/83/EC |
|-------|-------------|-------|---------------------------------------|

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| PM/REF No | CAS No | Name | Restrictions and/or specifications |
|-----------|--------|---|--|
| (1) | (2) | (3) | (4) |
| 95859 | — | Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks | In compliance with the specifications laid down in Annex V |
| 95883 | — | White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks | In compliance with the specifications laid down in Annex V |

*Appendix 2***List of additives in Annex III to Directive 90/128/EEC for which the content of column 'CAS No' is modified**

| PM/REF No | CAS No | Name | Restrictions and/or specifications |
|-----------|--|--------------------------------|------------------------------------|
| (1) | (2) | (3) | (4) |
| 39890 | 087826-41-3 069158-41-4 054686-97-4 081541-12-0 | Bis(methylbenzylidene)sorbitol | |
| 68125 | 037244-96-5 | Nepheline syenite | |

*Appendix 3***List of additives in Annex III to Directive 90/128/EEC deleted**

| PM/REF No | CAS No | Name | Restrictions and/or specifications |
|-----------|----------------------------|-----------------------|------------------------------------|
| (1) | (2) | (3) | (4) |
| 76720 | 009016-00-6 063148-62-9 | Polydimethylsiloxane' | |

▼B

ANNEX III

The following Annexes IV, V and VI are added:

ANNEX IV

PRODUCTS OBTAINED BY MEANS OF BACTERIAL FERMENTATION

▼C1

| PM/REF No | CAS No | Name | Restrictions and/or specifications |
|-----------|------------|---|--|
| (1) | (2) | (3) | (4) |
| 18888 | 80181-31-3 | 3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer | SML = 0,05 mg/kg for crotonic acid (as impurity) and in compliance with the specifications laid down in Annex IV |

▼B

ANNEX V

SPECIFICATIONS

Part A: General specifications

(to be fixed later)

Part B: Other specifications

| PM/Ref No | Other specifications |
|-----------|---|
| 18888 | <p>3-HYDROXYBUTANOIC ACID-3-HYDROXPENTANOIC ACID, COPOLYMER</p> <p><i>Definition</i></p> <p>These copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism <i>Alcaligenes eutrophus</i> strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat-treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt-formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications.</p> <p>— Chemical name Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)</p> <p>— CAS No 80181-31-3</p> <p>— Structural formula</p> $\begin{array}{ccccccc} & & & & \text{CH}_3 & & \\ & & & & & & \\ & & & & \text{CH}_2 & & \text{O} \\ & \text{CH}_3 & \text{O} & & & & \\ & & & & & & \\ (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_m & - & (\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_n & & & & \end{array}$ <p>where $n/(m+n)$ greater than 0 and less or equal to 0,25</p> |

▼B

| PM/Ref No | Other specifications |
|----------------------------------|---|
| — Average molecular weight | Not less than 150 000 daltons (measured by gel permeation chromatography). |
| ▼ <u>C1</u> — Assay | Not less than 98 % poly(3-D-hydroxybutanoato-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids |
| ▼ <u>B</u> <i>Description</i> | White to off-white powder after isolation |
| <i>Characteristics</i> | |
| — Identification tests: | |
| — Solubility | Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water. |
| — Migration | The migration of crotonic acid should not exceed 0,05 mg/kg food. |
| — Purity | Prior to granulation the raw material copolymer powder must contain: |
| — Nitrogen | Not more than 2 500 mg/kg of plastic |
| — Zinc | Not more than 100 mg/kg of plastic |
| — Copper | Not more than 5 mg/kg of plastic |
| — Lead | Not more than 2 mg/kg of plastic |
| — Arsenic | Not more than 1 mg/kg of plastic |
| — Chromium | Not more than 1 mg/kg of plastic. |
| 23547 | POLYDIMETHYLSILOXANE (Mw > 6 800) Minimum viscosity $100 \times 10^{-6} \text{ m}^2/\text{s}$ (= 100 centistokes) at 25 °C |
| 25385 | TRIALLYLAMINE 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use. |
| 38320 | 4-(2-BENZOXAZOLYL)-4'-(5-METHYL-2-BENZOXAZOLYL) STILBENE Not more than 0,05 % w/w (quantity of substance used/quantity of the formulation) |
| ▼ <u>C1</u> 76721 | POLYDIMETHYLSILOXANE (Mw > 6 800) Minimum viscosity $100 \times 10^{-6} \text{ m}^2/\text{s}$ (= 100 centistokes at 25 °C |
| ▼ <u>B</u> 88640 | SOYBEAN OIL, EPOXIDISED Oxirane < 8 %, iodine number < 6 |
| 95859 | WAXES, REFINED, DERIVED FROM PETROLEUM BASED OR SYNTHETIC HYDROCARBON FEEDSTOCKS |

▼B

| PM/Ref No | Other specifications |
|-----------|---|
| 95883 | <p>The product should have the following specifications:</p> <ul style="list-style-type: none">— Content of mineral hydrocarbons with carbon number less than 25: not more than 5 % (w/w)— Viscosity not less than 11×10^{-6} m²/s (= 11 centistokes) at 100 °C— Average molecular weight not less than 500 <p>WHITE MINERAL OILS, PARAFFINIC DERIVED FROM PETROLEUM BASED HYDROCARBON FEEDSTOCKS</p> <p>The product should have the following specifications:</p> <ul style="list-style-type: none">— Content of mineral hydrocarbons with carbon number less than 25: not more than 5 % (w/w)— Viscosity not less than $8,5 \times 10^{-6}$ m²/s (= 8,5 centistokes) at 100 °C— Average molecular weight not less than 480 |



ANNEX VI

NOTES RELATED TO THE COLUMN 'RESTRICTIONS AND/OR SPECIFICATIONS'

- (1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.
- (2) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 10060 and 23920.
- (3) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 15760, 16990, 47680, 53650, 89440.
- (4) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 19540, 19960.
- (5) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 14200, 14230.
- (6) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 66560 and 66580.
- (7) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200, 92030.
- (8) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 85840 and 95725.
- (9) SML(T) = in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances:
 - (a) Badge (=2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether:
 - (b) Badge.H₂O.
 - (d) Badge.HCl.
 - (e) Badge.2HCl
 - (f) Badge.H₂O.HCl

However in aqueous food simulants, the SML(T) should also include Badge.2H₂O (c) unless the material or article is labelled for use in contact only with those foods and/or beverages for which it has been demonstrated that the sum of the migration levels of the five abovementioned substances (a)(b)(d)(e)(f) cannot exceed 1 mg/kg.
- (10) Warning: there is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the finished product does not comply with the second indent of Article 2 of Directive 89/109/EEC.