

[^{X1}ANNEX I

Editorial Information

- X1** Substituted by [Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs \(Official Journal of the European Union L 91 of 31 March 2007\)](#).

Annex I to Directive 2002/72/EC is amended as follows:

- (1) The following points 2a and 2b are inserted:

- 2a. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF):

“Fat Reduction Factor” (FRF) is a factor between 1 and 5 by which measured migration of lipophilic substances into a fatty food or simulant D and its substitutes shall be divided before comparison with the specific migration limits.

General rules

Substances considered “lipophilic” for the application of the FRF are listed in Annex IVa. The specific migration of lipophilic substances in mg/kg (M) shall be corrected by the FRF variable between 1 and 5 (M_{FRF}). The following equations shall be applied before comparison with the legal limit:

$$M_{FRF} = M/FRF$$

and

$$FRF = (\text{g fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$$

This correction by the FRF is not applicable in the following cases:

- (a) when the material or article is or is intended to be brought in contact with food containing less than 20 % fat;
- (b) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 91/321/EEC and 96/5/EC;
- (c) for substances in the Community lists in Annexes II and III having a restriction in column (4) SML= ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg;
- (d) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm²/kg.

This correction by the FRF is applicable under certain conditions in the following case:

For containers and other fillable articles with a capacity of less than 500 millilitres or more than 10 litres and for sheets and films in contact with foods containing more

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than 20 % fat, either the migration is calculated as concentration in the food or food simulant (mg/kg) and corrected by the FRF, or it is re-calculated as mg/dm² without applying the FRF. If one of the two values is below the SML, the material or article shall be considered in compliance.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

2b. Correction of specific migration in food simulant D:

The specific migration of lipophilic substances into simulant D and its substitutes shall be corrected by the following factors:

- (a) the reduction factor referred to in point 3 of the Annex to Directive 85/572/EEC, hereinafter termed simulant D Reduction Factor (DRF).

The DRF may not be applicable when the specific migration into simulant D is higher than 80 % of the content of the substance in the finished material or article (for example thin films). Scientific or experimental evidence (for example testing with the most critical foods) is required to determine whether the DRF is applicable. It is also not applicable for substances in the Community lists having a restriction in column (4) SML = ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg.

- (b) the FRF is applicable to migration into simulants, provided the fat content of the food to be packed is known and the requirements mentioned in point 2a are fulfilled.
- (c) the Total Reduction Factor (TRF) is the factor, with a maximum value of 5, by which a measured specific migration into simulant D or a substitute shall be divided before comparison with the legal limit. It is obtained by multiplying the DRF by the FRF, when both factors are applicable.

- (2) The following point 5a is inserted:

5a. Caps, lids, gaskets, stoppers and similar sealing articles:

- (a) If the intended use is known, such articles shall be tested by applying them to the containers for which they are intended under conditions of closure corresponding to the normal or foreseeable use. It is assumed that these articles are in contact with a quantity of food filling the container. The results shall be expressed in mg/kg or mg/dm² in accordance to the rules of Articles 2 and 7 taking into account the whole contact surface of sealing article and container.
- (b) If the intended use of these articles is unknown, such articles shall be tested in a separate test and the result be expressed in mg/article. The value obtained shall be added, if appropriate, to the quantity migrated from the container for which it is intended to be used.

ANNEX II

Annex II to Directive 2002/72/EC is amended as follows:

(1) Section A is amended as follows:

(a) the following monomers and other starting substances are inserted, in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'15267	000080-08-0	4,4'-Diaminodiphenyl sulphone	SML = 5 mg/kg
21970	000923-02-4	N-Methylmethacrylamide	SML = 0,05 mg/kg
24886	046728-75-0	5-Sulphoisophthalic acid, monolithium salt	SML = 5 mg/kg and for lithium SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as lithium)'

(b) for the following monomers and other starting substances, the content of the column 4 'Restrictions and/or specifications' is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'12786	000919-30-2	3-Aminopropyltriethoxysilane	Residual content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers and SML = 0,05 mg/kg when used for the surface treatment of materials and articles.
16450	000646-06-0	1,3-Dioxolane	SML = 5 mg/kg
25900	000110-88-3	Trioxane	SML = 5 mg/kg'

(2) In section B, the following monomers and other starting substances are deleted:

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Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'21970	000923-02-4	N-Methylolmethacrylamide'	

ANNEX III

Annex III to Directive 2002/72/EC is amended as follows:

(1) Section A is amended as follows:

(a) the following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'38885	002725-22-6	2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	SML = 0,05 mg/kg. For aqueous foods only.
42080	001333-86-4	Carbon black	In compliance with the specifications laid down in Annex V.
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester	
62020	007620-77-1	12-Hydroxystearic acid, lithium salt	SML(T) = 0,6 mg/kg ⁽⁸⁾ (expressed as lithium)
67180	—	Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n-octyl ester.	SML = 5 mg/kg ⁽¹⁾

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71960	003825-26-1	Perfluorooctanoic acid, ammonium salt	Only to be used in repeated use articles, sintered at high temperatures.
74560	000085-68-7	Phthalic acid, benzyl butyl ester	<p>To be used only as:</p> <p>(a) plasticizer in repeated use materials and articles;</p> <p>(b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC;</p> <p>(c) technical support agent in concentrations up to</p>

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			0,1 % in the final product. SML = 30 mg/kg food simulant.
74640	000117-81-7	Phthalic acid, bis (2-ethylhexyl) ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non- fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product. SML = 1,5 mg/kg food simulant.
74880	000084-74-2	Phthalic acid, dibutyl ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non- fatty foods; (b) technical support agent in polyolefines in concentrations

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			up to 0,05 % in the final product. SML = 0,3 mg/kg food simulant.
75100	068515-48-0 028553-12-0	Phthalic acid, diesters with primary, saturated C ₈ -C ₁₀ branched alcohols, more than 60 % C ₉ .	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent

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			in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ⁽⁴²⁾ .
75105	068515-49-1 026761-40-0	Phthalic acid, diesters with primary, saturated C ₉ -C ₁₁ alcohols more than 90 % C ₁₀	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC;

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			(c) technical support agent in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ⁽⁴²⁾ .
79920	009003-11-6 106392-12-5	Poly(ethylene propylene) glycol	
81500	9003-39-8	Polyvinylpyrrolidone	In compliance with the specifications laid down in Annex V.
93760	000077-90-7	Tri-n-butyl acetyl citrate	
95020	6846-50-0	2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	SML = 5 mg/kg food. To be used in single-use gloves only.
95420	745070-61-5	1,3,5-tris (2,2-dimethylpropanamido)benzene	SML = 0,05 mg/kg food

(b) for the following additives, the entries in columns 3 'Name' and 4 'Restrictions and/or specifications' are replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
43480	064365-11-3	Charcoal, activated	In compliance with the specifications laid down in Annex V.
45200	001335-23-5	Copper iodide	SML(T) = 5 mg/kg ⁽⁷⁾ (expressed as copper) and SML = 1 mg/kg ⁽¹¹⁾ (expressed as iodine)

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76845	031831-53-5	Polyester of 1,4-butanediol with caprolactone	The restriction for Ref. No 14260 and Ref. No 13720 shall be respected. In compliance with the specifications laid down in Annex V.
81760	—	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 5 mg/kg (7) (expressed as copper); SML = 48 mg/kg (expressed as iron)
88640	008013-07-8	Soybean oil, epoxidised	SML = 60 mg/kg. However in the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 91/321/EEC or containing processed cereal-based foods and baby foods for infants and young children as defined by Directive 96/5/EC, the SML is lowered to 30 mg/kg. In compliance with the specifications laid down in Annex V.'

(c) the following additive is deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
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(1)	(2)	(3)	(4)
'35760	001309-64-4	Antimony trioxide	SML = 0,04 mg/kg ⁽³⁹⁾ (expressed as antimony).'

(2) Section B is amended as follows:

(a) the following additives are inserted, in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'35760	001309-64-4	antimony trioxide	SML = 0,04 mg/kg ⁽³⁹⁾ (expressed as antimony)
47500	153250-52-3	N,N'-Dicyclohexyl-2,6-naphthalene dicarboxamide	SML = 5 mg/kg.
72081/10	—	Petroleum hydrocarbon resins (hydrogenated)	SML = 5 mg/kg ⁽¹⁾ and in compliance with the specifications laid down in Annex V
93970	—	Tricyclodecanedimethane bis(hexahydrophthalate)	SML = 0,05 mg/kg

(b) for the following additives, the entries in columns 3 'Name' and 4 'Restrictions and/or specifications' are replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,05 mg/kg food ⁽⁴¹⁾ (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate),

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			mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML(T) = 0,05 mg/kg food ⁽⁴¹⁾ (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride'

(c) The following additives are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
67180	—	Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n- octyl ester.	SML = 5 mg/kg ⁽¹⁾
76681	—	Polycyclopentadiene hydrogenated	SML = 5 mg/kg ⁽¹⁾

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ANNEX IV

ANNEX IVa

LIPOPHILIC SUBSTANCES FOR WHICH THE FRF APPLIES

Ref. No	CAS No	Name
31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester
31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl]phenyl ester
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester
38240	000119-61-9	Benzophenone
38515	001533-45-5	4,4'-Bis(2-benzoxazolyl)stilbene
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene
38700	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)
38800	032687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite
38820	026741-53-7	Bis(2,4-di-tert-butylphenyl)pentaerythritol diphosphite
38840	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritoldiphosphite
39060	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane
39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethylhexane
40000	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol

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40800	013003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)
42000	063438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)
45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol
47540	027458-90-8	Di-tert-dodecyl disulphide
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)
48800	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane
48880	000131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)-phenol
49840	002500-88-1	Di-octadecyl disulphide
51680	000102-08-9	N,N'-Diphenylthiourea
52320	052047-59-3	2-(4-Dodecylphenyl)indole
53200	023949-66-8	2-Ethoxy-2'-ethyloxanilide
54300	118337-09-0	2,2'-Ethylidenebis(4,6-di-tert-butyl phenyl) fluorophosphonite
59120	023128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)
59200	035074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)
60320	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole
60400	003896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole
60480	003864-99-1	2-(2'-Hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole

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61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone
66360	085209-91-2	2,2'-Methylene bis(4,6-di-tert-butylphenyl) sodium phosphate
66400	000088-24-4	2,2'-Methylene bis(4-ethyl-6-tert-butylphenol)
66480	000119-47-1	2,2'-Methylene bis(4-methyl-6-tert-butylphenol)
66560	004066-02-8	2,2'-Methylene bis(4-methyl-6-cyclohexylphenol)
66580	000077-62-3	2,2'-Methylene bis(4-methyl-6-(1-methyl-cyclohexyl) phenol)
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]
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
68400	010094-45-8	Octadecylceramide
69840	016260-09-6	Oleypalmitamide
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)
72081/10	—	Petroleum Hydrocarbon Resins (hydrogenated)
72160	000948-65-2	2-Phenylindole
72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester
73160	—	Phosphoric acid, mono- and di-n-alkyl (C ₁₆ and C ₁₈) esters
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester
74400	—	Phosphorous acid, tris(nonyl-and/or dinonylphenyl) ester

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76866	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C ₁₂ -C ₁₈ or n-octanol and/or n-decanol
77440	—	Polyethyleneglycol diricinoleate
78320	009004-97-1	Polyethyleneglycol monoricinoleate
81200	071878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]
83599	068442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin
83700	000141-22-0	Ricinoleic acid
84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester
92320	—	Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid
92560	038613-77-3	Tetrakis(2,4-di-tert-butylphenyl)-4,4'-biphenylene diphosphonite
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
92800	000096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)
92880	041484-35-9	Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)
93120	000123-28-4	Thiodipropionic acid, didodecyl ester

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93280	000693-36-7	Thiodipropionic acid, dioctadecyl ester
95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite
95280	040601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
95360	027676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
95600	001843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane

ANNEX V

Annex V to Directive 2002/72/EC is amended as follows:

- (1) Part A is replaced by the following:

Part A:

General specifications

Plastic material and articles shall not release primary aromatic amines in a detectable quantity (DL = 0,01 mg/kg of food or food simulant). The migration of the primary aromatic amines appearing in the lists in Annex II and III is excluded from this restriction.

- (2) In Part B, the following new specifications are inserted, in the appropriate numerical order:

Ref. No	OTHER SPECIFICATIONS
'42080	Carbon black <i>Specifications:</i> — Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. — UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU

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	<p>for a 5 cm cell, determined according to a generally recognised method of analysis.</p> <p>— Benzo(a)pyrene content: max 0,25 mg/kg carbon black.</p> <p>— Maximum use level of carbon black in the polymer: 2,5 % w/w</p>
72081/10	<p>Petroleum hydrocarbon resins (hydrogenated)</p> <p><i>Specifications:</i> Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoid arylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing.</p> <p><i>Properties:</i> Viscosity: > 3 Pa.s at 120 °C. Softening point: > 95 °C as determined by ASTM Method E 28-67. Bromine number: < 40 (ASTM D1159) The colour of a 50 % solution in toluene < 11 on the Gardner scale Residual aromatic monomer ≤ 50 ppm</p>
76845	<p>Polyester of 1,4-butanediol with caprolactone MW fraction < 1 000 is less than 0,5 % (w/w)</p>
81500	<p>Polyvinylpyrrolidone The substance shall meet the purity criteria established in Commission Directive 96/77/EC^a</p>
88640	<p>Soybean oil, epoxidized Oxirane < 8 %, iodine number < 6</p>

^a OJ L 339, 30.12.1996, p. 1.’

ANNEX VI

Annex VI to Directive 2002/72/EC is amended as follows:

- (1) Note ⁽⁸⁾ is replaced by the following:
 - ⁽⁸⁾ 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 mentioned as Ref. Nos: 24886, 38000, 42400, 62020, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725.
- (2) The following notes 41 and 42 are added:
 - ⁽⁴¹⁾ 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 mentioned as Ref. Nos: 47600, 67360.
 - ⁽⁴²⁾ 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 mentioned as Ref. Nos: 75100 and 75105.

ANNEX VII

ANNEX VIa

DECLARATION OF COMPLIANCE

The written declaration referred to in Article 9 shall contain the following information:

- (1) the identity and address of the business operator which manufactures or imports the plastic materials or articles or the substances intended for the manufacturing of those materials and articles;
- (2) the identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles;
- (3) the date of the declaration;
- (4) confirmation that the plastic materials or articles meet relevant requirements laid down in this Directive and Regulation (EC) No 1935/2004;
- (5) adequate information relative to the substances used for which restrictions and/or specifications are in place under this Directive to allow the downstream business operators to ensure compliance with those restrictions;
- (6) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food;
- (7) specifications on the use of the material or article, such as:
 - (i) type or types of food with which it is intended to be put in contact;

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- (ii) time and temperature of treatment and storage in contact with the food;
 - (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;
- (8) when a plastic functional barrier is used in a plastic multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 7a(2), (3) and 4 of this Directive.

The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.

ANNEX VIII

The Annex to Directive 85/572/EEC is amended as follows:

- (1) Point 3 is replaced by the following:
3. When “X” is followed by an oblique stroke and a figure, the result of the migration tests should be divided by the figure indicated. In the case of certain types of fatty food, this conventional figure, known as “Simulant D Reduction Factor” (DRF), is used to take account of the greater extractive capacity of the simulant compared to the food.
- (2) The following point 4a is inserted:
- 4a. Where the letter (b) is shown in brackets after the “X”, the indicated test shall be carried out with ethanol 50 % (v/v).
- (3) In the table, Section 07 is replaced by the following:

07	Milk products				
07.01	Milk:				
	A. Whole				X(b)
	B. Partly dried				X(b)
	C. Skimmed or partly skimmed				X(b)
	D. Dried				
07.02	Fermented milk such as yoghurt, buttermilk		X		X(b)

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	and similar products				
07.03	Cream and sour cream		X(a)		X(b)
07.04	Cheeses:				
	A. Whole, with non-edible rind				
	B. All others	X(a)	X(a)		X/3*
07.05	Rennet				
	A. In liquid or viscous form	X(a)	X(a)		
	B. Powdered or dried				l