

**COMMISSION DIRECTIVE 2001/62/EC**  
**of 9 August 2001**  
**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<sup>(1)</sup>, and in particular Article 3 thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) Silicones should be regarded as elastomeric materials rather than plastic materials and therefore should be deleted from the definition of plastics.
- (2) The determination of a quantity of a substance in a finished material or article is simpler than the determination of its specific migration level. The verification of compliance through the determination of quantity rather than specific migration level should therefore be permitted under certain conditions.
- (3) For certain types of plastics, the availability of generally recognised diffusion models based on experimental data allows the estimation of the migration level of a substance under certain conditions, therefore avoiding complex, costly and time-consuming testing.
- (4) Recent collaborative tests indicate that there is greater variability in the results of analysis for the determination of overall migration of substances used in plastics when aqueous food simulants as well as volatile media such as isooctane, ethanol and other similar solutions are used.
- (5) Besides the monomers and other starting substances fully evaluated and authorised at Community level, there are also monomers and starting substances evaluated and authorised in at least one Member State, use of which may be continued pending their evaluation by the Scientific Committee on Food and the decision on their inclusion in the Community list.
- (6) On the basis of the new information available to the Scientific Committee on Food, certain monomers provisionally admitted at national level as well as other monomers requested for use following the adoption of

Commission Directive 90/128/EEC of 23 February 1990 relating to plastic materials and articles intended to come into contact with foodstuffs<sup>(2)</sup>, as last amended by Directive 1999/91/EC<sup>(3)</sup>, may be included in the Community list of approved substances.

- (7) For certain substances, the restrictions already established at Community level should be amended on the basis of the information available.
- (8) 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 only pending a decision on inclusion in the Community list.
- (9) This Directive establishes specifications for only a few substances, and therefore the other substances, which may require specifications remain regulated in this respect by national laws only pending a decision at Community level.
- (10) For certain additives the restrictions established in this Directive cannot yet be applied in all situations pending the collection and evaluation of all the data needed for a better estimation of the exposure of the consumer in some specific situations. Therefore, these additives appear in a list other than that of the additives fully regulated at Community level.
- (11) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of plastic materials and articles intended to come into contact with foodstuffs, to lay down rules on the definition of plastics and admitted substances. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.
- (12) Directive 90/128/EEC should therefore be amended accordingly.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

<sup>(1)</sup> OJ L 40, 11.2.1989, p. 38.

<sup>(2)</sup> OJ L 75, 21.3.1990, p. 19.

<sup>(3)</sup> OJ L 310, 4.12.1999, p. 41.

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

Directive 90/128/EEC is amended as follows:

1. In Article 1, paragraph 3 is replaced by the following:

'3. For the purposes of this Directive, "plastics" shall mean the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromoles. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as "plastics":

- (i) varnished or unvarnished regenerated cellulose film, covered by Commission Directive 93/10/EEC (\*);
- (ii) elastomers and natural and synthetic rubber;
- (iii) paper and paperboard, whether modified or not by the addition of plastics;
- (iv) surface coatings obtained from:
  - paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,
  - mixtures of the waxes listed in the first indent with each other and/or with plastics;
- (v) ion-exchange resins;
- (vi) silicones.

(\* ) OJ L 93, 17.4.1993, p. 27.'

2. In Article 3, paragraphs 4 and 5 are replaced by the following:

'4. Only those monomers and other starting substances listed in Annex II, Section A, shall be used for the manufacture of plastic materials and articles, subject to the restrictions specified therein.

By way of derogation from the first subparagraph, the monomers and other starting substances listed in Annex II, Section B, may continue to be used until 31 December 2004 at the latest, pending their evaluation by the Scientific Committee on Food.

5. The lists appearing in Annex II, Sections A and B, do not yet include monomers and other starting substances used only in the manufacture of:

- surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,
- epoxy resins,
- adhesives and adhesion promoters,
- printing inks.'

3. 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 restrictions and/or specifications on their use, is set out in Annex III, Sections A and B.

For the substances in Annex III, Section B, the specific migration limits are applied as from 1 January 2004 when the verification of compliance is carried out in simulant D or in test media of substitute tests as laid down in Directives 82/711/EEC and 85/572/EEC.'

4. In Article 3c, paragraph 1 is replaced by the following:

'1. General specifications related to plastics materials and articles are laid down in Annex V, part A. Other specifications related to some substances appearing in Annexes II, III and IV are laid down in Annex V, part B.'

5. In Article 5, the following paragraph 4 is added:

'4. The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.'

6. Annexes I, II, III, V and VI are amended as set out in Annexes I to V to this Directive.

*Article 2*

The requirements introduced by this Directive shall not apply to materials and articles containing the substances regulated by the Directive which have been put into free circulation in the Community before 1 December 2002.

*Article 3*

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 November 2002 at latest. They shall forthwith inform the Commission thereof.

When Member States adopt these 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 4*

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

*Article 5*

This Directive is addressed to the Member States.

Done at Brussels, 9 August 2001.

*For the Commission*  
David BYRNE  
*Member of the Commission*

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## ANNEX I

In Annex I, paragraph 7, the second indent is replaced by the following:

— 12 mg/kg or 2 mg/dm<sup>2</sup> in migration tests using the other simulants referred to in Directives 82/711/EEC and 85/572/EEC.

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## ANNEX II

Annex II is amended as follows:

1. Section A is amended as follows:

(a) The following monomers and other starting substances are inserted:

Ref. No	CAS No	Name	Restrictions and/or specifications
'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 Directive 85/572/EEC and for indirect food contact only, behind the PET layer
12765	84434-12-8	N-(2-aminoethyl)-beta-alanine, sodium salt	SML = 0,05 mg/kg
13395	04767-03-7	2,2-Bis(hydroxymethyl)propionic acid	QMA = 0,05 mg/6 dm <sup>2</sup>
15030	00931-88-4	Cyclooctene	SML = 0,05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Directive 85/572/EEC
19110	04098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg in FP (as NCO)
21765	106246-33-7	4,4'-Methylenebis(3-chloro-2,6-diethylaniline)	QMA = 0,05 mg/6 dm <sup>2</sup>
22778	07456-68-0	4,4'-Oxybis(benzenesulphonyl azide)	QMA = 0,05 mg/6 dm <sup>2</sup>
24073	000101-90-6	Resorcinol diglycidyl ether	QMA = 0,005 mg/6 dm <sup>2</sup> . Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer'

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

Ref. No	CAS No	Name	Restrictions and/or specifications
'13510	01675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (= BADGE)	According to Commission Directive 2001/61/EC of 8 August 2001 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs (OJ L 215, 9.8.2001, p. 26).
13610	01675-54-3	Bisphenol A bis(2,3-epoxypropyl) ether	See "2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether"

Ref. No	CAS No	Name	Restrictions and/or specifications
14200	0105-60-2	Caprolactam	SML(T) = 15 mg/kg <sup>(5)</sup>
14230	02123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg <sup>(5)</sup> (expressed as caprolactam)
15970	00611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg <sup>(15)</sup>
17260	00050-00-0	Formaldehyde	SML(T) = 15 mg/kg <sup>(22)</sup>
18670	00100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg <sup>(22)</sup> (expressed as formaldehyde)
19540	00110-16-7	Maleic acide	SML(T) = 30 mg/kg <sup>(4)</sup>
19960	00108-31-6	Maleic anhydride	SML(T) = 30 mg/kg <sup>(4)</sup> (expressed as maleic acid)
23050	00108-45-2	1,3-Phenylenediamine	SML = ND (DL = 0,02 mg/kg, analytical tolerance included) <sup>7</sup>

(c) The following monomers and other starting substances are transferred from section B to section A:

Ref. No	CAS No	Name	Restrictions and/or specifications
11530	00999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0,05 mg/6 dm <sup>2</sup>
13617	00080-09-1	Bisphenol S	See "4,4'-Dihydroxydiphenylsulphone"
13810	00505-65-7	1,4-Butanediol formal	QMA = 0,05 mg/6 dm <sup>2</sup>
13932	00598-32-3	3-Buten-2-ol	QMA = ND (DL = 0,02 mg/6 dm <sup>2</sup> ) To be used only as a co-monomer for the preparation of polymeric additive
15370	03236-53-1	1,6-Diamino-2,2,4-trimethylhexane	QMA = 5 mg/6 dm <sup>2</sup>
15400	03236-54-2	1,6-Diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm <sup>2</sup>
15610	00080-07-9	4,4'-Dichlorodiphenyl sulphone	SML = 0,05 mg/kg
16090	00080-09-1	4,4'-Dihydroxydiphenyl sulphone	SML = 0,05 mg/kg
16390	00126-30-7	2,2-Dimethyl-1,3-propanediol	SML = 0,05 mg/kg
19243	00078-79-5	Isoprene	Voir "2-Methyl-1,3-butadiene"
19490	00947-04-6	Lauro lactam	SML = 5 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
20260	00101-43-9	Methacrylic acid, cyclohexyl ester	SML = 0,05 mg/kg
20410	02082-81-7	Methacrylic acid, diester with 1,4-butanediol	SML = 0,05 mg/kg
20590	00106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QMA = 0,02 mg/6 dm <sup>2</sup>
21520	01561-92-8	Methallylsulphonic acid, sodium salt	SML = 5 mg/kg
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)
21821	00505-65-7	1,4-(Methylenedioxy)butane	See "1,4-Butanediol formal"
22360	01141-38-4	2,6-Naphthalenedicarboxylic acid	SML = 5 mg/kg
22437	00126-30-7	Neopentylglycol	See "2,2-Dimethyl-1,3-propanediol"
22900	00109-67-1	1-Pentene	SML = 5 mg/kg
25380	—	Trialkyl acetic acid (C7-C17), vinyl esters (= vinyl versatate)	QMA = 0,05 mg/6 dm <sup>2</sup>
25450	26896-48-0	Tricyclodecanedimethanol	SML = 0,05 mg/kg
25900	00110-88-3	Trioxane	SML = 0,05 mg/kg'

2. Section B is replaced by the following:

'SECTION B

**List of monomers and other starting substances which may continue to be used pending a decision on inclusion in Section A**

Ref. No	CAS No	Name	Restrictions and/or specifications
10599/90A	61788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	
10599/91	61788-89-4	Acids, fatty, unsaturated (C18), dimers, non-distilled	
10599/92A	68783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled	
10599/93	68783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non-distilled	
11500	00103-11-7	Acrylic acid, 2-ethylhexyl ester	
13050	00528-44-9	1,2,4-Benzenetricarboxylic acid	See "Trimellitic acid"
13075	00091-76-9	Benzoguanamine	See "2,4-Diamino-6-phenyl-1,3,5-triazine"
13720	00110-63-4	1,4-Butanediol	

Ref. No	CAS No	Name	Restrictions and/or specifications
14260	00502-44-3	Caprolactone	
14800	03724-65-0	Crotonic acid	
15310	00091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	
15730	00077-73-6	Dicyclopentadiene	
16210	06864-37-5	3,3'-Dimethyl-4-4'-diaminodicyclohexylmethane	
16690	01321-74-0	Divinylbenzene	
16697	00693-23-2	Dodecanedioic acid	
17110	16219-75-3	5-Ethylidenebicyclo[2.2.1]hept-2-ene	
18370	00592-45-0	1,4-Hexadiene	
18700	00629-11-8	1,6-Hexanediol	
21370	10595-80-9	Methacrylic acid, 2-sulphoethyl ester	
21400	54276-35-6	Methacrylic acid, sulphopropyl ester	
21970	00923-02-4	N-methylmethacrylamide	
22210	00098-83-9	Alpha-methylstyrene	
25540	00528-44-9	Trimellitic acid	QM(T) = 5 mg/kg in FP
25550	00552-30-7	Trimellitic anhydride	QM(T) = 5 mg/kg in FP (expressed as trimellitic acid)
25840	03290-92-4	1,1,1-Trimethylolpropane trimethacrylate	
26230	00088-12-0	Vinylpyrrolidone'	



## ANNEX III

Annex III is amended as follows:

1. The table 'Incomplete list of additives' is amended as follows:

(a) The title is replaced by the following:

## 'SECTION A

**Incomplete list of additives fully harmonised at Community level'**

(b) The following additives are inserted:

Ref. No	CAS No	Name	Restrictions and/or specifications
'35160	06642-31-5	6-Amino-1,3-dimethyluracil	SML = 5 mg/kg
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 Directive 85/572/EEC and for indirect food contact only, behind the PET layer
35284	00111-41-1	N-(2-aminoethyl)ethanolamine	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer
38840	154862-43-8	Bis-(2,4-dicumylphenyl) pentaerythritoldiphosphate	SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis (2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)
39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5 - dimethyl hexane	SML = 0,05 mg/kg
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methyl-phenol	SML = 6 mg/kg
41120	10043-52-4	Calcium chloride	
41840	00105-60-2	Caprolactam	SML(T) = 15 mg/kg (5)
47210	26427-07-6	Dibutylthiostannoic acid polymer [= thiobis(butyl-tin sulphide), polymer]	In compliance with the specifications laid down in Annex V
47540	27458-90-8	Di-tert-dodecyl disulfide	SML = 0,05 mg/kg
48620	00123-31-9	1,4-Dihydroxybenzene	SML = 0,6 mg/kg
48720	00611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg (15)
52645	10436-08-5	Cis-11-eicosenamide	

Ref. No	CAS No	Name	Restrictions and/or specifications
64800	00110-16-7	Maleic acid	SML(T) = 30 mg/kg (*)
65920	66822-60-4	[N-methacryloyloxyethyl-N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt-octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers	
73160	—	Phosphoric acid, mono- and di-n-alkyl (C16 and C18) esters	SML = 0,05 mg/kg
76730	—	Polydimethylsiloxane, gamma-hydroxypropylated	SML = 6 mg/kg
81220	192268-64-7	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidiny)-n-butylamino]-1,3,5-triazine-2,4-diyl][2,2,6,6-tetramethyl-4-piperidiny]imino]-1,6-hexanediy[[2,2,6,6-tetramethyl-4-piperidiny]imino]]-alpha-[N,N,N',N'-tetrabutyl-N''''-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl][1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine]	SML = 5 mg/kg
83599	68442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	SML(T) = 0,18 mg/kg <sup>(16)</sup> (expressed as tin)
85680	01343-98-2	Silicic acid	
92150	01401-55-4	Tannic acids	According to the JECFA specifications
93720	00108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl 2-butyl-2-ethyl-1,3-propanediol phosphate	SML = 2 mg/kg (as sum of phosphite, phosphate and the hydrolysis product = TTBP)

(c) For the following additives, the content of column 'Restriction and/or specifications' is replaced by the following:

Ref No	CAS No	Name	Restrictions and/or specifications
'40120	—	Bis (polyethylene-glycol)hydroxymethylphosphonate	SML = 0,6 mg/kg and authorised until 1 January 2004
45200	01335-23-5	Copper iodide	SML(T) = 30 mg/kg <sup>(7)</sup> (expressed as copper) and SML = 1 mg/kg <sup>(11)</sup> (expressed as iodine)

Ref No	CAS No	Name	Restrictions and/or specifications
60480	03864-99-1	2-(2'-Hydroxy-3,5'-di-tert-butyl-phenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg <sup>(19)</sup>
85840	53320-86-8	Silicic acid, lithium magnesium sodium salt	SML(T) = 0,6 mg/kg <sup>(8)</sup> (expressed as lithium)
95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	SML(T) = 0,6 mg/kg <sup>(8)</sup> (expressed as lithium)

(d) The following additives are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
'85980	—	Silicic acid, salts'	

2. The following Section B is added:

'SECTION B

**Incomplete list of additives referred to in Article 3a, second paragraph**

Ref. No	CAS No	Name	Restrictions and/or specifications
30180	02180-18-9	Acetic acid, manganese salt	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
31520	61167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	SML = 6 mg/kg
31920	00103-23-1	Adipic acid, bis(2-ethylhexyl) ester	SML = 18 mg/kg <sup>(1)</sup>
34230	—	Alkyl(C8-C22)sulphonic acids	SML = 6 mg/kg
35760	01309-64-4	Antimony trioxide	SML = 0,02 mg/kg (expressed as antimonium and analytical tolerance included)
36720	17194-00-2	Barium hydroxide	SML(T) = 1 mg/kg <sup>(12)</sup> (expressed as barium)
36800	10022-31-8	Barium nitrate	SML(T) = 1 mg/kg <sup>(12)</sup> (expressed as barium)
38240	00119-61-9	Benzophenone	SML = 0,6 mg/kg
38560	07128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML = 0,6 mg/kg
38700	63397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	SML = 18 mg/kg
38800	32687-78-8	N,N'-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	SML = 15 mg/kg
38820	26741-53-7	Bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	SML = 0,6 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
39060	35958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butyl-phenyl)ethane	SML = 5 mg/kg
39090	—	N,N-Bis(2-hydroxyethyl)alkyl(C8-C18) amine	SML(T) = 1,2 mg/kg <sup>(13)</sup>
39120	—	N,N-bis(2-hydroxyethyl)alkyl(C8-C18) amine hydrochlorides	SML(T) = 1,2 mg/kg <sup>(13)</sup> (expressed as N,N-bis(2-hydroxyethyl)alkyl(C8-C18) amine)
40000	00991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	SML = 30 mg/kg
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	SML = 6 mg/kg
40160	61269-61-2	N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	SML = 2,4 mg/kg
40800	13003-12-8	4,4'-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	SML = 6 mg/kg
40980	19664-95-0	Butyric acid, manganese salt	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
42000	63438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	SML = 30 mg/kg
42400	10377-37-4	Carbonic acid, lithium salt	SML(T) = 0,6 mg/kg <sup>(8)</sup> (expressed as lithium)
42480	00584-09-8	Carbonic acid, rubidium salt	SML = 12 mg/kg
43600	04080-31-3	1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	SML = 0,3 mg/kg
43680	00075-45-6	Chlorodifluoromethane	SML = 6 mg/kg and in compliance with the specifications laid down in Annex V
44960	11104-61-3	Cobalt oxide	SML(T) = 0,05 mg/kg <sup>(14)</sup> (expressed as cobalt)
45440	—	Cresols, butylated, styrenated	SML = 12 mg/kg
46720	04130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4,8 mg/6 dm <sup>2</sup>
47600	84030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML = 12 mg/kg
48640	00131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6 mg/kg <sup>(15)</sup>
48800	00097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	SML = 12 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
48880	00131-53-3	2,2'-Dihydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg <sup>(15)</sup>
49600	26636-01-1	Dimethyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,18 mg/kg <sup>(16)</sup> (expressed as tin)
49840	02500-88-1	Diocetadecyl disulphide	SML = 3 mg/kg
50160	—	Di-n-octyltin bis(n-alkyl(C10-C16) mercapto acetate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50240	10039-33-5	Di-n-octyltin bis(2-ethylhexyl maleate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50320	15571-58-1	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50360	—	Di-n-octyltin bis(ethyl maleate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50400	33568-99-9	Di-n-octyltin bis(isooctyl maleate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50480	26401-97-8	Di-n-octyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50560	—	Di-n-octyltin 1,4-butanediol bis(mercaptoacetate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50640	03648-18-8	Di-n-octyltin dilaurate	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50720	15571-60-5	Di-n-octyltin dimaleate	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50800	—	Di-n-octyltin dimaleate, esterified	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50880	—	Di-n-octyltin dimaleate, polymers (n = 2-4)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
50960	69226-44-4	Di-n-octyltin ethyleneglycol bis(mercaptoacetate)	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
51040	15535-79-2	Di-n-octyltin mercaptoacetate	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
51120	—	Di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate	SML(T) = 0,04 mg/kg <sup>(17)</sup> (expressed as tin)
51570	00127-63-9	Diphenyl sulphone	SML = 3 mg/kg
51680	00102-08-9	N,N'-diphenylthiourea	SML = 3 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
52000	27176-87-0	Dodecylbenzenesulphonic acid	SML = 30 mg/kg
52320	52047-59-3	2-(4-Dodecylphenyl)indole	SML = 0,06 mg/kg
52880	23676-09-7	4-Ethoxybenzoic acid, ethyl ester	SML = 3,6 mg/kg
53200	23949-66-8	2-Ethoxy-2'-ethyloxanilide	SML = 30 mg/kg
58960	00057-09-0	Hexadecyltrimethylammonium bromide	SML = 6 mg/kg
59120	23128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	SML = 45 mg/kg
59200	35074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 6 mg/kg
60320	70321-86-7	2-(2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl)benzotriazole	SML = 1,5 mg/kg
60400	03896-11-5	2-(2'-Hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg <sup>(19)</sup>
60800	65447-77-0	1-(2-Hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	SML = 30 mg/kg
61280	03293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	SML(T) = 6 mg/kg <sup>(15)</sup>
61360	00131-57-7	2-Hydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg <sup>(15)</sup>
61440	02440-22-4	2-(2-Hydroxy-5-methylphenyl)benzotriazole	SML(T) = 30 mg/kg <sup>(19)</sup>
61600	01843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	SML(T) = 6 mg/kg <sup>(15)</sup>
63200	51877-53-3	Lactic acid, manganese salt	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
64320	10377-51-2	Lithium iodide	SML(T) = 1 mg/kg <sup>(11)</sup> (expressed as iodine) and SML(T) = 0,6 mg/kg <sup>(8)</sup> (expressed as lithium)
65120	07773-01-5	Manganese chloride	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
65200	12626-88-9	Manganese hydroxide	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
65280	10043-84-2	Manganese hypophosphite	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
65360	11129-60-5	Manganese oxide	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)

Ref. No	CAS No	Name	Restrictions and/or specifications
65440	—	Manganese pyrophosphite	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
66360	85209-91-2	2,2'-Methylene bis(4,6-di-tert-butylphenyl)sodium phosphate	SML = 5 mg/kg
66400	00088-24-4	2,2'-Methylenebis(4-ethyl-6-tert-butylphenol)	SML(T) = 1,5 mg/kg <sup>(20)</sup>
66480	00119-47-1	2,2'-Methylenebis(4-methyl-6-tert-butylphenol)	SML(T) = 1,5 mg/kg <sup>(20)</sup>
67360	67649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML = 24 mg/kg
67520	54849-38-6	Monomethyltin tris(isooctyl mercaptoacetate)	SML(T) = 0,18 mg/kg <sup>(16)</sup> (expressed as tin)
67600	—	Mono-n-octyltin tris(alkyl(C10-C16)-mercaptoacetate)	SML(T) = 1,2 mg/kg <sup>(18)</sup> (expressed as tin)
67680	27107-89-7	Mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)	SML(T) = 1,2 mg/kg <sup>(18)</sup> (expressed as tin)
67760	26401-86-5	Mono-n-octyltin tris(isooctyl mercaptoacetate)	SML(T) = 1,2 mg/kg <sup>(18)</sup> (expressed as tin)
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 <sup>(14)</sup> (expressed as cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
68320	02082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML = 6 mg/kg
68400	10094-45-8	Octadecylceramide	SML = 5 mg/kg
69840	16260-09-6	Oleylpalmitamide	SML = 5 mg/kg
72160	00948-65-2	2-Phenylindole	SML = 15 mg/kg
72800	01241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	SML = 2,4 mg/kg
73040	13763-32-1	Phosphoric acid, lithium salts	SML(T) = 0,6 mg/kg <sup>(8)</sup> (expressed as lithium)
73120	10124-54-6	Phosphoric acid, manganese salt	SML(T) = 0,6 mg/kg <sup>(10)</sup> (expressed as manganese)
74400	—	Phosphorous acid, tris(nonyl- and/or dimonylphenyl) ester	SML = 30 mg/kg
77440	—	Polyethyleneglycol diricinoleate	SML = 42 mg/kg

Ref. No	CAS No	Name	Restrictions and/or specifications
77520	61791-12-6	Polyethyleneglycol ester of castor oil	SML = 42 mg/kg
78320	09004-97-1	Polyethyleneglycol monoricinoleate	SML = 42 mg/kg
81200	71878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl) amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]	SML = 3 mg/kg
81680	07681-11-0	Potassium iodide	SML(T) = 1 mg/kg <sup>(11)</sup> (expressed as iodium)
82020	19019-51-3	Propionic acid, cobalt salt	SML(T) = 0,05 mg/kg <sup>(14)</sup> (expressed as cobalt)
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 mentioned in Annex V
83700	00141-22-0	Ricinoleic acid	SML = 42 mg/kg
84800	00087-18-3	Salicylic acid, 4-tert-butylphenyl ester	SML = 12 mg/kg
84880	00119-36-8	Salicylic acid, methyl ester	SML = 30 mg/kg
85760	12068-40-5	Silicic acid, lithium aluminium salt (2:1:1)	SML(T) = 0,6 mg/kg <sup>(8)</sup> (expressed as lithium)
85920	12627-14-4	Silicic acid, lithium salt	SML(T) = 0,6 mg/kg <sup>(8)</sup> (expressed as lithium)
86800	07681-82-5	Sodium iodide	SML(T) = 1 mg/kg <sup>(11)</sup> (expressed as iodium)
86880	—	Sodium monoalkyl dialkylphenoxybenzenedisulphonate	SML = 9 mg/kg
89170	13586-84-0	Stearic acid, cobalt salt	SML(T) = 0,05 mg/kg <sup>(14)</sup> (expressed as cobalt)
92000	07727-43-7	Sulphuric acid, barium salt	SML(T) = 1 mg/kg <sup>(12)</sup> (expressed as barium)
92320	—	Tetradecyl-polyethyleneglycol (EO = 3-8) ether of glycolic acid	SML = 15 mg/kg
92560	38613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4-4'-biphenylene diphosphonite	SML = 18 mg/kg



Ref. No	CAS No	Name	Restrictions and/or specifications
92800	00096-69-5	4,4'-Thiobis(6-tert-butyl-3-methylphenol)	SML = 0,48 mg/kg
92880	41484-35-9	Thiodiethanol bis(3-(3-5-di-tert-butyl-4-hydroxyphenyl)propionate)	SML = 2,4 mg/kg
93120	00123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5 mg/kg <sup>(21)</sup>
93280	00693-36-7	Thiodipropionic acid, dioctadecyl ester	SML(T) = 5 mg/kg <sup>(21)</sup>
94560	00122-20-3	Triisopropanolamine	SML = 5 mg/kg
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
95360	27676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione	SML = 5 mg/kg
95600	01843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane	SML = 5 mg/kg'

## ANNEX IV

Annex V is amended as follows:

1. Part A of Annex V is replaced by the following:

**'Part A: General specifications**

The material and article manufactured by using aromatic isocyanates or colorants prepared by diazo-coupling, shall not release primary aromatic amines (expressed as aniline) in a detectable quantity (DL 0,02 mg/kg of food or food simulant, analytical tolerance included). However the migration value of the primary aromatic amines listed in this Directive are excluded from this restriction.'

2. The following specifications are inserted in the table of Part B of Annex V:

PM/Ref. No	Other specifications
'43680	CHLORODIFLUOROMETHANE
—	Content of chlorofluoromethane less than 1 mg/kg of the substance
47210	DIBUTYLTHIOSTANNOIC ACID POLYMER
—	Molecular unit = (C <sub>8</sub> H <sub>18</sub> S <sub>3</sub> Sn <sub>2</sub> ) <sub>n</sub> (n = 1,5-2)
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
	<b>Composition</b>
	— 4,4'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 38613-77-3) (36-46 % w/w <sup>(1)</sup> )
	— 4,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 118421-00-4) (17-23 % w/w)
	— 3,3'-Biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 118421-01-5) (1-5 % w/w)
	— 4-Biphenylene-0,0-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 91362-37-7) (11-19 % w/w)
	— Tris(2,4-di-tert-butylphenyl)phosphite (CAS No 31570-04-4) (9-18 % w/w)
	— 4,4'-Biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 112949-97-0) < 5 % w/w)
	<b>Other specifications</b>
	— Phosphor content of minimum 5,4 % to 5,9 %
	— Acid value of maximum 10 mg KOH per gram
	— Melt range of 85-110 °C

<sup>(1)</sup> Quantity of substance used/quantity of formulation.'

## ANNEX V

Annex VI is replaced by the following text:

## 'ANNEX VI

**NOTES RELATED TO THE COLUMN "RESTRICTIONS AND/OR SPECIFICATIONS"**

- (<sup>1</sup>) Warning: there is a risk that the SML could be exceeded in fatty food simulants.
- (<sup>2</sup>) 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.
- (<sup>3</sup>) 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 and 89440.
- (<sup>4</sup>) 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 and 64800.
- (<sup>5</sup>) 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 and 41840.
- (<sup>6</sup>) 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.
- (<sup>7</sup>) 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 PM/REF Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.
- (<sup>8</sup>) 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 PM/REF Nos: 42400, 64320, 73040, 85760, 85840, 85920 and 95725.
- (<sup>9</sup>) 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.
- (<sup>10</sup>) 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 PM/REF Nos: 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.
- (<sup>11</sup>) 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 PM/REF Nos: 45200, 64320, 81680 and 86800.
- (<sup>12</sup>) 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 PM/REF Nos: 36720, 36800 and 92000.
- (<sup>13</sup>) 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 PM/REF Nos: 39090 and 39120.
- (<sup>14</sup>) 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 PM/REF Nos: 44960, 68078, 82020 and 89170.
- (<sup>15</sup>) 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 PM/REF Nos: 15970, 48640, 48720, 48880, 61280, 61360 and 61600.
- (<sup>16</sup>) 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 PM/REF Nos: 49600, 67520 and 83599.
- (<sup>17</sup>) 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 PM/REF Nos: 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.
- (<sup>18</sup>) 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 PM/REF Nos: 67600, 67680 and 67760.
- (<sup>19</sup>) 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 PM/REF Nos: 60400, 60480 and 61440.
- (<sup>20</sup>) 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 PM/REF Nos: 66400 and 66480.
- (<sup>21</sup>) 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 PM/REF Nos: 93120 and 93280.
- (<sup>22</sup>) 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 PM/REF Nos: 17260 and 18670.'
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