COMMISSION DIRECTIVE 95/3/EC

of 14 February 1995

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

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 for Food,

Whereas the Community measures envisaged by this Directive are not only necessary but also indispensable for the attainment of the objectives of the internal market; whereas those objectives cannot be achieved by Member States individually; whereas, furthermore, their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas Commission Directive 90/128/EEC [2], as last amended by Directive 93/9/EEC [3], and in particular Article 3 (4) thereof, provides for the revision of Annex II and particularly Section B;

Whereas, on the basis of the information available, certain substances provisionally admitted at national level may be included in the Community list;

Whereas certain substances provisionally admitted at national level may continue to be permitted for a further specified period, since the data requested by the Scientific Committee for Food are not yet available although the requisite studies are in progress or are planned;

Whereas other substances have been requested for use following the adoption of Directive 90/128/EEC, and the technical data supplied permit their inclusion in the Community list;

Whereas, for certain substances, the restrictions already set out should be amended according to the information available;

Whereas it is necessary to extend this list to additives in order to obtain a more complete harmonization of this sector;

Whereas the number of substances to be included in a complete list of additives is so large that it is necessary to proceed step by step, although the final step will be a complete list of additives (positive list);

Whereas the list which appears in this Directive is an initial, incomplete list which, therefore, does not contain all the substances which are currently accepted in one or more Member States and then these substances can continue to be regulated by national laws pending a decision on inclusion in the Community list;

Whereas certain substances may require specific rules concerning purity criteria which are not yet included in this Directive, and therefore this aspect continues to be governed by national laws pending a decision at Community level;

Whereas 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 following Article 3a is inserted:

   'Article 3a

   An incomplete list of additives which may be used for the manufacture of plastics materials and articles is set out in Annex III.'

2. Annex II is amended as shown in Annex I to this Directive.

3. Annex II to this Directive is added as Annex III.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 1 April 1996. They shall immediately inform the Commission thereof.

Member States shall:

— permit, as from 1 April 1996, the trade in and use of plastic materials and articles intended to come into contact with foodstuffs complying with this Directive;

[1] OJ No L 40, 11. 2. 1989, p. 38.
[2] OJ No L 75, 21. 3. 1990, p. 19, corrected by OJ No L 349, 13. 12. 1990, p. 26.
[3] OJ No L 90, 14. 4. 1993, p. 26.

— prohibit, as from 1 April 1998, the trade in and use 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 these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

Article 3

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

Done at Brussels, 14 February 1995.

For the Commission

Martin BANGEMANN

Member of the Commission

ANNEX I

Annex II to Directive 90/128/EEC is amended as follows:

(a) In paragraph 4, the words 'as regards the purity criteria' are added after 'quality'.

(b) Section A is amended as shown in Appendices 1, 2 and 3.

(c) Section B is amended as shown in Appendix 4.

Appendix 1

List of monomers and other starting substances added to Section A

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
12789	007664-41-7	Ammonia	
14411	008001-79-4	Castor oil	

Appendix 2

List of monomers and other starting substances in Section A for which the content of the column 'Restrictions' is modified

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
24130	008050-09-7	Rosin gum	See 'Rosin'
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	SML = 5 mg/kg

Appendix 3

List of monomers and other starting substances deleted

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
14410	008001-79-4	Castor oil (food grade quality)	

Appendix 4

List of monomers and other starting substances transferred to Section A

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
10660	015214-89-8	2-Acrylamido-2-methylpropanesulphonic acid	SML = 0,05 mg/kg
15070	001647-16-1	1,9-Decadiene	SML = 0,05 mg/kg
17050	000104-76-7	2-Ethyl-1-hexanol	SML = 30 mg/kg
19270	000097-65-4	Itaconic acid	
26140	000075-38-7	Vinylidene fluoride	SML = 5 mg/kg

ANNEX II

'ANNEX III

INCOMPLETE LIST OF ADDITIVES WHICH MAY BE USED IN THE MANUFACTURE OF PLASTICS MATERIALS AND ARTICLES

General introduction

1. This Annex contains the list of:

   (a) substances which are incorporated into plastics to achieve a technical effect in the finished product. They are intended to be present in the finished articles;

   (b) substances used to provide a suitable medium in which polymerization occurs (e.g. emulsifiers, surfactants, buffering agents etc.).

   The list does not include the substances which directly influence the formation of polymers (e.g. the catalytic system).

2. The list does not include the salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium and zinc of the authorized acids, phenols or alcohols which are also authorized. However, names containing "...acid(s), salts" appear in the lists if the corresponding free acid(s) is (are) not mentioned. In such cases the meaning of the term "salts" is "salts of aluminium ammonium, calcium, iron, magnesium, potassium, sodium and zinc".

3. The list does not include the following substances although they may be present:

   (a) substances which could be present in the finished product such as:

   — impurities in the substances used,
   — reaction intermediates,
   — decomposition products;

   (b) mixtures of the authorized substances.

   The materials and articles which contain the substances indicated in (a) and (b) shall comply with the requirements stated in Article 2 of Directive 89/109/EEC.

4. Substances shall be of good technical quality as regards the purity criteria.

5. The list contains the following information:

   — column 1 (PM-REF No): the EEC packaging material reference number of the substances on the list,
   — column 2 (CAS No): the CAS (Chemical Abstracts Service) registry number,
   — column 3 (Name): the chemical name,
   — column 4 (Restrictions). These may include:
   — specific migration limit (SML),
   — maximum permitted quantity of the "residual", substance in the material or article (QM),
   — any other restriction specifically mentioned.

6. If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

7. Where there is any inconsistency between the CAS number and the chemical name, the chemical name shall take precedence over the CAS number. If there is an inconsistency between the CAS number reported in Einecs and the CAS registry, the CAS number in the CAS registry shall apply.

Incomplete list of additives

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
30000	000064-19-7	Acetic acid	
30045	000123-86-4	Acetic acid, butyl ester	
30140	000141-78-6	Acetic acid, ethyl ester	
30280	000108-24-7	Acetic anhydride	
30295	000067-64-1	Acetone	
30370	—	Acetylacetic acid, salts	
30400	—	Acetylated glycerides	
30960	—	Acids, aliphatic, monocarboxylic (C_6-C_{22}), esters with polyglycerol	
31328	—	Acids, fatty, from animal or vegetable food fats and oils	
31730	000124-04-9	Adipic acid	
33120	—	Alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{24})	
33350	009005-32-7	Alginic acid	
34480	—	Aluminium fibers, flakes and powders	
34560	021645-51-2	Aluminium hydroxide	
34690	011097-59-9	Aluminium magnesium carbonate hydroxide	
34720	001344-28-1	Aluminium oxide	
35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether	
35320	007664-41-7	Ammonia	
35440	012124-97-9	Ammonium bromide	
35600	001336-21-6	Ammonium hydroxide	
35840	000506-30-9	Arachidic acid	
35845	007771-44-0	Arachidonic acid	
36000	000050-81-7	Ascorbic acid	
36080	000137-66-6	Ascorbyl palmitate	
36160	010605-09-1	Ascorbyl stearate	
36880	008012-89-3	Beeswax	
36960	003061-75-4	Behenamide	
37040	000112-85-6	Behenic acid	
37280	001302-78-9	Bentonite	
37600	000065-85-0	Benzoic acid	
37680	000136-60-7	Benzoic acid, butyl ester	
37840	000093-89-0	Benzoic acid, ethyl ester	
38080	000093-58-3	Benzoic acid, methyl ester	
38160	002315-68-6	Benzoic acid, propyl ester	
38950	079072-96-1	Bis (4-ethylbenzylidene) sorbitol	
39890	087826-41-3 069158-41-4 054686-97-4	Bis (methylbenzylidene) sorbitol	
40400	010043-11-5	Boron nitride	
40570	000106-97-8	Butane	
41040	005743-36-2	Calcium butyrate	
41280	001305-62-0	Calcium hydroxide	
41520	001305-78-8	Calcium oxide	
41600	012004-14-7 037293-22-4	Calcium sulphoaluminate	
41760	008006-44-8	Candelilla wax	

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
41960	000124-07-2	Caprylic acid	
42160	000124-38-9	Carbon dioxide	
42500	—	Carbonic acid, salts	
42640	009000-11-7	Carboxymethylcellulose	
42720	008015-86-9	Carnauba wax	
42800	009000-71-9	Casein	
42960	064147-40-6	Castor oil, dehydrated	
43200	—	Castor oil, mono- and diglycerides	
43280	009004-34-6	Cellulose	
43300	009004-36-8	Cellulose acetate butyrate	
43360	068442-85-3	Celulose, regenerated	
43440	008001-75-0	Ceresin	
44160	000077-92-9	Citric acid	
44640	000077-93-0	Citric acid, triethyl ester	
45280	—	Cotton fibers	
45560	014464-46-1	Cristobalite	
45760	000108-91-8	Cyclohexylamine	
45920	009000-16-2	Dammar	
45940	000334-48-5	n-Decanoic acid	
46070	010016-20-3	alpha-Dextrin	
46080	007585-39-9	beta-Dextrin	
46375	061790-53-2	Diatomaceous earth	
46480	032647-67-9	Dibenzylidene sorbitol	
46790	004221-80-1	3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	
46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	
46870	003135-18-0	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	
47440	000461-58-5	Dicyanodiamide	
49540	000067-68-5	Dimethyl sulphoxide	
51200	000126-58-9	Dipentaerythritol	
51760	025265-71-8 000110-98-5	Dipropyleneglycol	
52640	016389-88-1	Dolomite	
52730	000112-86-7	Erucic acid	
52800	000064-17-5	Ethanol	
53270	037205-99-5	Ethylcarboxymethylcellulose	
53280	009004-57-3	Ethylcellulose	
53360	000110-31-6	N,N′-Ethylenebisoleamide	
53440	005518-18-3	N,N′-Ethylenebispalmitamide	
53520	000110-30-5	N,N′-Ethylenebisstearamide	
53600	000060-00-4	Ethylenediaminetetraacetic acid	
54005	005136-44-7	Ethylene-N-palmitamide-N′-stearamide	
54260	009004-58-4	Ethylhydroxyethylcellulose	
54270	—	Ethylhydroxymethylcellulose	
54280	—	Ethylhydroxypropylcellulose	
54450	—	Fats and oils, from animal or vegetable food sources	
54480	—	Fats and oils, hydrogenated, from animal or vegetable food sources	
55040	000064-18-6	Formic acid	
55120	000110-17-8	Fumaric acid	
55190	029204-02-2	Gadoleic acid	
55440	009000-70-8	Gelatin	
55680	000110-94-1	Glutaric acid	

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
55920	000056-81-5	Glycerol	
56020	099880-64-5	Glycerol dibehenate	
56360	—	Glycerol, esters with acetic acid	
56487	—	Glycerol, esters with butyric acid	
56490	—	Glycerol, esters with erucic acid	
56495	—	Glycerol, esters with 12-hydroxystearic acid	
56500	—	Glycerol, esters with lauric acid	
56510	—	Glycerol, esters with linoleic acid	
56520	—	Glycerol, esters with myristic acid	
56540	—	Glycerol, esters with oleic acid	
56550	—	Glycerol, esters with palmitic acid	
56565	—	Glycerol, esters with nonanoic acid	
56570	—	Glycerol, esters with propionic acid	
56580	—	Glycerol, esters with ricinoleic acid	
56585	—	Glycerol, esters with stearic acid	
56610	030233-64-8	Glycerol monobehenate	
56720	026402-23-3	Glycerol monohexanoate	
56800	030899-62-8	Glycerol monolaurate diacetate	
56880	026402-26-6	Glycerol monooctanoate	
57040	—	Glycerol monooleate, ester with ascorbic acid	
57120	—	Glycerol monooleate, ester with citric acid	
57200	—	Glycerol monopalmitate, ester with ascorbic acid	
57280	—	Glycerol monopalmitate, ester with citric acid	
57600	—	Glycerol monostearate, ester with ascrobic acid	
57680	—	Glycerol monostearate, ester with citric acid	
57920	000620-67-7	Glycerol triheptanoate	
58300	—	Glycine, salts	
58320	007782-42-5	Graphite	
58400	009000-30-0	Guar gum	
58480	009000-01-5	Gum arabic	
58720	000111-14-8	Heptanoic acid	
59360	000142-62-1	Hexanoic acid	
59760	019569-21-2	Huntite	
59990	007647-01-0	Hydrochloric acid	
60030	012072-90-1	Hydromagnesite	
60080	012304-65-3	Hydrotalcite	
60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester	
60180	004191-73-5	4-Hydroxybenzoic acid, isopropyl ester	
60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester	
60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester	
60560	009004-62-0	Hydroxyethylcellulose	
60880	009032-42-2	Hydroxyethylmethylcellulose	
61120	009005-27-0	Hydroxyethyl starch	
61390	037353-59-6	Hydroxymethylcellulose	
61680	009004-64-2	Hydroxypropylcellulose	
61800	009049-76-7	Hydroxypropyl starch	
61840	000106-14-9	12-Hydroxystearic acid	

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
62140	006303-21-5	Hypophosphorous acid	
62240	001332-37-2	Iron oxide	
62450	000078-78-4	Isopentane	
62640	008001-39-6	Japan wax	
62720	001332-58-7	Kaolin	
62800	—	Kaolin, calcined	
62960	000050-21-5	Lactic acid	
63040	000138-22-7	Lactic acid, butyl ester	
63280	000143-07-7	Lauric acid	
63760	008002-43-5	Lecithin	
63840	000123-76-2	Levulinic acid	
63920	000557-59-5	Lignoceric acid	
64015	000060-33-3	Linoleic acid	
64150	028290-79-1	Linolenic acid	
64500	—	Lysine, salts	
64640	001309-42-8	Magnesium hydroxide	
64720	001309-48-4	Magnesium oxide	
65020	006915-15-7	Malic acid	
65040	000141-82-2	Malonic acid	
65520	000087-78-5	Mannitol	
66200	037206-01-2	Methylcarboxymethylcellulose	
66240	009004-67-5	Methylcellulose	
66640	009004-59-5	Methylethylcellulose	
66695	—	Methylhydroxymethylcellulose	
66700	009004-65-3	Methylhydroxypropylcellulose	
67120	012001-26-2	Mica	
67200	001317-33-5	Molybdenum disulphide	
67840	—	Montanic acids and/or their esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol	
67850	008002-53-7	Montan wax	
67891	000544-63-8	Myristic acid	
68040	003333-62-8	7-[2H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	
68125	068187-64-4	Nepheline syenite	
69040	000112-80-1	Oleic acid	
69760	000143-28-2	Oleyl alcohol	
70000	070331-94-1	2,2'-Oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	
70240	012198-93-5	Ozokerite	
70400	000057-10-3	Palmitic acid	
71020	000373-49-9	Palmitoleic acid	
71440	009000-69-5	Pectin	
71600	000115-77-5	Pentaerythritol	
71680	006683-19-8	Pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	
71720	000109-66-0	Pentane	
72640	007664-38-2	Phosphoric acid	
74240	031570-04-4	Phosphorous acid, tris(2,4-di-tert-butylphenyl)ester	
74480	000088-99-3	o-Phthalic acid	
76320	000085-44-9	Phthalic anhydride	
76720	009016-00-6 063148-62-9	Polydimethylsiloxane	
76960	025322-68-3	Polyethyleneglycol	

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
77600	061788-85-0	Polyethyleneglycol ester of hydrogenated castor oil	
77702	—	Polyethyleneglycol esters of aliphatic monocarboxylic acids (C_6-C_{22}), and their ammonium and sodium sulphates	
79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate	
79120	009005-65-6	Polyethyleneglycol sorbitan monooleate	
79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate	
79280	009005-67-8	Polyethyleneglycol sorbitan monostearate	
79360	009005-70-3	Polyethyleneglycol sorbitan trioleate	
79440	009005-71-4	Polyethyleneglycol sorbitan tristearate	
80240	029894-35-7	Polyglycerol ricinoleate	
80640	—	Polyoxyalkyl(C_2-C_4)dimethylpolysiloxane	
80720	008017-16-1	Polyphosphoric acids	
81520	007758-02-3	Potassium bromide	
81600	001310-58-3	Potassium hydroxide	
81840	000057-55-6	1,2-Propanediol	
81882	000067-63-0	2-Propanol	
82000	000079-09-4	Propionic acid	
82080	009005-37-2	1,2-Propyleneglycol alginate	
82240	022788-19-8	1,2-Propyleneglycol dilaurate	
82400	000105-62-4	1,2-Propyleneglycol dioleate	
82560	033587-20-1	1,2-Propyleneglycol dipalmitate	
82720	006182-11-2	1,2-Propyleneglycol distearate	
82800	027194-74-7	1,2-Propyleneglycol monolaurate	
82960	001330-80-9	1,2-Propyleneglycol monooleate	
83120	029013-28-3	1,2-Propyleneglycol monopalmitate	
83300	001323-39-3	1,2-Propyleneglycol monostearate	
83320	—	Propylhydroxyethylcellulose	
83325	—	Propylhydroxymethylcellulose	
83330	—	Propylhydroxypropylcellulose	
83440	002466-09-3	Pyrophosphoric acid	
83455	013445-56-2	Pyrophosphorous acid	
83460	012269-78-2	Pyrophyllite	
83470	014808-60-7	Quartz	
83610	073138-82-6	Resin acids and rosin acids	
83840	008050-09-7	Rosin	
84000	008050-31-5	Rosin, ester with glycerol	
84080	008050-26-8	Rosin, ester with pentaerythritol	
84210	065997-06-0	Rosin, hydrogenated	
84240	065997-13-9	Rosin, hydrogenated, ester with glycerol	
84320	008050-15-5	Rosin, hydrogenated, ester with methanol	
84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol	
84560	009006-04-6	Rubber, natural	
84640	000069-72-7	Salicylic acid	
85600	—	Silicates, natural	
85980	—	Silicic acid, salts	
86000	—	Silicic acid, silylated	
86160	000409-21-2	Silicon carbide	
86240	007631-86-9	Silicon dioxide	
86560	007647-15-6	Sodium bromide	
86720	001310-73-2	Sodium hydroxide	
87200	000110-44-1	Sorbic acid	
87280	029116-98-1	Sorbitan dioleate	

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
87520	062568-11-0	Sorbitan monobehenate	
87600	001338-39-2	Sorbitan monolaurate	
87680	001338-43-8	Sorbitan monooleate	
87760	026266-57-9	Sorbitan monopalmitate	
87840	001338-41-6	Sorbitan monostearate	
87920	061752-68-9	Sorbitan tetrastearate	
88080	026266-58-0	Sorbitan trioleate	
88160	054140-20-4	Sorbitan tripalmitate	
88240	026658-19-5	Sorbitan tristearate	
88320	000050-70-4	Sorbitol	
88600	026836-47-5	Sorbitol monostearate	
88800	009005-25-8	Starch, edible	
88880	068412-29-3	Starch, hydrolysed	
89040	000057-11-4	Stearic acid	
90720	058446-52-9	Stearoylbenzoylmethane	
90800	005793-94-2	Stearoyl-2-lactylic acid, calcium salt	
90960	000110-15-6	Succinic acid	
91200	000126-13-6	Sucrose acetate isobutyrate	
91360	000126-14-7	Sucrose octaacetate	
91840	007704-34-9	Sulphur	
91920	007664-93-9	Sulphuric acid	
92080	014807-96-6	Talc	
92160	000087-69-4	Tartaric acid	
92195	—	Taurine, salts	
92205	057569-40-1	Terephthalic acid, diester with 2,2′-methylenebis(4-methyl-6-tert-butylphenol)	
92350	000112-60-7	Tetraethyleneglycol	
92640	000102-60-3	N,N,N′,N′-Tetrakis(2-hydroxypropyl)ethylenediamine	
93440	013463-67-7	Titanium dioxide	
93520	000059-02-9 010191-41-0	alpha-Tocopherol	
93680	009000-65-1	Tragacanth gum	
94320	000112-27-6	Triethyleneglycol	
95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	
95905	013983-17-0	Wollastonite	
95920	—	Wood flour and fibers, untreated	
95935	011138-66-2	Xanthan gum	
96190	020427-58-1	Zinc hydroxide	
96240	001314-13-2	Zinc oxide	
96320	001314-98-3	Zinc sulphide'	