II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DIRECTIVE 92/39/EEC

of 14 May 1992

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 Economic 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,

Whereas Commission Directive 90/128/EEC (2) of 23 February 1990, and in particular Article 3 (4), provides for the revision of Annex II and particularly section B ;

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

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 but the required studies are ongoing or are planned ;

Whereas other substances have been requested for use following the adoption of the Directive, 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 available information ;

Whereas it is necessary to permit the continued use of certain well-defined substances contained in those groups of substances which are not well-defined and are now deleted, pending a decision on their inclusion in the Community list ;

Whereas the Scientific Committee for Food has been consulted ;

Whereas the measures laid down by this Directive comply with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE :

Article 1

Directive 90/128/EEC is hereby amended as follows :

1. Article 3 (4) is replaced by the following :

'4. As from 1 January 1997, 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. However, the substances listed in Annex II, Section B may be deleted before the abovementioned date if the data requested for inclusion in Section A are not supplied in time to permit their evaluation by the Scientific Committee for Food. Moreover, before 1 January 1996 it may be decided that, in some justified cases, for certain substances listed in Annex II, Section B, this time-limit will be postponed.'

2. Annex II of Directive 90/128/EEC is amended as

(1) OJ No L 40, 11. 2. 1989, p. 38.
(2) OJ No L 75, 21. 3. 1990, p. 19, rectified by OJ No L 349, 13. 12. 1990, p. 26.

follows :

(a) Section A :

— the substances appearing in Annex I to this Directive are added ;

— the content of the column 'Restrictions' for the substances appearing in Annex II of this Directive is modified as indicated therein.

(b) Section B :

— the substances appearing in Annex III to this Directive are added, as a replacement for those groups of substances which are not well-defined and which are deleted by this Directive ;

— the substances appearing in Annex IV to this Directive are deleted ;

— the content of the column 'Restrictions' for the substance appearing in Annex V to this Directive is modified as indicated therein.

(c) The substances appearing in Annex VI to this Directive are transferred from Section B to A and are now subject to the restrictions, if any, specified.

(d) Point 8 is hereby amended as follows :

— the following text is inserted after 'NCO = isocyanate moiety ;'

'ND = not detectable.

For the purpose of this Directive "not detectable" means that the substance should not be detected by a validated method of analysis which should detect it at the detection limit (DL) specified.

If such a method does not currently exist, an analytical method with appropriate performance characteristics at the detection limit may be used, pending the development of a validated method.'

— the following text is inserted after 'SML = specific migration limit in food or in food stimulant, unless it is specified otherwise.'

'For the purpose of this Directive "SML" means that the specific migration of the substance should be determined by a validated method of analysis at the specified limit. If such a method does not currently exist, an analytical method with appropriate performance characteristics at the specified limit may be used, pending the development of a validated method.'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1992. They shall immediately inform the Commission thereof.

Member States should :

— permit trade in and use of plastic materials and articles complying with this Directive by 31 March 1994 ;

— prohibit trade in and use of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive with effect from 1 April 1995.

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 is addressed to the Member States.

Done at Brussels, 14 May 1992.

For the Commission

Martin BANGEMANN

Vice-President

ANNEX I

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES ADDED TO SECTION A

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
12788	002432-99-7	11-Aminoundecanoic acid	SML = ND (DL = 0,01 mg/kg)
13530	038103-06-9	2,2-Bis(4-hydroxyphenyl)propane bis(phtalic anhydride)	SML = 0,05 mg/kg
13614	038103-06-9	Bisphenol A bis(phtalic anhydride)	See 13530
19470	000143-07-7	Lauric acid	
22350	000544-63-8	Myristic acid	
22763	000112-80-1	Oleic acid	
24270	000069-72-7	Salicylic acid	
24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	SML = 0,05 mg/kg
25910	024800-44-0	Tripropyleneglycol	

ANNEX II

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)
17005	000151-56-4	Ethyleneimine	SML = ND (DL = 0,01 mg/kg)
18670	000100-97-0	Hexamethylenetetramine	SML (T) = 15 mg/kg (expressed as formaldehyde)
22150	000691-37-2	4-Methyl-1-pentene	SML = 0,02 mg/kg

ANNEX III

LIST OF MONOMERS AND OTHER STARTING SUBSTANCES ADDED TO SECTION B

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
10160	002206-94-2	alpha-Acetoxystyrene	
10162	010521-96-7	beta-Acetoxystyrene	
10599/70		Acids, fatty, unsaturated (C 18)	
10599/90	061788-89-4	Acids, fatty, unsaturated (C18), dimers	
10599/92	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated	
10775	084100-23-2	Acrylic acid, 4-tert-butylcyclohexyl ester	
11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	
11005	012542-30-2	Acrylic acid, dicyclopentenyl ester	
11010	024447-78-7	Acrylic acid, diester with 2,2-bis(4-hydroxyphenyl)propane bis(2-hydroxyethyl) ether	
11180	017831-71-9	Acrylic acid, diester with tetraethyleneglycol	
11195	068901-05-3	Acrylic acid, diester with tripropyleneglycol	

PM/Ref No	CAS No	Name	Restrictions
(1)	(2)	(3)	(4)
11245	002156-97-0	Acrylic acid, dodecyl ester	
11520	002918-23-2	Acrylic acid, 2-hydroxyisopropyl ester (= acrylic acid, 2-hydroxy-1-methylethyl ester)	
11532	002761-08-2	Acrylic acid, 3-hydroxypropyl ester	
11695	003121-61-7	Acrylic acid, 2-methoxyethyl ester	
11875	004813-57-4	Acrylic acid, octadecyl ester	
12055	094160-26-6	Acrylic acid, triester with glycerol tris(2-hydroxypropyl) ether	
12062	075577-70-7	Acrylic acid, triester with 1,1,1-trimethylolpropane tris (2-hydroxyethyl) ether	
12265	004074-90-2	Adipic acid, divinyl ester	
13328	000104-38-1	Bis(2-hydroxyethyl) ether of hydroquinone	
13932	000598-32-3	3-Buten-2-ol	
14008	000098-52-2	4-tert-Butylcyclohexanol	
14035	001746-23-2	4-tert-Butylstyrene	
14833	000623-43-8	Crotonic acid, methyl ester	
15020	002182-05-0	Cyclohexyl vinyl ether	
15030	000931-88-4	Cyclooctene	
15060	000142-29-0	Cyclopentene	
15095	000334-48-5	Decanoic acid	
15260	000646-25-3	1,10-Diaminodecane	
15270	002783-17-7	1,12-Diaminododecane	
15295	000373-44-4	1,8-Diaminooctane	
16252	000110-03-2	2,5-Dimethyl-2,5-hexanediol	
16697	000693-23-2	Dodecanedioic acid	
16719	003813-52-3	Endomethylenetetrahydrophthalic acid	
17040	000149-57-5	2-Ethylhexanoic acid	
17116	005877-42-9	4-Ethyl-1-octyn-3-ol	
17150	000078-27-3	1-Ethynylcyclohexanol	
17305	000141-02-6	Fumaric acid, bis(2-ethylhexyl) ester	
17398	007283-68-3	Fumaric acid, dioctadecyl ester	
18436	001687-30-5	Hexahydrophthalic acid	
18441	000085-42-7	Hexahydrophthalic anhydride	
18865	003031-66-1	3-Hexyn-2,5-diol	
18905	002628-17-3	4-Hydroxystyrene	
19130	026896-18-4	Isononanoic acid	
19490	000947-04-6	Laurolactam	
19915	000925-21-3	Maleic acid, monobutyl ester	
19936	007423-42-9	Maleic acid, mono(2-ethylhexyl) ester	
20095	046729-07-1	Methacrylic acid, 4-tert-butylcyclohexyl ester	
20455	006606-59-3	Methacrylic acid, diester with 1,6-hexanediol	
20945	004664-49-7	Methacrylic acid, 2-hydroxyisopropyl ester (= methacrylic acid, 2-hydroxy-1-methylethyl ester)	
20965	002761-09-3	Methacrylic acid, 3-hydroxypropyl ester	
21115	000816-74-0	Methacrylic acid, methallyl ester	
21170	000997-46-6	Methacrylic acid, monoester with 1,4-butanediol	
21733	000115-19-5	2-Methyl-3-butyn-2-ol	
21736	002549-61-3	alpha-Methyl-epsilon-caprolactone	
21739	002549-60-2	beta-Methyl-epsilon-caprolactone	
21742	002549-58-8	delta-Methyl-epsilon-caprolactone	
21745	002549-59-9	epsilon-Methyl-epsilon-caprolactone	
21748	002549-42-0	gamma-Methyl-epsilon-caprolactone	
21837	001116-90-1	4-Methyl-1,4-hexadiene	SML = ND (DL = 0,05 mg/kg)
22428	051000-52-3	Neodecanoic acid, vinyl ester	
22465	000112-05-0	Nonanoic acid	
22585	003710-30-3	1,7-Octadiene	