

## COMMISSION DIRECTIVE 93/9/EEC

of 15 March 1993

amending Directive 90/128/EEC relating to plastic 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<sup>(1)</sup> 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, 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 these objectives cannot be achieved by Member States individually, and whereas furthermore their attainment at Community level is already provided for by Directive 89/109/EEC;

Whereas Commission Directive 90/128/EEC<sup>(2)</sup>, as amended by Directive 92/39/EEC<sup>(3)</sup>, and in particular Article 3 (4) thereof, 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 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 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 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 paragraph 3 is added to Article 5:

'3. The verification of compliance with the specific migration limits provided for in paragraph 1 shall not be compulsory, if it can be established that, by assuming complete migration of the residual substance in the material or article, it cannot exceed the specific limit of migration.'

2. Annex II is amended as follows:

(a) Point 8 is hereby amended as follows:

— the following text is inserted after 'QM (T) = maximum permitted quantity of the "residual" substance in the material or article expressed as total of moiety or substance(s) indicated':

'For the purpose of this Directive "QM (T)" means that the maximum permitted quantity of the "residual" substance in the material or article 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.'

— the following text is inserted after 'SML (T) = specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated':

'For the purpose of this Directive "SML (T)" means that the specific migration of the substances 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.'

<sup>(1)</sup> OJ No L 40, 11. 2. 1989, p. 38.

<sup>(2)</sup> OJ No L 75, 21. 3. 1990, p. 19, rectified by

OJ No L 349, 13. 12. 1990, p. 26.

<sup>(3)</sup> OJ No L 168, 23. 6. 1992, p. 21.

## (b) 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 to this Directive is amended as indicated therein ;

## (c) 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 ;

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

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive as from 1 April 1994. They shall immediately inform the Commission thereof.

## Member States shall :

- permit, as from 1 April 1994, the trade in and use of plastic materials and articles intended to come into contact with foodstuffs complying with this Directive,
- prohibit, as from 1 April 1996, 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 the measures referred to in paragraph 1, 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, 15 March 1993.

*For the Commission*

Martin BANGEMANN

*Member of the Commission*

## ANNEX I

## LIST OF MONOMERS AND OTHER STARTING SUBSTANCES ADDED TO SECTION A

| PM/REF No | CAS No      | Name  | Restrictions                                      |
|-----------|-------------|---|---|
| (1)       | (2)         | (3)   | (4)   |
| 15565     | 000106-46-7 | 1,4-Dichlorobenzene                                       | SML = 12 mg/kg                                    |
| 15820     | 000345-92-6 | 4,4'-Difluorobenzophenone                                 | SML = 0,05 mg/kg                                  |
| 17160     | 000097-53-0 | Eugenol   | SML = 0,01 mg/kg                                  |
| 22390     | 000840-65-3 | 2,6-Naphtalenedicarboxylic acid, dimethyl ester           | SML = 0,05 mg/kg                                  |
| 24057     | 000089-32-7 | Pyromellitic anhydride                                    | SML = 0,05 mg/kg (expressed as pyromellitic acid) |
| 24475     | 001313-82-2 | Sodium sulphide   |   |
| 24540     | 009005-25-8 | Starch, edible  |   |
| 24888     | 003965-55-7 | 5-Sulphoisophthalic acid, monosodium salt, dimethyl ester | SML = 0,05 mg/kg                                  |

## 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)           |
| 12788     | 002432-99-7 | 11-Aminoundecanoic acid | SML = 5 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)          |
| 10599/90A | 061788-89-4 | Acids, fatty, unsaturated (C18), dimers, distilled                    |              |
| 10599/91  | 061788-89-4 | Acids, fatty, unsaturated (C 18), dimers, non-distilled               |              |
| 10599/92A | 068783-41-5 | Acids, fatty, unsaturated (C 18), dimers, hydrogenated, distilled     |              |
| 10599/93  | 068783-41-5 | Acids, fatty, unsaturated (C 18), dimers, hydrogenated, non-distilled |              |

## ANNEX IV

## LIST OF MONOMERS AND OTHER STARTING SUBSTANCES DELETED

| PM/REF No | CAS No      | Name   | Restrictions |
|-----------|-------------|--|--------------|
| (1)       | (2)         | (3)  | (4)          |
| 10599/90  | 061788-89-4 | Acids, fatty, unsaturated (C 18), dimers   |              |
| 10599/92  | 068783-41-5 | Acids, fatty, unsaturated (C 18), dimers, hydrogenated   |              |
| 10600     | —           | Acids, linear, with an even number of carbon atoms (C 8-C 22), and the dimers and trimers of the unsaturated acids |              |
| 10720     | 000999-55-3 | Acrylic acid, allyl ester  |              |
| 10775     | 084100-23-2 | Acrylic acid, 4-tert-butylcyclohexyl ester   |              |
| 10990     | 002156-96-9 | Acrylic acid, decyl ester  |              |
| 11005     | 012542-30-2 | Acrylic acid, dicyclopentenyl ester  |              |
| 11010     | 024447-78-7 | Acrylic acid, diester with 2,2-bis (4-hydroxyphenyl)propane (2-hydroxyethyl) ether                                 |              |
| 11020     | 019485-03-1 | Acrylic acid, diester with 1,3-butanediol  |              |
| 11080     | 004074-88-8 | Acrylic acid, diester with diethyleneglycol  |              |
| 11110     | 002274-11-5 | Acrylic acid, diester with ethyleneglycol  |              |
| 11140     | 013048-33-4 | Acrylic acid, diester with 1,6-hexanediol  |              |
| 11170     | 026570-48-9 | Acrylic acid, diester with polyethyleneglycol  |              |
| 11200     | 002426-54-2 | Acrylic acid, 2-(diethylamino) ethyl ester   |              |
| 11230     | 002439-35-2 | Acrylic acid, 2-(dimethylamino) ethyl ester  |              |
| 11260     | 000106-90-1 | Acrylic acid, 2,3-epoxypropyl ester  |              |
| 11532     | 002761-08-2 | Acrylic acid, 3-hydroxypropyl ester  |              |
| 11860     | —           | Acrylic acid, monoester with propyleneglycol   |              |
| 11875     | 004813-57-4 | Acrylic acid, octadecyl ester  |              |
| 12640     | 000106-92-3 | Allyl 2,3-epoxypropyl ether  |              |
| 13210     | 001761-71-3 | Bis (4-aminocyclohexyl) methane  |              |
| 14008     | 000098-52-2 | 4-tert-Butylcyclohexanol   |              |
| 14035     | 001746-23-2 | 4-tert-Butylstyrene  |              |
| 14560     | 000126-99-8 | 2-Chloro-1,3-butadiene   |              |
| 14650     | 000079-38-9 | Chlorotrifluoroethylene  |              |
| 14833     | 000623-43-8 | Crotonic acid, methyl ester  |              |
| 14980     | 001631-25-0 | N-Cyclohexylmaleimide  |              |
| 15030     | 000931-88-4 | Cyclooctene  |              |
| 15060     | 000142-29-0 | Cyclopentene   |              |
| 15260     | 000646-25-3 | 1,10-Diaminododecane   |              |
| 15270     | 002783-17-7 | 1,12-Diaminododecane   |              |
| 15295     | 000373-44-4 | 1,8-Diaminooctane  |              |
| 16120     | 000110-97-4 | Diisopropanolamine   |              |
| 16180     | 005205-93-6 | N- (Dimethylaminopropyl) methacrylamide  |              |
| 16252     | 000110-03-2 | 2,5-Dimethyl-2,5-hexanediol  |              |
| 16510     | 000138-86-3 | Dipentene  |              |
| 16719     | 003813-52-3 | Endomethylenetetrahydrophthalic acid   |              |
| 16900     | 013036-41-4 | N-(Ethoxymethyl)acrylamide   |              |
| 17116     | 005877-42-9 | 4-Ethyl-1-octyn-3-01   |              |
| 17150     | 000078-27-3 | 1-Ethynylcyclohexanol  |              |
| 17305     | 000141-02-6 | Fumaric acid, bis (2-ethylhexyl) ester   |              |
| 17320     | 002807-54-7 | Fumaric acid, diallyl ester  |              |
| 17380     | 000623-91-6 | Fumaric acid, diethyl ester  |              |
| 17398     | 007283-68-3 | Fumaric acid, dioctadecyl ester  |              |

| PM/REF No | CAS No      | Name   | Restrictions |
|-----------|-------------|--|--------------|
| (1)       | (2)         | (3)  | (4)          |
| 17800     | —           | Glucosides obtained from glucose and pentaerythritol   |              |
| 17830     | —           | Glucosides obtained from glucose and polyethyleneglycol (molecular weight greater than 200)    |              |
| 17860     | —           | Glucosides obtained from glucose and polypropyleneglycol (molecular weight greater than 400)   |              |
| 18436     | 001687-30-5 | Hexahydrophthalic acid   |              |
| 18490     | 015511-81-6 | Hexamethylenediamine adipate   |              |
| 18610     | 006422-99-7 | Hexamethylenediamine sebacate  |              |
| 18850     | 000107-41-5 | Hexyleneglycol   |              |
| 18865     | 003031-66-1 | 3-Hexyn-2,5-diol   |              |
| 19140     | 026952-21-6 | Isooctanol   |              |
| 19480     | 002146-71-6 | Lauric acid, vinyl ester   |              |
| 19660     | 000141-05-9 | Maleic acid, diethyl ester   |              |
| 19690     | 014234-82-3 | Maleic acid, diisobutyl ester  |              |
| 19720     | 001330-76-3 | Maleic acid, diisooctyl ester  |              |
| 19750     | 000624-48-6 | Maleic acid, dimethyl ester  |              |
| 19915     | 000925-21-3 | Maleic acid, monobutyl ester   |              |
| 20095     | 046729-07-1 | Methacrylic acid, 4-tert-butylcyclohexyl ester   |              |
| 20200     | 001888-94-4 | Methacrylic acid, 2-chloroethyl ester  |              |
| 20320     | 003179-47-3 | Methacrylic acid, decyl ester  |              |
| 20455     | 006606-59-3 | Methacrylic acid, diester with 1,6-hexanediol  |              |
| 20560     | 000142-90-5 | Methacrylic acid, dodecyl ester  |              |
| 20830     | —           | Methacrylic acid, ester with 1,2-propanediol   |              |
| 20920     | 000688-84-6 | Methacrylic acid, 2-ethylhexyl ester   |              |
| 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  |              |
| 20980     | 007534-94-3 | Methacrylic acid, isobornyl ester  |              |
| 21040     | 029964-84-9 | Methacrylic acid, isodecyl ester   |              |
| 21070     | 028675-80-1 | Methacrylic acid, isooctyl ester   |              |
| 21170     | 000997-46-6 | Methacrylic acid, monoester with 1,4-butanediol  |              |
| 21250     | 002157-01-9 | Methacrylic acid, n-octyl ester  |              |
| 21430     | 004245-37-8 | Methacrylic acid, vinyl ester  |              |
| 21670     | 000563-46-2 | 2-Methyl-1-butene  |              |
| 21733     | 000115-19-5 | 2-Methyl-3-butyne-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  |              |
| 21850     | 000095-71-6 | Methylhydroquinone   |              |
| 21880     | 000717-27-1 | Methylhydroquinone diacetate   |              |
| 22465     | 000112-05-0 | Nonanoic acid  |              |
| 22690     | 001806-26-4 | 4-Octylphenol  |              |
| 22811     | 000591-93-5 | 1,4-Pentadiene   |              |
| 22842     | 002590-16-1 | Pentaerythritol diallyl ether  |              |
| 22858     | 005343-92-0 | 1,2-Pentanediol  |              |
| 22861     | 000111-29-5 | 1,5-Pentanediol  |              |
| 22901     | 000109-68-2 | 2-Pentene  |              |
| 22935     | 003823-94-7 | Perfluoromethyl vinyl ether  |              |
| 22940     | 006996-01-6 | Perfluoropropyl vinyl ether  |              |
| 23140     | 000092-69-3 | 4-Phenylphenol   |              |
| 25158     | 000088-98-2 | 1,2,3,6-Tetrahydrophthalic acid  |              |
| 25630     | 037275-47-1 | 1,1,1-Trimethylolpropane diacrylate  |              |

| PM/REF<br>No | CAS No      | Name                                   | Restrictions |
|--------------|-------------|--|--------------|
| (1)          | (2)         | (3)                                    | (4)          |
| 25645        | 000682-09-7 | 1,1,1-Trimethylolpropane diallyl ether |              |
| 25780        | 025723-16-4 | 1,1,1-Trimethylolpropane, propoxylated |              |
| 25930        | 001067-53-4 | Tris (2-methoxyethoxy) vinylsilane     |              |
| 26200        | 002867-48-3 | N-Vinyl-N-methylformamide              |              |
| 26260        | 001184-84-5 | Vinylsulphonic acid                    |              |

## ANNEX V

## LIST OF MONOMERS AND OTHER STARTING SUBSTANCES TRANSFERRED TO SECTION A

| PM/REF No | CAS No      | Name                             | Restrictions   |
|-----------|-------------|----------------------------------|--|
| (1)       | (2)         | (3)                              | (4)  |
| 10750     | 002495-35-4 | Acrylic acid, benzyl ester       |  |
| 11890     | 002499-59-4 | Acrylic acid, n-octyl ester      |  |
| 15095     | 000334-48-5 | Decanoic acid                    |  |
| 15790     | 000111-40-0 | Diethylenetriamine               | SML = 5 mg/kg  |
| 19210     | 001459-93-4 | Isophthalic acid, dimethyl ester | SML = 0,05 mg/kg                                       |
| 20080     | 002495-37-6 | Methacrylic acid, benzyl ester   |  |
| 21280     | 002177-70-0 | Methacrylic acid, phenyl ester   |  |
| 24940     | 000100-20-9 | Terephthalic acid dichloride     | SML(T) = 7,5 mg/kg<br>(expressed as terephthalic acid) |
| 25120     | 000116-14-3 | Tetrafluoroethylene              | SML = 0,05 mg/kg                                       |