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 [1] 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 [2], as amended by Directive 92/39/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 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)" menas 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.'

[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.
[3] 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	