

COMMISSION DIRECTIVE 2002/17/EC
of 21 February 2002
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,

by national laws only pending a decision at Community level.

Having regard to the Treaty establishing the European Community,

(6) Directive 90/128/EEC should therefore be amended accordingly.

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,

(7) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

After consulting the Scientific Committee on Food,

HAS ADOPTED THIS DIRECTIVE:

Whereas:

Article 1

(1) On the basis of the new information available to the Scientific Committee on Food, certain monomers provisionally permitted 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 ⁽²⁾, as last amended by Directive 2001/62/EC ⁽³⁾, may be included in the Community list of permitted substances in Annex II to Directive 90/128/EEC.

Annexes II, III, V and VI to Directive 90/128/EEC are amended as set out in the Annex to this Directive.

Article 2

(2) Annex III to Directive 90/128/EEC contains an incomplete list of additives which may be used in the manufacture of plastics materials and articles. That list should be amended so as to include other additives evaluated by the Scientific Committee on Food.

Member States shall adopt and publish, by 28 February 2003 at the latest, the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions in such a way as to:

(3) For certain substances, the restrictions already established at Community level should be amended on the basis of the information available.

(a) permit the trade in and use of plastic materials and articles intended to come into contact with foodstuffs and complying with this Directive, from 1 March 2003;

(4) The current 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.

(b) prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive, from 1 March 2004. However, for materials and articles which contain divinylbenzene and do not comply with the restriction set in this Directive, Member States shall prohibit their manufacture and importation into the Community as from 1 March 2003.

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.

(5) This Directive establishes specifications for only a few substances. The other substances, which may require specifications, therefore remain regulated in this respect

Article 3

⁽¹⁾ OJ L 40, 11.2.1989, p. 38.

⁽²⁾ OJ L 75, 21.3.1990, p. 19.

⁽³⁾ OJ L 221, 17.8.2001, p. 18.

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 21 February 2002.

For the Commission

David BYRNE

Member of the Commission

ANNEX

The Annexes to Directive 90/128/EEC are amended as follows:

1. Annex II is amended as follows:

(a) In point 8:

(i) The definition of QM(T) is replaced by the following:

'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 the quantity of the substance in the material or article should be determined by a validated method of analysis. 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.'

(ii) the following text is inserted after QM(T):

'QMA = Maximum permitted quantity of the "residual" substance in the finished material or article expressed as mg per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. 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;

QMA(T) = Maximum permitted quantity of the "residual" substance in the material or article expressed as mg of total of moiety or substance(s) indicated per 6 dm² of the surface in contact with foodstuffs. For the purpose of this Directive the quantity of the substance in the surface of the material or article should be determined by a validated method of analysis. 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.'

(iii) The definitions of SML and SML(T) are replaced by the following:

'SML = Specific migration limit in food or in food simulant, unless it is specified otherwise. For the purpose of this Directive the specific migration of the substance should be determined by a validated method of analysis. 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;

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 the specific migration of the substances should be determined by a validated method of analysis. 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.'

(b) Section A is amended as follows:

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

REF. No	CAS No	Name	Restrictions and/or specifications
13620	10043-35-3	Boric acid	SML(T) = 6 mg/kg (23) (expressed as boron) without prejudice to the provisions of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p.32)
16650	00127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg (25)
18897	16712-64-4	6-Hydroxy-2-naphtalenecarboxylic acid	SML = 0,05 mg/kg
18898	103-90-2	N-(4-Hydroxyphenyl) acetamide	Only to be used in liquid crystals and behind a barrier layer in multilayered plastics
22332	28679-16-5	Mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)

(ii) 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(2,3epoxypropyl) ether (= Badge)	According to Commission Directive 2002/16/EC of 20 February 2002 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs (OJ L 51, 22.2.2002, p. 27)
13560	05124-30-1	Bis(4-isocyanatocyclohexyl)methane	See 'Dicyclohexylmethane-4,4'-diisocyanate'
14650	00079-38-9	Chlorotrifluoroethylene	QMA = 0,5 mg/6 dm ²
14950	03173-53-3	Cyclohexyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
15700	05124-30-1	Dicyclohexylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
16240	00091-97-4	3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	QM(T) = 1 mg/kg (expressed as NCO) (26)
16570	04128-73-8	Diphenylether-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
16600	05873-54-1	Diphenylmethane-2,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
16630	00101-68-8	Diphenylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
18640	00822-06-0	Hexamethylene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
19110	04098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg (expressed as NCO) (26)
22420	03173-72-6	1,5-Napthalene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
22570	00112-96-9	Octadecyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
25210	00584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
25240	00091-08-7	2,6-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
25270	26747-90-0	2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg (expressed as NCO) (26)

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

REF. No	CAS No	Name	Restrictions and/or specifications
13075	00091-76-9	Benzoguanamine	See '2,4-Diamino-6-phenyl-1,3,5-triazine'
13720	00110-63-4	1,4-Butanediol	SML(T) = 0,05 mg/kg (24)
15310	00091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	QMA = 5 mg/6 dm ²
16690	01321-74-0	Divinylbenzene	QMA = 0,01 mg/6 dm ² or SML = ND (DL = 0,02 mg/kg, analytical tolerance included) for the sum of Divinylbenzene and Ethylvinylbenzene and in compliance with the specifications laid down in Annex V
16697	00693-23-2	n-Dodecanedioic acid	
25840	03290-92-4	1,1,1-Trimethylolpropane trimethacrylate	SML = 0,05 mg/kg

2. Annex III is amended as follows:

(a) The table of Section A is amended as follows:

(i) The following additives are inserted:

REF. No	CAS No	Name	Restrictions and/or specifications
36840	12007-55-5	Barium tetraborate	SML(T) = 1 mg/kg expressed as barium (12) and SML(T) = 6 mg/kg (23) (expressed as boron) without prejudice to the provisions of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32)
40320	10043-35-3	Boric acid	SML(T) = 6 mg/kg (23) (expressed as boron) without prejudice to the provisions of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32)
40580	00110-63-4	1,4-Butanediol	SML(T) = 0,05 mg/kg (24)
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	SML = 0,05 mg/kg
87040	01330-43-4	Sodium tetraborate	SML(T) = 6 mg/kg (23) (expressed as boron) without prejudice to the provisions of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32)

(ii) 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
37360	000100-52-7	Benzaldehyde	In compliance with note 9 in Annex VI
40120	68951-50-8	Bis(polyethyleneglycol)hydroxymethylphosphonate	SML = 0,6 mg/kg
41680	000076-22-2	Camphor	In compliance with note 9 in Annex VI

(iii) The following additive is deleted

REF. No	CAS No	Name	Restrictions and/or specifications
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol	SML = 6 mg/kg

(b) The table of Section B is amended as follows:

(i) The following additives are inserted:

REF. No	CAS No	Name	Restrictions and/or specifications
45650	6197-30-4	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	SML = 0,05 mg/kg
68860	04724-48-5	n-Octylphosphonic acid	SML = 0,05 mg/kg
95000	28931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer	

(ii) 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
39120	—	N,N-Bis(2-Hydroxyethyl)alkyl(C8-C18)amine hydrochlorides	SML(T) = 1,2 mg/kg (13) expressed as tertiary amine (expressed excluding HCl)
51570	00127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg (25)

3. Annex V is amended as follows:

The following specifications are inserted in the table of Part B:

PM/REF. No	Other specifications
16690	Divinylbenzene It may contain up to 40 % of Ethylvinylbenzene

4. Annex VI is amended as follows:

(a) The notes (12) and (13) are replaced by the following:

'(12) 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, 36840 and 92000.

(13) 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.'

(b) The following notes are added:

'(23) 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: 13620, 36840, 40320 and 87040.

(24) 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: 13720 and 40580.

(25) 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: 16650 and 51570.

(26) QM(T) in this specific case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances mentioned as PM/REF. Nos: 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240, 25270.'