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	