COMMISSION DIRECTIVE 2001/62/EC

of 9 August 2001

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,

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 on Food,

Whereas:

(1) Silicones should be regarded as elastomeric materials rather than plastic materials and therefore should be deleted from the definition of plastics.

(2) The determination of a quantity of a substance in a finished material or article is simpler than the determination of its specific migration level. The verification of compliance through the determination of quantity rather than specific migration level should therefore be permitted under certain conditions.

(3) For certain types of plastics, the availability of generally recognised diffusion models based on experimental data allows the estimation of the migration level of a substance under certain conditions, therefore avoiding complex, costly and time-consuming testing.

(4) Recent collaborative tests indicate that there is greater variability in the results of analysis for the determination of overall migration of substances used in plastics when aqueous food simulants as well as volatile media such as isooctane, ethanol and other similar solutions are used.

(5) Besides the monomers and other starting substances fully evaluated and authorised at Community level, there are also monomers and starting substances evaluated and authorised in at least one Member State, use of which may be continued pending their evaluation by the Scientific Committee on Food and the decision on their inclusion in the Community list.

(6) On the basis of the new information available to the Scientific Committee on Food, certain monomers provisionally admitted 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 1999/91/EC [3], may be included in the Community list of approved substances.

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

(8) The current total 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.

(9) This Directive establishes specifications for only a few substances, and therefore the other substances, which may require specifications remain regulated in this respect by national laws only pending a decision at Community level.

(10) For certain additives the restrictions established in this Directive cannot yet be applied in all situations pending the collection and evaluation of all the data needed for a better estimation of the exposure of the consumer in some specific situations. Therefore, these additives appear in a list other than that of the additives fully regulated at Community level.

(11) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of ensuring the free movement of plastic materials and articles intended to come into contact with foodstuffs, to lay down rules on the definition of plastics and admitted substances. This Directive confines itself to what is necessary in order to achieve the objectives pursued in accordance with the third paragraph of Article 5 of the Treaty.

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

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

[1] OJ L 40, 11.2.1989, p. 38.

[2] OJ L 75, 21.3.1990, p. 19.
[3] OJ L 310, 4.12.1999, p. 41.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/128/EEC is amended as follows:

1. In Article 1, paragraph 3 is replaced by the following:

'3. For the purposes of this Directive, "plastics" shall mean the organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromoles. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as "plastics":

(i) varnished or unvarnished regenerated cellulose film, covered by Commission Directive 93/10/EEC (*);

(ii) elastomers and natural and synthetic rubber;

(iii) paper and paperboard, whether modified or not by the addition of plastics;

(iv) surface coatings obtained from:

— paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes,

— mixtures of the waxes listed in the first indent with each other and/or with plastics;

(v) ion-exchange resins;

(vi) silicones.

(*) OJ L 93, 17.4.1993, p. 27.'

2. In Article 3, paragraphs 4 and 5 are replaced by the following:

'4. 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.

By way of derogation from the first subparagraph, the monomers and other starting substances listed in Annex II, Section B, may continue to be used until 31 December 2004 at the latest, pending their evaluation by the Scientific Committee on Food.

5. The lists appearing in Annex II, Sections A and B, do not yet include monomers and other starting substances used only in the manufacture of:

— surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes, lacquers, paints, etc.,

— epoxy resins,

— adhesives and adhesion promoters,

— printing inks.'

3. Article 3a is replaced by the following:

'*Article 3a*

An incomplete list of additives which may be used for the manufacture of plastic materials and articles, together with restrictions and/or specifications on their use, is set out in Annex III, Sections A and B.

For the substances in Annex III, Section B, the specific migration limits are applied as from 1 January 2004 when the verification of compliance is carried out in simulant D or in test media of substitute tests as laid down in Directives 82/711/EEC and 85/572/EEC.'

4. In Article 3c, paragraph 1 is replaced by the following:

'1. General specifications related to plastics materials and articles are laid down in Annex V, part A. Other specifications related to some substances appearing in Annexes II, III and IV are laid down in Annex V, part B.'

5. In Article 5, the following paragraph 4 is added:

'4. The verification of compliance with the specific migration limits provided for in paragraph 1 may be ensured by the determination of the quantity of a substance in the finished material or article provided that a relationship between that quantity and the value of the specific migration of the substance has been established either by an adequate experimentation or by the application of generally recognised diffusion models based on scientific evidence. To demonstrate the non-compliance of a material or article, confirmation of the estimated migration value by experimental testing is obligatory.'

6. Annexes I, II, III, V and VI are amended as set out in Annexes I to V to this Directive.

Article 2

The requirements introduced by this Directive shall not apply to materials and articles containing the substances regulated by the Directive which have been put into free circulation in the Community before 1 December 2002.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 November 2002 at latest. They shall forthwith inform the Commission thereof.

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.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 9 August 2001.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

In Annex I, paragraph 7, the second indent is replaced by the following:

'— 12 mg/kg or 2 mg/dm^2 in migration tests using the other simulants referred to in Directives 82/711/EEC and 85/572/EEC.'

ANNEX II

Annex II is amended as follows:

1. Section A is amended as follows:

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

Ref. No	CAS No	Name	Restrictions and/or specifications
'12763	00141-43-5	2-Aminoethanol	SML = 0,05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer
12765	84434-12-8	N-(2-aminoethyl)-beta-alanine, sodium salt	SML = 0,05 mg/kg
13395	04767-03-7	2,2-Bis(hydroxymethyl)propionic acid	QMA = 0,05 mg/6 dm^2
15030	00931-88-4	Cyclooctene	SML = 0,05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Directive 85/572/EEC
19110	04098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg in FP (as NCO)
21765	106246-33-7	4,4′-Methylenebis(3-chloro-2,6-diethylaniline)	QMA = 0,05 mg/6 dm^2
22778	07456-68-0	4,4′-Oxybis(benzenesulphonyl azide)	QMA = 0,05 mg/6 dm^2
24073	000101-90-6	Resorcinol diglycidyl ether	QMA = 0,005 mg/6 dm^2. Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC and for indirect food contact only, behind the PET layer'

(b) 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(2,3-epoxypropyl) ether (= BADGE)	According to Commission Directive 2001/61/EC of 8 August 2001 on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs (OJ L 215, 9.8.2001, p. 26).
13610	01675-54-3	Bisphenol A bis(2,3-epoxypropyl) ether	See "2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether"