

DIRECTIVES

COMMISSION DIRECTIVE 2008/39/EC

of 6 March 2008

amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC ⁽¹⁾, and in particular Article 5(2) thereof,

Whereas:

- (1) Commission Directive 2002/72/EC ⁽²⁾ is a specific Directive within the meaning of Regulation (EC) No 1935/2004 and harmonises the rules on the authorisation of plastic materials and articles intended to come into contact with food.
- (2) Directive 2002/72/EC establishes lists of authorised substances for the manufacture of these materials and articles, in particular additives and monomers, restrictions on their use, as well as rules on labelling and on the information to be given to consumers or food business operators for the correct use of these materials and articles.
- (3) The current list of additives contained in Directive 2002/72/EC is an incomplete list inasmuch as it does not contain all substances currently accepted in one or more Member States.
- (4) According to Article 4(1) of Directive 2002/72/EC as it stands, the list of additives is considered to be an incomplete list until the Commission decides, in accordance with Article 4a, that it becomes a positive Community list of authorised additives.
- (5) For those additives which are currently permitted in the Member States, the time limit for the submission of data for their safety evaluation by the European Food Safety

Authority (hereinafter the Authority) with a view to their inclusion in the Community list expired on 31 December 2006. Therefore the date when the Community list of additives becomes a positive list can now be set. Taking into account the time the Authority will need to evaluate all valid applications submitted on time this date should be January 2010.

- (6) It is also appropriate to clarify the role of the provisional list referred to in Article 4a (4) and (5) of Directive 2002/72/EC as it stands and how it will be updated. The provisional list contains those additives for which the necessary data were supplied on time and in accordance with the Authority's requirements, but where no decision on their inclusion in the positive list has yet been taken.
- (7) This provisional list provides information to the public on the additives that are under evaluation in view of their possible inclusion in the Community list of additives. As it is impossible to know if the evaluations for all the additives included in the provisional list will be completed by the date when the list of additives becomes a positive list, it should be possible to continue to use those additives, in accordance with national law, until their evaluation is completed and a decision is taken on their inclusion in the positive list of additives.
- (8) When an additive included in the provisional list is inserted in the Community list of additives or when it is decided not to include it in the Community list, that additive should be removed from the provisional list of additives.
- (9) If, during the examination of the data on an additive included in the provisional list, the Authority calls for supplementary information, that additive should be maintained in the provisional list until a decision is taken in relation to it, provided that the information is submitted within the time limits specified by the Authority.

⁽¹⁾ OJ L 338, 13.11.2004, p. 4.

⁽²⁾ OJ L 220, 15.8.2002, p. 18. Directive as last amended by Directive 2007/19/EC (OJ L 97, 12.4.2007, p. 50).

- (10) On the basis of new information related to the risk assessment of monomers and additives evaluated by the Authority ⁽¹⁾, certain additives admitted at national level as well as new monomers and additives should be included in the respective Community lists of authorised substances. For other substances, the restrictions and/or specifications already established at Community level should be amended on the basis of this new information. Therefore, Annexes II, III, IVa, V and VI of Directive 2002/72/EC should be amended accordingly.
- (11) Commission Directive 2005/79/EC ⁽²⁾ introduced in the list of additives the additive Ref. No 30340 with the name *12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester* and CAS number 330198-91-9. The name and CAS number introduced in that Directive reflect only the main component of the application. However the opinion delivered by the Authority covers the mixture of substances referred to in the application and not only its main component. The mixture of substances is now registered in the CAS register under CAS number 736150-63-3 with the name *Glycerides, castor-oil mono-, hydrogenated, acetates*. For this reason it is now appropriate to change the name and CAS number to update the authorisation to all substances in the mixture. Taking into account the change of name a new Ref. No 55910 is assigned. As the substance is now covered by Ref. No 55910, Ref. No 30340 should be deleted.
- (12) As a consequence, Directive 2002/72/EC should be updated to take account of new information related to the risk assessment of substances evaluated by the Authority, to establish the date when the list of additives becomes a positive list and to clarify the role of the provisional list of additives.
- (13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2002/72/EC is amended as follows:

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

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

⁽¹⁾ The EFSA Journal (2007) 555 to 563, 1-32.
The EFSA Journal (2007) 516 to 518, 1-12.
The EFSA Journal (2007) 452 to 454, 1-10.
The EFSA Journal (2006) 418 to 427, 1-25.
⁽²⁾ OJ L 302, 19.11.2005, p. 35.

Until 31 December 2009, additives which are not included in the Community list of additives may continue to be used subject to national law.

As from 1 January 2010, only additives included in the Community list of additives may be used for the manufacture of plastic materials and articles (positive list).’

2. Article 4a is amended as follows:

- (a) Paragraphs 3 and 4 are replaced by the following:

‘3. A provisional list of additives that are under evaluation by the Authority shall be made public by the Commission by 11 April 2008 at the latest. It shall be kept updated.

4. By derogation from the third subparagraph of Article 4(1), additives not included in the Community list referred to in that Article may continue to be used subject to national law after 1 January 2010 for as long as they are included in the provisional list.’

- (b) Paragraph 6 is added:

‘6. An additive shall be removed from the provisional list:

- (a) when it is included in the Community list of additives; or
- (b) when a decision is taken by the Commission not to include it in the Community list of additives; or
- (c) if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.’

3. Annexes II, III, IVa, V and VI are amended in accordance with Annexes I, II, III, IV and V to this Directive.

Article 2

1. Member States shall adopt and publish, by 7 March 2009 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those 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.

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

- (a) permit the trade in and use of plastic materials and articles intended to come into contact with food and complying with Directive 2002/72/EC, as amended by this Directive, from 7 March 2009;
- (b) prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food and which do not comply with Directive 2002/72/EC, as amended by this Directive, from 7 March 2010.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 6 March 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX I

Section A of Annex II to Directive 2002/72/EC is amended as follows:

- (a) the following monomers and other starting substances are inserted, in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'15404	000652-67-5	1,4:3,6-Dianhydrosorbitol	SML = 5 mg/kg. Only for use as a co-monomer in poly(ethylene-co-isosorbide terephthalate)
19180	000099-63-8	Isophthalic acid dichloride	SML(T) = 5 mg/kg (43) (expressed as isophthalic acid)
26305	000078-08-0	Vinyltriethoxysilane	SML = 0,05 mg/kg. Only to be used as a surface treatment agent'

- (b) for the following monomers and 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
(1)	(2)	(3)	(4)
'19150	000121-91-5	Isophthalic acid	SML(T) = 5 mg/kg (43)'

ANNEX II

Annex III to Directive 2002/72/EC is amended as follows:

(1) Section A is amended as follows:

(a) The following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'38875	002162-74-5	Bis(2,6-diisopropylphenyl) carbodiimide	SML = 0,05 mg/kg. For use behind a PET layer
45703	491589-22-1	cis-1,2-Cyclohexanedicarboxylic acid, calcium salt	SML = 5 mg/kg
48960	—	9,10-dihydroxy stearic acid and its oligomers	SML = 5 mg/kg
55910	736150-63-3	Glycerides, castor-oil mono-, hydrogenated, acetates	
60025	—	Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene	In compliance with the specifications laid down in Annex V. Not to be used for articles in contact with fatty foods.
62280	009044-17-1	Isobutylene-butene copolymer	
70480	000111-06-8	Palmitic acid, butyl ester	
76463	—	Polyacrylic acid, salts	SML(T) = 6 mg/kg (36) (for acrylic acid)
76723	167883-16-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate	In compliance with the specifications laid down in Annex V
76725	661476-41-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	In compliance with the specifications laid down in Annex V
77732	—	Polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	SML = 0,05 mg/kg. Only for use in PET
77733	—	Polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	SML = 0,05 mg/kg. Only for use in PET
77897	—	Polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C ₈ -C ₂₀) sulphate, salts	SML = 5 mg/kg
89120	000123-95-5	Stearic acid, butyl ester	
95858	—	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	SML = 0,05 mg/kg and in compliance with the specifications laid down in Annex V. Not to be used for articles in contact with fatty foods.'

- (b) for the following additives, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene	SML = 0,05 mg/kg
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0,5 mg/kg. Only to be used in aqueous polymer dispersions and emulsions and at concentrations which do not result in an anti-microbial effect at the surface of the polymer or on the food itself.'

- (c) the following additives are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'30340	330198-91-9	12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester'	

- (2) Section B is amended as follows:

- (a) the following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'34130	—	Alkyl, linear with even number of carbon atoms (C ₁₂ -C ₂₀) dimethylamines	SML = 30 mg/kg
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	SML = 6 mg/kg'

- (b) for the following additives, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'72081/10	—	Petroleum Hydrocarbon Resins (hydrogenated)	In compliance with the specifications laid down in Annex V'

ANNEX III

In Annex IVa to Directive 2002/72/EC the following substances are inserted in the appropriate numerical order:

Ref. No	CAS No	Name
'34130	—	Alkyl, linear with even number of carbon atoms (C12-C20) dimethylamines
39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]'

ANNEX IV

In Part B of Annex V to Directive 2002/72/EC the following new specifications are inserted, in the appropriate numerical order:

Ref. No	Other specifications
'60025	Specifications: — Minimum viscosity (at 100 °C) = 3,8 cSt — Average Mw > 450
76723	Specifications: The fraction with molecular weight below 1 000 should not exceed 1,5 % w/w
76725	Specifications: The fraction with molecular weight below 1 000 should not exceed 1 % w/w
95858	Specifications: — Average molecular weight not less than 350 — Viscosity at 100 °C min 2,5 cSt — Content of hydrocarbons with carbon number less than 25, not more than 40 % w/w'

ANNEX V

Annex VI to Directive 2002/72/EC is amended as follows:

(1) Note (36) is replaced by the following:

‘⁽³⁶⁾ 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 Reference Nos 10690, 10750, 10780, 10810, 10840, 11470, 11590, 11680, 11710, 11830, 11890, 11980, 31500 and 76463.’

(2) Note (43) is added:

‘⁽⁴³⁾ 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 Reference Nos 19150 and 19180.’
