# COMMISSION REGULATION (EC) No 975/2009

## of 19 October 2009

## amending Directive 2002/72/EC 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 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 of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs [2] establishes a Community list of monomers and other starting substances, which may be used for the manufacture of plastic materials and articles. Recently additional monomers and starting substances have received a favourable scientific evaluation by the European Food Safety Authority (the Authority) and should now be added to the existing list.

(2) Directive 2002/72/EC also contains a Community list of additives which may be used for the manufacture of plastic materials and articles. Recently additional additives have received a favourable scientific evaluation by the Authority and should now be added to the existing list.

(3) Directive 2002/72/EC should therefore be amended accordingly.

(4) According to Article 4(1) of Directive 2002/72/EC, the Community list of additives contained in Annex III to that Directive will become a positive list from 1 January 2010. Consequently, the titles in Annex III to that Directive should no longer refer to an 'incomplete' list of additives.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annexes II, III, IVa, V and VI to Directive 2002/72/EC are amended in accordance with Annexes I to V to this Regulation.

*Article 2*

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 October 2009.

*For the Commission*
Androulla VASSILIOU
*Member of the Commission*

[1] OJ L 338, 13.11.2004, p. 4.
[2] OJ L 220, 15.8.2002, p. 18.

*ANNEX I*

In section A to Annex II to Directive 2002/72/EC the following lines are inserted in the table in numerical order:

| Ref. No | CAS No | Name | Restrictions and/or specifications |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| '14627 | 0000117-21-5 | 3-chlorophthalic anhydride | SML = 0,05 mg/kg expressed as 3-chlorophthalic acid |
| 14628 | 0000118-45-6 | 4-chlorophthalic anhydride | SML = 0,05 mg/kg expressed as 4-chlorophthalic acid |
| 14876 | 0001076-97-7 | 1,4-cyclohexanedicarboxylic acid | SML = 5 mg/kg<br>Only to be used for manufacture of polyesters |
| 18117 | 0000079-14-1 | glycolic acid | For indirect food contact only, behind a polyethylene terephthalate (PET) layer |
| 19965 | 0006915-15-7 | malic acid | Only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis |
| 21498 | 0002530-85-0 | [3-(methacryloxy) propyl]trimethoxysilane | SML = 0,05 mg/kg<br>Only to be used as a surface treatment agent of inorganic fillers' |

*ANNEX II*

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

(1) The word 'incomplete' is deleted from the general title of Annex III as well as from the titles of Sections A and B.

(2) In section A the following lines are inserted in numerical order:

| Ref. No | CAS No | Name | Restrictions and/or specifications |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| '30607 | — | acids, $C_2$-$C_{24}$, aliphatic, linear, mono-carboxylic, from natural oils and fats, lithium salt | SML(T) = 0,6 mg/kg (expressed as Lithium) ([8]) |
| 33105 | 0146340-15-0 | alcohols, $C_{12}$-$C_{14}$ secondary, β-(2-hydroxyethoxy), ethoxylated | SML = 5 mg/kg ([44]) |
| 33535 | 0152261-33-1 | α-alkenes($C_{20}$-$C_{24}$) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine | Not to be used for articles in contact with fatty foods for which simulant D is laid down<br>Not to be used in contact with alcoholic foods |
| 38550 | 0882073-43-0 | bis(4-propylbenzylidene)propylsorbitol | SML = 5 mg/kg (including the sum of its hydrolysis products) |
| 40155 | 0124172-53-8 | N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylene-diamine | SML = 0,05 mg/kg ([1]) ([44]) |
| 49080 | 0852282-89-4 | N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione | SML = 0,05 mg/kg ([39]) ([45]) ([46])<br>Only for use in polyethylene terephthalate (PET) |
| 60027 | — | hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12 000) | Not to be used for articles in contact with fatty foods for which simulant D is laid down.<br>In compliance with the specification laid down in Annex V |
| 62215 | 0007439-89-6 | iron | SML = 48 mg/kg |
| 68119 | — | neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid | SML = 5 mg/kg<br>Not to be used for articles in contact with fatty foods for which simulant D is laid down. |
| 72141 | 0018600-59-4 | 2,2'-(1,4-phenylene)bis[4H-3,1-benz-oxazin-4-one] | SML = 0,05 mg/kg (including the sum of its hydrolysis products) |
| 76807 | 00073018-26-5 | polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol | SML = 30 mg/kg |
| 77708 | — | polyethyleneglycol (EO = 1-50) ethers of linear and branched primary ($C_8$-$C_{22}$) alcohols | SML = 1,8 mg/kg<br>In compliance with the specification laid down in Annex V |
| 80077 | 0068441-17-8 | polyethylene waxes, oxidised | SML = 60 mg/kg |

| (1) | (2) | (3) | (4) |
|---|---|---|---|
| 80350 | 0124578-12-7 | poly(12-hydroxystearic acid)-polyethyleneimine copolymer | Only to be used in polyethylene terephthalate (PET), polystyrene (PS), high impact polystyrene (HIPS) and polyamide (PA) up to 0,1 % w/w.<br>In compliance with the specification laid down in Annex V |
| 80480 | 0090751-07-8; 0082451-48-7 | poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino)]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino)] | SML = 5 mg/kg ([47])<br>In compliance with the specification laid down in Annex V |
| 80510 | 1010121-89-7 | poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid | Only to be used as a polymerisation production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS) |
| 91530 | — | sulphosuccinic acid alkyl ($C_4$-$C_{20}$) or cyclohexyl diesters, salts | SML = 5 mg/kg |
| 91815 | — | sulphosuccinic acid monoalkyl ($C_{10}$-$C_{16}$) polyethyleneglycol esters, salts | SML = 2 mg/kg |
| 92200 | 0006422-86-2 | terephthalic acid, bis(2-ethylhexyl)ester | SML = 60 mg/kg |
| 92470 | 0106990-43-6 | N,N',N',N'-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine | SML = 0,05 mg/kg |
| 92475 | 0203255-81-6 | 3,3',5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid | SML = 5 mg/kg (expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products) |
| 93450 | — | titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt] | In compliance with the specification laid down in Annex V |
| 94000 | 0000102-71-6 | triethanolamine | SML = 0,05 mg/kg (including the hydrochloride adduct) |
| 94425 | 0000867-13-0 | triethyl phosphonoacetate | Only for use in polyethylene terephthalate (PET) |
| 94985 | — | trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid | SML = 5 mg/kg<br>Not to be used for articles in contact with fatty food for which simulant D is laid down' |

*ANNEX III*

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

| Ref. No | CAS No | Name |
|---|---|---|
| '49080 | 852282-89-4 | N-(2,6-Diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione |
| 72141 | 0018600-59-4 | 2,2′-(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one] |
| 76807 | 0007308-26-5 | polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol |
| 92475 | 0203255-81-6 | 3,3′,5,5′-tetrakis(tert-butyl)-2,2′-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid' |

*ANNEX IV*

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

| Ref. No | Other specifications |
|---|---|
| '60027 | hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440-12 000)<br>Average molecular weight not less than 440 Da<br>Viscosity at 100 °C not less than 3,8 cSt (3,8 x $10^{-6}$ $m^2/s$) |
| 77708 | polyethyleneglycol (EO = 1-50) ethers of linear and branched primary ($C_8$-$C_{22}$) alcohols<br>Maximum residual quantity of ethylene oxide in the material or article = 1 mg/kg |
| 80350 | poly(12-hydroxystearic acid)-polyethyleneimine copolymer<br>Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine |
| 80480 | poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino)]-hexamethylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino)]<br>Average molecular weight not less than 2 400 Da<br>Residual content of morpholine ≤ 30 mg/kg, of N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine < 15 000 mg/kg, and of 2,4-dichloro-6-morpholino-1,3,5-triazine ≤ 20 mg/kg |
| 93450 | titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]<br>The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w' |

*ANNEX V*

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

1. The note (8) is replaced by the following:

'([8]) 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 Ref. Nos: 24886, 62020, 30607, 38000, 42400, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725.'

2. The following notes are added:

'([44]) The SML could be exceeded from polyolefins.

([45]) The SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.

([46]) The SML could be exceeded in contact with foods with high alcoholic content.

([47]) The SML could be exceeded from low-density polyethylene (LDPE) containing more than 0,3 % w/w of the substance when in contact with fatty foods.'