COMMISSION DIRECTIVE 2004/45/EC

of 16 April 2004

amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption [1], and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) Commission Directive 96/77/EC [2] of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners sets out the purity criteria for the additives mentioned in Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners [3].

(2) The Scientific Committee on Food concluded in its opinion of 5 March 2003 that the presence of low molecular weight carrageenan should be kept to a minimum. Consequently, the relevant criterion of the existing purity criteria for E 407 Carrageenan and E 407a (Processed Eucheuma Seaweed) set out in Directive 96/77/EC needs to be adapted.

(3) It is necessary to adopt specifications for the new additives authorised through Directive 2003/114/EC of the European Parliament and of the Council of 22 December 2003 amending Directive 95/2/EC on food additives other than colours and sweeteners: E 907 Hydrogenated poly-1-decene, E 1517 Glyceryl diacetate and E 1519 Benzyl alcohol.

(4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

(5) Directive 96/77/EC should therefore be amended accordingly.

(6) 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

The Annex to Directive 96/77/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 April 2005 at the latest. 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 shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

Products put on the market or labelled before 1 April 2005 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 16 April 2004.

For the Commission

David BYRNE

Member of the Commission

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[1] OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

[2] OJ L 339, 30.12.1996, p. 1. Directive as last amended by Directive 2003/95/EC (OJ L 283, 31.10.2003, p. 71).

[3] OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2003/114/EC (OJ L 24, 29.1.2003, p. 58).

ANNEX

The Annex to Directive 96/77/EC is amended as follows:

1. The texts concerning E 407 Carrageenan and E 407a Processed Eucheuma Seaweed are replaced by the following:

'E 407 CARRAGEENAN

Synonyms	Products of commerce are sold under different names such as: Irish moss gelose Eucheuman (from *Eucheuma* spp.) Iridophycan (from *Iridaea* spp.) Hypnean (from *Hypnea* spp.) Furcellaran or Danish agar (from *Furcellaria fastigiata*) Carrageenan (from *Chondrus* and *Gigartina* spp.)
Definition	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of *Gigartinaceae*, *Solieriaceae*, *Hypneaeceae* and *Furcellariaceae*, families of the class *Rhodophyceae* (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded
EINECS	232-524-2
Description	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO_4)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
E. coli	Negative in 5 g
Salmonella spp.	Negative in 10 g

E 407a PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed)
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds *Eucheuma cottonii* and *Eucheuma spinosum*, of the class *Rhodophyceae* (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consist chiefly of the potassium salt of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded
Description	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO_4)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
E. coli	Negative in 5 g
Salmonella spp.	Negative in 10 g'

2. The following text concerning E 907 Hydrogenated poly-1-decene is inserted after E 905 Microcrystalline wax:

'E 907 HYDROGENATED POLY-1-DECENE

Synonyms	Hydrogenated polydec-1-ene Hydrogenated poly-alpha-olefin
Definition	
Chemical formula	$C_{10n}H_{20n+2}$ where n = 3 — 6
Molecular weight	560 (average)
Assay	Not less than 98,5 % of hydrogenated poly-1-decene, having the following oligomer distribution: C_{30}: 13 — 37 % C_{40}: 35 — 70 % C_{50}: 9 — 25 % C_{60}: 1 — 7 %
Description	Colourless, odourless, viscous liquid
Identification	
A. Solubility	Insoluble in water; slightly soluble in ethanol; soluble in toluene
B. Burning	Burns with a bright flame and a paraffin-like characteristic smell
Purity	
Viscosity	Between 5,7 × 10^{-6} and 6,1 × 10^{-6} m^2s^{-1} at 100 °C
Compounds with carbon number less than 30	Not more than 1,5 %
Readily carbonisable substances	After 10 minutes shaking in a boiling water bath, a tube of sulfuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour
Nickel	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg'

3. The following text concerning E 1517 Glyceryl diacetate and E 1519 Benzyl alcohol is added:

'E 1517 GLYCERYL DIACETATE

Synonyms	Diacetin
Definition	Glyceryl diacetate consists predominantly of a mixture of the 1,2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters
Chemical names	Glyceryl diacetate 1,2,3-propanetriol diacetate
Chemical formula	$C_7H_{12}O_5$
Molecular weight	176,17
Assay	Not less than 94,0 %
Description	Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour
Identification	
A. Solubility	Soluble in water. Miscible with ethanol
B. Positive tests for glycerol and acetate	
C. Specific gravity	d_{20}^{20}: 1,175 — 1,195
D. Boiling range	Between 259 and 261 °C
Purity	
Total ash	Not more than 0,02 %
Acidity	Not more than 0,4 % (as acetic acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 1519 BENZYL ALCOHOL

Synonyms	Phenylcarbinol Phenylmethyl alcohol Benzenemethanol Alpha-hydroxytoluene
Definition	
Chemical names	Benzyl alcohol Phenylmethanol
Chemical formula	C_7H_8O
Molecular weight	108,14
Assay	Not less than 98,0 %
Description	Colourless, clear liquid with a faint, aromatic odour
Identification	
A. Solubility	Soluble in water, ethanol and ether
B. Refractive index	$[n]D^{20}$:1,538 – 1,541
C. Specific gravity	d_{25}^{25}: 1,042 — 1,047
D. Positive test for peroxides	
Purity	
Distillation range	Not less than 95 % v/v distils between 202 and 208 °C
Acid value	Not more than 0,5
Aldehydes	Not more than 0,2 % v/v (as benzaldehyde)
Lead	Not more than 5 mg/kg'