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(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2001/30/EC

of 2 May 2001

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], as amended by Directive 94/34/EC of the European Parliament and of the Council [2] and in particular Article 3(3)(a) thereof,

After consulting Scientific Committee on Food,

Whereas:

(1) It is necessary to establish purity criteria for all additives other than colours and sweeteners 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], as last amended by Directive 2001/5/EC [4].

(2) Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners [5], as last amended by Directive 2000/63/EC [6] set out purity criteria for a number of food additives. This Directive should now be completed with purity criteria for the remaining food additives mentioned in Directive 95/2/EC.

(3) 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).

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/77/EC is hereby amended as follows:

In the Annex, the text of the Annex to this Directive shall be added.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 June 2002 at the latest. They shall forthwith inform the Commission thereof.

2. 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.

3. Products put on the market or labelled before 1 June 2002 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 2 May 2001.

For the Commission

David BYRNE

Member of the Commission

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[1] OJ L 40, 11.2.1989, p. 27.

[2] OJ L 237, 10.9.1994, p. 1.

[3] OJ L 61, 18.3.1995, p. 1.

[4] OJ L 55, 24.2.2001, p. 59.

[5] OJ L 339, 30.12.1996, p. 1.

[6] OJ L 227, 30.10.2000, p. 1.

ANNEX

E 170 (i) CALCIUM CARBONATE

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs [1].

[1] OJ L 226, 22.9.1995, p. 13.

E 353 METATARTARIC ACID

Synonyms	Ditartaric acid
Definition	
Chemical name	Metatartaric acid
Chemical formula	$C_4H_6O_6$
Assay	Not less than 99,5 %
Description	Crystalline or powder form with a white or yellowish colour. Very deliquescent with a faint odour of caramel
Identification	
A.	Very soluble in water and ethanol.
B.	Place a sample of 1 to 10 mg of this substance in a test tube with 2 ml of concentrated sulfuric acid and 2 drops of sulpho-resorcinol reagent. When heated to 150 °C, an intense violet coloration appears
Purity	
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 354 CALCIUM TARTRATE

Synonyms	L-Calcium tartrate
Definition	
Chemical name	Calcium L(+)-2,3-dihydroxybutanedioate di-hydrate
Chemical formula	$C_4H_4CaO_6 \cdot 2H_2O$
Molecular weight	224,18
Assay	Not less than 98,0 %
Description	Fine crystalline powder with a white or off-white colour
Identification	
A. Slightly soluble in water. Solubility approximately 0,01 g/100 ml water (20 °C). Sparingly soluble in ethanol. Slightly soluble in diethyl ether. Soluble in acids	

B. Specific rotation $[\alpha]^{20}_D$	+7,0° to +7,4° (0,1 % in a 1N de HCl solution)
C. pH of a 5 % slurry	Between 6,0 and 9,0
Purity	
Sulphates (as H_2SO_4)	Not more than 1 g/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 356 SODIUM ADIPATE

Definition	
Chemical name	Sodium adipate
EINECS	231-293-5
Chemical formula	$C_6H_8Na_2O_4$
Molecular weight	190,11
Assay	Content not less than 99,0 % (on anhydrous basis)
Description	White odourless crystals or crystalline powder
Identification	
A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 50 g/100 ml water (20 °C)
C. Positive test for sodium	
Purity	
Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 357 POTASSIUM ADIPATE

Definition	
Chemical name	Potassium adipate
EINECS	242-838-1
Chemical formula	$C_6H_8K_2O_4$
Molecular weight	222,32
Assay	Content not less than 99,0 % (on anhydrous basis)
Description	White odourless crystals or crystalline powder

Identification	
A. Melting range	151 °C-152 °C (for adipic acid)
B. Solubility	Approximately 60 g/100 ml water (20 °C)
C. Positive test for potassium	
Purity	
Water	Not more than 3 % (Karl Fischer)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 420(i) SORBITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs [1].

E 420(ii) SORBITOL SYRUP

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

E 421 MANNITOL

Purity criteria for this additive are the same as set out for this additive in the Annex to Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs.

[1] OJ L 178, 28.7.1995, p. 1.

E 425(i) KONJAC GUM

Definition	Konjac gum is a water-soluble hydrocolloid obtained from the Konjac flour by aqueous extraction. Konjac flour is the unpurified raw product from the root of the perennial plant *Amorphophallus konjac* The main component of Konjac gum is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ration of 1,6:1,0, connected by β(1-4)-glycosidic bonds. Shorter side chains are attached through β(1-3)-glycosidic bonds, and acetyl groups occur at random at a ratio of about 1 group per 9 to 19 sugar units
Molecular weight	The main component, glucomannan, has an average molecular weight of 200 000 to 2 000 000
Assay	Not less than 75 % carbohydrate
Description	A white to cream to light tan powder

Identification	
A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 4,0 and 7,0
B. Gel formation	Add 5 ml of a 4 % sodium borate solution to a 1 % solution of the sample in a test tube, and shake vigorously. A gel forms
C. Formation of heat-stable gel	Prepare a 2 % solution of the sample by heating it in a boiling water bath for 30 min, with continuous agitation and then cooling the solution to room temperature. For each g of the sample used to prepare 30 g of the 2 % solution, add 1 ml of 10 % potassium carbonate solution to the fully hydrated sample at ambient temperature. Heat the mixture in a water bath to 85 °C, and maintain for 2 h without agitation. Under these conditions a thermally stable gel is formed
D. Viscosity (1 % solution)	Not less than 3 $kgm^{-1}s^{-1}$ at 25 °C
Purity	
Loss on drying	Not more than 12 % (105 °C, 5 h)
Starch	Not more than 3 %
Protein	Not more than 3 % (N × 5,7) Determine nitrogen by Kjeldahl method. The percentage of nitrogen in the sample multiplied by 5,7 gives the percent of protein in the sample
Ether-soluble material	Not more than 0,1 %
Total ash	Not more than 5,0 % (800 °C, 3 to 4h)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg
Salmonella spp.	Absent in 12,5 g
E. coli	Absent in 5 g

E 425(ii) KONJAC GLUCOMANNAN

Definition	Konjac glucomannan is a water-soluble hydrocolloid obtained from Konjac flour by washing with water-containing ethanol. Konjac flour is the unpurified raw product from the tuber of the perennial plant *Amorphophallus konjac*. The main component is the water-soluble high-molecular-weight polysaccharide glucomannan, which consists of D-mannose and D-glucose units at a molar ration of 1,6:1,0, connected by β(1-4)-glycosidic bonds with a branch at about each 50th or 60th unit. About each 19th sugar residue is acetylated
Molecular weight	500 000 to 2 000 000
Assay	Total dietary fibre: not less than 95 % on a dry weight basis
Description	White to slightly brownish fine particle size, free flowing and odourless powder
Identification	
A. Solubility	Dispersible in hot or cold water forming a highly viscous solution with a pH between 5,0 and 7,0. Solubility is increased by heat and mechanical agitation