COMMISSION DIRECTIVE 2000/51/EC

of 26 July 2000

amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in 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 89/107/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 European Parliament and Council Directive 94/34/EC [2], and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

(1) European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs [3], as amended by Directive 96/83/EC [4], lists those substances which may be used as sweeteners in foodstuffs.

(2) Commission Directive 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs [5], as amended by Directive 98/66/EC [6], sets out the purity criteria for the sweeteners mentioned in Directive 94/35/EC.

(3) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/31/EC for mannitol (E 421) and maltitol syrup (E 965(ii)). It is consequently necessary to adapt that Directive.

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

In the Annex to Directive 95/31/EC, the text concerning (E 421) mannitol and (E 965 (ii)) maltitol syrup shall be replaced by the text in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2001 at the latest. They shall forthwith inform the Commission thereof.

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.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 July 2000.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 40, 11.2.1989, p. 27.
[2] OJ L 237, 10.9.1994, p. 1.
[3] OJ L 237, 10.9.1994, p. 3.
[4] OJ L 48, 19.2.1997, p. 16.
[5] OJ L 178, 28.7.1995, p. 1.
[6] OJ L 257, 19.9.1998, p. 35.

ANNEX

'E 421 MANNITOL

1. **Mannitol**	
Synonyms	D-mannitol
Definition	Mannitol is manufactured by catalytic hydrogenation of a mixture of glucose and fructose made from invert sugar
Chemical name	D-mannitol
Einecs	200-711-8
Chemical formula	$C_6H_{14}O_6$
Molecular weight	182,2
Assay	Content not less than 96,0 % D-mannitol and not more than 102 % on the dried basis
Description	White, odourless, crystalline powder
Identification	
A. Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range	Between 164 and 169 °C.
C. Thin layer chromatography	Passes test
D. Specific rotation	$[\alpha]\ ^{20}_{D}$: + 23° to + 25° (borate solution)
E. pH	Between 5 and 8 Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH
Purity	
Loss on drying	Not more than 0,3 % (105 °C, 4 hours)
Reducing sugars	Not more than 0,3 % (as glucose)
Total sugars	Not more than 1 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 70 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
2. **Mannitol manufactured by fermentation**	
Synonyms	D-mannitol
Definition	Mannitol can also be manufactured by discontinous fermentation under aerobic conditions a conventional strain of the yeast *Zygosaccharomyces rouxii*
Chemical name	D-mannitol
Einecs	200-711-8
Chemical formula	$C_6H_{14}O_6$
Molecular weight	182,2
Assay	Not less than 99 % on the dried basis
Description	White, odourles crystalline powder

Identification	
A. Solubility	Soluble in water, very slightly soluble in ethanol, practically insoluble in ether
B. Melting range	Between 164 and 169 °C.
C. Thin layer chromatography	Passes test
D. Specific rotation	$[\alpha]\ ^{20}_{D}$: + 23° to + 25° (borate solution)
E. pH	Between 5 and 8 Add 0,5 ml of a saturated solution of potassium chloride to 10 ml of a 10 % w/v solution of the sample, then measure the pH
Purity	
Arabitol	Not more than 0,3 %
Loss on drying	Not more than 0,3 % (105 °C, 4 hours)
Reducing sugars	Not more than 0,3 % (as glucose)
Total sugars	Not more than 1 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 70 mg/kg
Sulphate	Not more than 100 mg/kg
Lead	Not more than 1 mg/kg
Aerobic mesophilic bacteria	Not more than 10^3/g
Coliforms	Absent in 10 g
Salmonella	Absent in 10 g
E. coli	Absent in 10 g
Staphylococcus aureus	Absent in 10 g
Pseudomonas aeruginosa	Absent in 10 g
Moulds	Not more than 100/g
Yeasts	Not more than 100/g'

'E 965(ii) SYRUP MALTITOL

Synonyms	Hydrogenated high-maltose-glucose syrup, hydrogenated glucose syrup
Definition	A mixture consisting of mainly maltitol with sorbitol and hydrogenated oligo- and polysaccharides. It is manufactured by the catalytic hydrogenation of high maltose-content glucose syrup. The article of commerce is supplied both as a syrup and as a solid product.
Assay	Content not less than 99 % of total hydrogenated saccharides on the anhydrous basis and not less than 50 % of maltitol on the anhydrous basis
Description	Colourless and odourless, clear viscous liquids or white crystalline masses
Identification	
A. Solubility	Very soluble in water, slightly soluble in ethanol
B. Thin layer chromatography	Passes test
Purity	
Water	Not more than 31 % (Karl Fischer)
Reducing sugars	Not more than 0,3 % (as glucose)
Sulphated ash	Not more than 0,1 %
Chlorides	Not more than 50 mg/kg
Sulphate	Not more than 100 mg/kg
Nickel	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg'