COMMISSION DIRECTIVE 2004/46/EC

of 16 April 2004

amending Directive 95/31/EC as regards E 955 sucralose and E 962 salt of aspartame-acesulfame

(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 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs [2] sets out the purity criteria for the sweeteners mentioned in Directive 94/35/EC of the European Parliament and of the Council of 30 June 1994 on sweeteners for use in foodstuffs [3].

(2) It is necessary to establish purity criteria for E 955 sucralose and E 962 salt of aspartame-acesulfame.

(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) Directive 95/31/EC should therefore be amended accordingly.

(5) 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 95/31/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

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

Article 4

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 178, 28.7.1995, p. 1. Directive as last amended by Directive 2001/52/EC (OJ L 190, 12.7.2001, p. 18).

[3] OJ L 237, 10.9.1994, p. 3. Directive as last amended by Directive 2003/115/EC of the European Parliament and of the Council (OJ L 24, 29.1.2004, p. 65).

ANNEX

In the Annex, the following text is inserted:

'E955 E 955 SUCRALOSE

Synonyms	4,1',6'-trichlorogalactosucrose
Definition	
Chemical name	1,6-Dichloro-1,6-dideoxy-b-D-fructofuranosyl-4-chloro-4-deoxy-a-D-galactopyranoside
Einecs	259-952-2
Chemical formula	$C_{12}H_{19}Cl_3O_8$
Molecular weight	397,64
Assay	Content not less than 98 % and not more than 102 % $C_{12}H_{19}Cl_3O_8$ calculated on an anhydrous basis.
Description	White to off-white, practically odourless crystalline powder.
Identification	
A. pH of a 10 % solution	Not less than 5,0 and not more than 7,0
B. Solubility	Freely soluble in water, methanol and ethanol Slightly soluble in ethyl acetate
C. Infrared absorption	The infrared spectrum of a potassium bromide dispersion of the sample exhibits relative maxima at similar wave numbers as those shown in the reference spectrum obtained using a sucralose reference standard.
D. Thin-layer chromatography	The main spot in the test solution has the same Rf value as that of the main spot of standard solution A referred to in the test for other chlorinated disaccharides. This standard solution is obtained by dissolving 1,0 g of sucralose reference standard in 10 ml of methanol.
E. Specific rotation	$[\alpha]_D^{20}$: + 84,0° to + 87,5° calculated on the anhydrous basis (10 % w/v solution)
Purity	
Water	Not more than 2,0 % (Karl Fischer method)
Sulphated ash	Not more than 0,7 %
Lead	Not more than 1 mg/kg
Other chlorinated disaccharides	Not more than 0,5 %
Chlorinated monosaccharides	Not more than 0,1 %
Triphenylphosphine oxide	Not more than 150 mg/kg
Methanol	Not more than 0,1 %

E962 E 962 SALT OF ASPARTAME-ACESULFAME

Synonyms	Aspartame-acesulfame Aspartame-acesulfame salt
Definition	The salt is prepared by heating an approximately 2:1 ratio (w/w) of aspartame and acesulfame K in solution at acidic pH and allowing crystallisation to occur. The potassium and moisture are eliminated. The product is more stable than aspartame alone.
Chemical name	6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-dioxide salt of L-phenylalanyl-2-methyl-L-a-aspartic acid
Chemical formula	$C_{18}H_{23}O_9N_3S$
Molecular weight	457,46
Assay	63,0 % to 66,0 % aspartame (dry basis) and 34,0 % to 37,0 % acesulfame (acid form on a dry basis)

Description	A white, odourless, crystalline powder.
Identification	
A. Solubility	Sparingly soluble in water; slightly soluble in ethanol.
B. Transmittance	The transmittance of a 1 % solution in water determined in a 1 cm cell at 430 nm with a suitable spectrophotometer using water as a reference, is not less than 0,95, equivalent to an absorbance of not more than approximately 0,022.
C. Specific rotation	$[\alpha]_D^{20}$: +14,5° to +16,5° Determine at a concentration of 6,2 g in 100 ml formic acid (15N) within 30 min of preparation of the solution. Divide the calculated specific rotation by 0,646 to correct for the aspartame content of the salt of aspartame-acesulfame.
Purity	
Loss on drying	Not more than 0,5 % (105 °C, 4 h)
5-Benzyl-3,6-dioxo-2-piperazineacetic acid	Not more than 0,5 %
Lead	Not more than 1 mg/kg'