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(Acts whose publication is obligatory)

COMMISSION DIRECTIVE 2000/63/EC

of 5 October 2000

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

After consulting the Scientific Committee for 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 98/72/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 amended by Directive 98/86/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, in the light of technical development, to amend the purity criteria set out in Directive 96/77/EC for butylated hydroxyanisole (BHA). It is consequently necessary to adapt that Directive.

(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) Food additives, if prepared by production methods or starting materials significantly different from those evaluated by the Scientific Committee for Food, or if different from those mentioned in this Directive, should be submitted for safety evaluation by the Scientific Committee for Food with emphasis on the purity criteria.

(6) 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

Directive 96/77/EC shall be amended as follows:

1. In the Annex, the text concerning E 320 — butylated hydroxyanisole (BHA) shall be replaced by the text in Annex I to this Directive.

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

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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 295, 4.11.1998, p. 18.
(5) OJ L 339, 30.12.1996, p. 1.
(6) OJ L 334, 9.12.1998, p. 1.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 31 March 2001. They shall immediately inform the Commission thereof.

2. When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

3. Products put on the market or labelled before 31 March 2001 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 its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 5 October 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

'E 320 BUTYLATED HYDROXYANISOLE (BHA)

Synonyms	BHA
Definition	
Chemical names	3-Tertiary-butyl-4-hydroxyanisole A mixture of 2-tertiary-butyl-4-hydroxyanisole and 3-tertiary-butyl-4-hydroxyanisole
EINECS	246-563-8
Chemical formula	$C_{11}H_{16}O_2$
Formula weight	180,25
Assay	Content not less than 98,5 % of $C_{11}H_{16}O_2$ and not less than 85 % of 3-tertiary-butyl-4-hydroxyanisole isomer
Description	White or slightly yellow crystals or waxy solid with a slight aromatic smell
Identification	
A. Solubility	Insoluble in water, freely soluble in ethanol
B. Melting range	Between 48 °C and 63 °C
C. Colour reaction	Passes test for phenol groups
Purity	
Sulphated ash	Not more than 0,05 % after calcination at 800 ± 25 °C
Phenolic impurities	Not more than 0,5 %
Specific absorption $E^{1\%}_{1cm}$	$E^{1\%}_{1cm}$ (290 nm) not less than 190 and not more than 210
Specific absorption $E^{1\%}_{1cm}$	$E^{1\%}_{1cm}$ (228 nm) not less than 326 and not more than 345
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg'

ANNEX II

'POLYETHYLENEGLYCOL 6000

Synonyms	PEG 6000 Macrogol 6000
Definition	Polyethylene glycol 6000 is a mixture of polymers with the general formula H-(OCH_2-CH)-OH corresponding to an average relative molecular mass of approximately 6 000
Chemical formula	$(C_2H_4O)_n H_2O$ (n = number of ethylene oxide units corresponding to a molecular weight of 6000, about 140)
Molecular weight	5 600 - 7 000
Assay	Not less than 90,0 % and not more than 110,0 %
Description	A white or almost white solid with a waxy or paraffin-like appearance
Identification	
A. Solubility	Very soluble in water and in methylene chloride Practically insoluble in alcohol, in ether and in fatty and mineral oils
B. Melting range	Between 55 °C and 61 °C
Purity	
Viscosity	Between 0,220 and 0,275 $kgm^{-1}s^{-1}$ at 20 °C
Hydroxyl value	Between 16 and 22
Sulphated ash	Not more than 0,2 %
Ethylene oxide	Not more than 1 mg/kg
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 296 MALIC ACID

Synonyms	DL-Malic acid, pomalous acid
Definition	
Chemical name	DL-Malic acid, hydroxybutanedioic acid, hydroxysuccinic acid
EINECS	230-022-8
Chemical formula	$C_4H_6O_5$
Molecular weight	134,09
Assay	Content not less than 99,0 %
Description	White or nearly white crystalline powder or granules

Identification	
A. Melting range between 127 °C and 132 °C	
B. Positive test for malate	
C. Solutions of this substance are optically inactive in all concentrations	
Purity	
Sulphated ash	Not more than 0,1 %
Fumaric acid	Not more than 1,0 %
Maleic acid	Not more than 0,05 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg

E 297 FUMARIC ACID

Definition	
Chemical name	Trans-butenedioic acid, trans-1,2-ethylene-dicarboxylic acid
EINECS	203-743-0
Chemical formula	$C_4H_4O_4$
Molecular weight	116,07
Assay	Content not less than 99,0 % on the anhydrous basis
Description	White crystalline powder or granules
Identification	
A. Melting range	286 °C - 302 °C (closed capillary, rapid heating)
B. Positive tests for double bonds and for 1,2-dicarboxylic acid	
C. pH of a 0,05 % solution at 25 °C	3,0 – 3,2
Purity	
Loss on drying	Not more than 0,5 % (120 °C, 4h)
Sulphated ash	Not more than 0,1 %
Maleic acid	Not more than 0,1 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg