

COMMISSION DIRECTIVE 2004/47/EC
of 16 April 2004

amending Directive 95/45/EC as regards mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii))

(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 for Food,

Whereas:

- (1) Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs ⁽²⁾ sets out the purity criteria for the colours mentioned in Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs ⁽³⁾.
- (2) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/45/EC for mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii)).
- (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 95/45/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 95/45/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 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

⁽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 226, 22.9.1995, p. 1. Directive as last amended by Directive 2001/50/EC (OJ L 190, 12.7.2001, p. 14).

⁽³⁾ OJ L 237, 10.9.1994, p. 13. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

ANNEX

In the Annex, the text concerning mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii)) is replaced by the following:

E 160 a (i) MIXED CAROTENES**1. Plant carotenes**

Synonyms	CI Food Orange 5
Definition	Mixed carotenes are obtained by solvent extraction of natural strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle. The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha, gamma-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material. Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane (*), dichloromethane and carbon dioxide.
Class	Carotenoid
Colour index No	75130
EINECS	230-636-6
Chemical formula	Beta-carotene: $C_{40}H_{56}$
Molecular weight	Beta-carotene: 536,88
Assay	Content of carotenes (calculated as beta-carotene) is not less than 5 %. For products obtained by extraction of vegetable oils: not less than 0,2 % in edible fats $E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Identification

A. Spectrometry Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm

Purity

Solvent residues	Acetone	} Not more than 50 mg/kg, singly or in combination
	Methyl ethyl ketone	
	Methanol	
	Propan-2-ol	
	Hexane	
	Ethanol	
	Dichloromethane	Not more than 10 mg/kg
Lead	Not more than 5 mg/kg	

(*) Benzene not more than 0,05 % v/v.

2. Algal carotenes

Synonyms	CI Food Orange 5
Definition	Mixed carotenes may also be produced from natural strains of the algae <i>Dunaliella salina</i> , grown in large saline lakes located in Whyalla, South Australia. Beta-carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29. The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.
Class	Carotenoid
Colour index No	75130
Chemical formula	Beta-carotene: C ₄₀ H ₅₆
Molecular weight	Beta-carotene: 536,88
Assay	Content of carotenes (calculated as beta-carotene) is not less than 20 %. E _{1 cm} ^{1 %} 2 500 at approximately 440 nm to 457 nm in cyclohexane
Identification	
A. Spectrometry	Maximum in cyclohexane at 440 nm to 457 nm and 474 nm to 486 nm
Purity	
Natural tocopherols in edible oil	Not more than 0,3 %
Lead	Not more than 5 mg/kg

E 160 a (ii) BETA-CAROTENE

1. Beta-carotene

Synonyms	CI Food Orange 5
Definition	These specifications apply predominantly to all trans isomers of beta-carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios.
Class	Carotenoid
Colour index No	40800
EINECS	230-636-6
Chemical names	Beta-carotene, beta,beta-carotene
Chemical formula	C ₄₀ H ₅₆
Molecular weight	536,88
Assay	Not less than 96 % total colouring matters (expressed as beta-carotene) E _{1 cm} ^{1 %} 2 500 at approximately 440 nm to 457 nm in cyclohexane
Description	Red to brownish-red crystals or crystalline powder
Identification	
A. Spectrometry	Maximum in cyclohexane at 453 to 456 nm
Purity	
Sulfated ash	Not more than 0,2 %
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters
Lead	Not more than 2 mg/kg

2. Beta-carotene from *Blakeslea trispora*

Synonyms	CI Food Orange 5										
Definition	Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (-) of natural strains of the fungus <i>Blakeslea trispora</i> . The beta-carotene is extracted from the biomass with ethyl acetate, or isobutyl acetate followed by isopropyl alcohol, and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process, approximately 3 % of the product consists of mixed carotenoids, which is specific for the product.										
Class	Carotenoid										
Colour index No	40800										
EINECS	230-636-6										
Chemical names	Beta-carotene, beta,beta-carotene										
Chemical formula	C ₄₀ H ₅₆										
Molecular weight	536,88										
Assay	Not less than 96 % total colouring matters (expressed as beta-carotene)										
	$E_{1\text{cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane										
Description	Red, brownish-red or purple-violet crystals or crystalline powder (colour varies according to extraction solvent used and conditions of crystallisation)										
Identification											
A. Spectrometry	Maximum in cyclohexane at 453 nm to 456 nm										
Purity											
Solvent residues	<table border="0"> <tr> <td>Ethyl acetate</td> <td rowspan="2">}</td> <td rowspan="2">Not more than 0,8 %, singly or in combination</td> </tr> <tr> <td>Ethanol</td> </tr> <tr> <td>Isobutyl acetate:</td> <td></td> <td>Not more than 1,0 %</td> </tr> <tr> <td>Isopropyl alcohol:</td> <td></td> <td>Not more than 0,1 %</td> </tr> </table>	Ethyl acetate	}	Not more than 0,8 %, singly or in combination	Ethanol	Isobutyl acetate:		Not more than 1,0 %	Isopropyl alcohol:		Not more than 0,1 %
Ethyl acetate	}	Not more than 0,8 %, singly or in combination									
Ethanol											
Isobutyl acetate:		Not more than 1,0 %									
Isopropyl alcohol:		Not more than 0,1 %									
Sulfated ash	Not more than 0,2 %										
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters										
Lead	Not more than 2 mg/kg										
Mycotoxins:											
Aflatoxin B1	Absent										
Trichothecene (T2)	Absent										
Ochratoxin	Absent										
Zearalenone	Absent										
Microbiology:											
Moulds	Not more than 100/g										
Yeasts	Not more than 100/g										
<i>Salmonella</i>	Absent in 25 g										
<i>Escherichia coli</i>	Absent in 5 g										
