ISSN 0378-6986

Official Journal

of the European Communities

C 278

Volume 28

30 October 1985

English edition

Information and Notices

Notice No | Contents | Page

I

(Information)

COMMISSION

ECU (1)

29 October 1985

(85/C 278/01)

Currency amount for one unit:

Belgian and Luxembourg franc con.	44,8118	United States dollar	0,840196
Belgian and Luxembourg franc fin.	45,1395	Swiss franc	1,81230
German mark	2,21140	Spanish peseta	135,692
Dutch guilder	2,49496	Swedish krona	6,64133
Pound sterling	0,585706	Norwegian krone	6,63965
Danish krone	8,02093	Canadian dollar	1,14821
French franc	6,74089	Portuguese escudo	137,372
Italian lira	1493,03	Austrian schilling	15,5436
Irish pound	0,715060	Finnish markka	4,74501
Greek drachma	129,945	Japanese yen	178,710
		Australian dollar	1,20028
		New Zealand dollar	1,48707

The Commission has installed a telex with an automatic answering device which gives the conversion rates in a number of currencies. This service is available every day from 3.30 p.m. until 1 p.m. the following day.

Users of the service should do as follows:

— call telex number Brussels 23789;

— give their own telex code;

— type the code 'cccc' which puts the automatic system into operation resulting in the transmission of the conversion rates of the ECU;

— the transmission should not be interrupted until the end of the message, which is marked by the code 'ffff'.

Note: The Commission also has an automatic telex answering service (No 21791) providing daily data on calculation of monetary compensatory amounts for the purposes of the common agricultural policy.

---

(1) Council Regulation (EEC) No 3180/78 of 18 December 1978 (OJ No L 379, 30. 12. 1978, p. 1), as amended by Regulation (EEC) No 2626/84 (OJ No L 247, 16. 9. 1984, p. 1).
Council Decision 80/1184/EEC of 18 December 1980 (Convention of Lomé) (OJ No L 349, 23. 12. 1980, p. 34).
Commission Decision No 3334/80/ECSC of 19 December 1980 (OJ No L 349, 23. 12. 1980, p. 27).
Financial Regulation of 16 December 1980 concerning the general budget of the European Communities (OJ No L 345, 20. 12. 1980, p. 23).
Council Regulation (EEC) No 3308/80 of 16 December 1980 (OJ No L 345, 20. 12. 1980, p. 1).
Decision of the Council of Governors of the European Investment Bank of 13 May 1981 (OJ No L 311, 30. 10. 1981, p. 1).

Recapitulation of current tenders, published in the *Supplement to the Official Journal of the European Communities*, financed by the European Economic Community under the European Development Fund (EDF) or the European Communities budget

(week: 22 to 26 October 1985)

(85/C 278/02)

Invitation to tender No	Number and date of 'S' Journal	Country	Subject	Final date for submission of bids
2316	S 204, 23. 10. 1985	Benin	BI-Cotonou: various supplies	18. 12. 1985
2312	S 204, 23. 10. 1985	Papua New Guinea	PG-Konedibu: wood gasifier generating plant	12. 12. 1985
2313	S 204, 23. 10. 1985	Fiji	FJ-Suva: refrigerated containers	10. 12. 1986

Nomination of the members of the Joint Committee on Railways

(85/C 278/03)

By a Decision of 19 December 1984 (85/13/EEC), the Commission set up a Joint Committee on Railways (OJ No L 8, 10. 1. 1985, p. 26).

On 26 September 1985, the Commission, on a proposal from the professional organizations, appointed the persons listed below as members and alternate members of the Joint Committee for a period of four years.

Categories represented	Full members		Alternates	
Employers	1. Mr VERBERCKT L.	(B)	Mr ROGISSART J.	(B)
	2. Mr BOUQUIAUX	(B)	Mr DE MUYNCK	(B)
	3. Mr MARNEF	(B)	Mr VANKEER	(B)
	4. Mr KRAGBALLE G.	(DK)	Mr NIELSEN B. M.	(DK)
	5. Mr SUIKOFF V.	(DK)	Mr JENSEN O. H.	(DK)
	6. Mr HAEFNER P.	(D)	Mr HANSEN K. H.	(D)
	7. Mr FRIESER H.	(D)	Mr MEISTER R.	(D)
	8. Mr VLANDIKAS P.	(GR)	Mr PROFYLLIDIS V.	(GR)
	9. Mr SIAMOS V.	(GR)	Mr MANOLAS E.	(GR)
	10. Mr GRATREAU R.	(F)	Mr VIAL A.	(F)
	11. Mr DESCOUTURES P.	(F)	Ms PERTHUIS Y. H.	(F)
	12. Mr AUROY M.	(F)	Mr PRESSON G.	(F)
	13. Mr MARKHAM J.	(IRL)	Mr AUNGIER	(IRL)
	14. Mr MURPHY P.	(IRL)	Mr HODGINS J. B.	(IRL)
	15. Mr STEFANELLI F.	(I)	Ms BOVONE D.	(I)
	16. Ms VOLPI P.	(I)	Ms SEMENZA A.	(I)
	17. Mr SCHMIT G.	(L)	Mr BOLLENDORFF N.	(L)
	18. Mr GILSON F.	(L)	Mr GIELEN R.	(L)
	19. Ms GERBERS O. D.	(NL)	Mr NIEUWENHUIS	(NL)
	20. Mr KOK W.	(NL)	Mr PLANTINGA	(NL)
	21. Mr CRAMMER	(UK)	Mr MEARA J. M.	(UK)
	22. Mr CROWE J. H.	(UK)	Mr ETHERTON T.	(UK)
Workers	1. Mr THYS W.	(B)	Mr DE GRAEVE F.	(B)
	2. Mr POTUMS P.	(B)	Mr DAMILOT J.	(B)
	3. Mr NYGAARD JESPERSEN E.	(DK)	Mr BJARNDAHL I.	(DK)
	4. Mr JENSEN K.	(DK)	Mr LANTOW L.	(DK)
	5. Mr KILIAN H.	(D)	Mr RESCH H.	(D)
	6. Mr SCHAEFER R.	(D)	Mr HOFMANN R.	(D)
	7. Mr JUNGKUNZ B.	(D)	Mr SEITENZAHL R.	(D)
	8. Mr POLITIS D.	(GR)	Mr BABASIS N.	(GR)
	9. Mr ZAOUI J.	(F)	Mr STIMAMIGLIO A.	(F)
	10. Mr CARMANTRAN J.	(F)	Mr BONNEFOI P.	(F)
	11. Mr MALLET J.	(F)	Mr OLIVIER B.	(F)
	12. Mr LANOUE G.	(F)	Mr DECAILLON N.	(F)
	13. Mr COX	(IRL)		
	14. Mr CALCAGNINI U.	(I)	Mr DE AUGELIS S.	(I)
	15. Mr MEZZANOTTE S.	(I)	Mr CEVA A.	(I)
	16. Mr BLESER R.	(L)	Mr RASSEL T.	(L)
	17. Mr VAN DEN BERG J. C.	(NL)	Mr VAN STRATEN W. J.	(NL)
	18. Mr JONGSMA E.	(NL)	Mr MARIJS H. A.	(NL)
	19. Mr KNAPP J.	(UK)	Mr TURNOCK C. E.	(UK)
	20. Mr LYONS C. A.	(UK)	Mr ROSSER R. A.	(UK)
	21. Mr BUCKTON R.	(UK)	Mr MILLIGAN N.	(UK)
	22.			

II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive amending for the eighth time the Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption

COM(85) 474 final

(Submitted by the Commission to the Council on 30 September 1985)

(85/C 278/04)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (1), as last amended by Directive 81/20/EEC (2), lays down in Annex II lists of colouring matters and substances used for diluting and dissolving colouring matters which may be authorized at national level by the Member States;

Whereas, having regard to the most recent scientific and toxicological information on these substances, with the exception of Yellow 2G it is possible to authorize the use of substances in the said Annex II within the Community; whereas, also, this information makes it possible to introduce into the Directive the colouring matter Allura Red AC;

Whereas, in the light of present-day requirements regarding the safety in use of colouring matters, Yellow 2G should no longer be permitted for use in foodstuffs;

Whereas the prohibition so required should be given effect under conditions which ensure the protection of public health while avoiding as far as possible disruption of a technological and economic nature;

Whereas decisions should now be taken on the harmonization of the conditions governing the colouring of foodstuffs in the case of Brown FK, Red 2G, carrageenan (E 407) and gum arabic (E 414);

Whereas the authorization of colouring matters should be associated with the laying down of criteria of purity which these colouring matters should satisfy; whereas, in the light of scientific research, it is desirable that for the protection of public health the criteria of purity for the colouring matters authorized at Communtiy level should be revised;

Whereas this revision incorporates a re-examination of the nomenclature used to identify colouring matters in the Directive,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Directive of 23 October 1962 is hereby amended as follows:

1. The following substances are added to the list in Article 6:

   'ethyl acetate, diethyl ether, glycerol monoacetate, glycerol diacetate, isopropyl alcohol, propane-1,2,-diol, acetic acid, sodium hydroxide, ammonium hydroxide and, exclusively for the colouring matters listed under number E 160 and E 161 in Annex I, carrageenan and gum arabic'.

2. Article 8 is replaced by the following:

   'Article 8

   Member States shall take all measures necessary to ensure that the colouring matters listed in Annex I and the products listed in Article 6, where these are used to dilute or dissolve the colouring matters listed in Annex I, satisfy the general and specific criteria laid down in Annex III.'

(1) OJ No 115, 11. 11. 1962, p. 2645/62.
(2) OJ No L 43, 14. 2. 1981, p. 11.

3. The first indent of Article 11 (2) is replaced by the following:

'— the methods of analysis needed to verify that the general and specific criteria of purity laid down in Annex III are satisfied, where these are not already specified in the relevant purity criteria referred to in Annex III, and the modifications, where necessary, to methods specified in the purity criteria in question'.

4. Annex I is replaced in accordance with Annex 1 hereto.

5. Annex II is deleted.

6. Annex III is replaced in accordance with Annex 2 hereto.

Article 2

The marketing of foods containing Yellow 2G shall be prohibited as from [date: 18 months after notification].

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 12 months after notification and shall forthwith inform the Commission thereof.

Article 4

This Directive is addressed to the Member States.

ANNEX I

'ANNEX 1

The colouring matters referred to in Article 1 of this Directive are listed in the three sections below.

Aluminium lakes prepared from these colouring matters are also authorized.

The chemical name given is usually that of the sodium derivative of the colouring matter. The free acid form of the dye and its potassium and calcium salt may be present, although for the purposes of calculating the limits in the purity criteria these are calculated as the equivalent sodium derivative.

EEC No	Common name	Colour index number (1) and name, or chemical description
(1) **Colouring matters for both mass and surface colouring**		
E 100	Curcumin	75300 (Natural yellow 3)
E 101	(i) Riboflavin (ii) Riboflavin-5'-phosphate	
E 102	Tartrazine	19140 (Food yellow 4)
E 104	Quinoline yellow	47005 (Food yellow 13)
E 110	Sunset yellow FCF Orange yellow S	15985 (Food yellow 3)
E 120	Cochineal/Carminic acid/Carmines	75470 (Natural red 4)
E 122	Azorubine Carmoisine	14720 (Food red 3)
E 123	Amaranth	16185 (Food red 9)
E 124	Ponceau 4R Cochineal red A	16255 (Food red 7)
E 127	Erythrosine	45430 (Food red 14)
E 129	Allura red AC	16035 (Food red 17)
E 131	Patent blue V	42051 (Food blue 5)
E 132	Indigotine Indigo carmine	73015 (Food blue 1)
E 133	Brilliant blue FCF	42090 (Food blue 2)
E 140	Chlorophylls and chlorophyllins	75810 (Natural green 3) 75815 (Natural green 5)
	(i) chlorophylls (ii) chlorophyllins	
E 141	Copper complexes of chlorophylls and chlorophyllins	75815 (Natural green 5)
	(i) copper complexes of chlorophylls (ii) copper complexes of chlorophyllins	

EEC No	Common name	Colour index number (1) and name, or chemical description
E 142	Green S	44090 (Food green 4)
E 150 a	Plain (spirit) caramel	Caramel (2) prepared by the controlled heat treatment of carbohydrates with or without the presence of alkali or acid
E 150 b	Caustic sulphite caramel	Caramel prepared by the controlled heat treatment of carbohydrates with sulphite-containing compounds
E 150 c	Ammonia caramel	Caramel prepared by the controlled heat treatment of carbohydrates with ammonia
E 150 d	Sulphite ammonia caramel	Caramel prepared by the controlled heat treatment of carbohydrates with ammonium and sulphite-containing compounds
E 151	Brilliant black PN, Black PN	28440 (Food black 1)
E 153	Vegetable carbon	
E 155	Brown HT	20285 (Food brown 3)
E 160 a	(i) Mixed carotenes (ii) Beta-carotene	75130 (Food orange 5) 40800 (Food orange 5)
E 160 b	Annatto extracts	75120 (Natural orange 4)
E 160 c	Paprika extract	
E 160 d	(deleted)	
E 160 e	Beta-apo-8'-carotenal (C 30)	40820 (Food orange 6)
E 160 f	Ethyl ester of Beta-apo-8'-carotenic acid (C 30)	40825 (Food orange 7)
E 161	Xanthophylls	Prepared by physical means from natural foods
E 161 b	(deleted)	
E 161 c	(deleted)	
E 161 d	(deleted)	
E 161 e	(deleted)	
E 161 f	(deleted)	
E 161 g	Canthaxanthin	40850 (Food orange 8)
E 162	Beetroot red	
E 163	Anthocyanins	Prepared by physical means from edible fruits and vegetables
E 171	Titanium dioxide	77891 (Pigment white 6)
E 172	Iron oxides and hydroxides	77491, 77492, 77499 (Pigment yellow 42 and 43, Pigment red 101 and 102, Pigment black 11)
(2) **Colouring matters for surface colouring only**		
E 170	Calcium carbonate	77220
E 173	Aluminium	77000 (Pigment metal 1)
E 174	Silver	
E 175	Gold	
(3) **Colouring matters for certain uses only**		
E 128	Red 2G (not for use in foodstuffs subject to high temperature during processing, nor in products of high acidity)	18050 (Food red 10)
E 154	Brown FK (for cured fish only)	
E 180	Lithol Rubine BK (for cheese rind only)	15851:1 (Pigment red 57:1)

(1) Colour index figures are taken from the 3rd edition 1982, volumes 1-7, 1315. Also amendments 37-40 (125), 41-44 (127-50), 45-48 (130), 49-52 (132-50), 53-56 (135).

(2) The term "caramel" relates to products of a more or less intense brown colour which are intended for colouring. It does not correspond to the sugary aromatic product obtained from heating sugar and which is used for flavouring food (e.g. confectionery, pastry).'

ANNEX III

'ANNEX 2

CRITERIA OF PURITY

A. GENERAL CRITERIA OF PURITY

1. *Colouring matters and substances for diluting or dissolving colouring matters*

They shall not contain a toxicologically dangerous amount of any element.

Arsenic (total):	not more than 3 mg/kg.
Lead (total):	not more than 10 mg/kg.
Mercury (total):	not more than 1 mg/kg.
Heavy metals (total):	not more than 40 mg/kg.

2. *Aluminium lakes of colouring matters*

Definition:

Aluminium lakes are prepared by reacting colouring matter complying with the purity criteria set out in the appropriate specification monograph with alumina under aqueous conditions. The alumina is usually freshly prepared undried material made by reacting aluminium sulphate or chloride with sodium carbonate or bicarbonate or ammonia. Following lake formation, the product is filtered, washed with water, and dried.

Water soluble chloride and sulphate (calculated as sodium salts):	not more than 2 %.
HCL insoluble matter:	not more than 0,5 %.
Ether extractable matter:	not more than 0,2 %.
Arsenic (total):	not more than 3 mg/kg.
Lead (total):	not more than 10 mg/kg.
Mercury (total):	not more than 1 mg/kg.
Heavy metals (total):	not more than 40 mg/kg.

B. SPECIFIC CRITERIA OF PURITY

E 100 Curcumin

Chemical description:

Curcumin consists essentially of the pure colouring principle (1,7-bis(4 hydrox-3-methoxyphenyl)hepta-1,6 diene-3,5-dione).

Curcumin is obtained by solvent extraction of turmeric, which consists of the ground rhizomes of *Curcuma longa L.* It may contain other compounds such as di-desmethoxy derivatives.

Solvents used are: methanol, hexane, and acetone.

Content:

The concentrated curcumin contains not less than 90 % of total curcumins by absorption at 425 nm in ethanol.

Colour intensity:

$E^{1\,\%}_{425\ nm}$ = 1 607 in ethanol, 1 cm-layer, for pure curcumin.

Solvent residues:

Methanol:
Hexane:
Acetone:
} not more than 50 mg/kg singly or in combination.

E 101 (i) Riboflavin

Riboflavin shall comply with the monograph for riboflavin contained in FAO Food and Nutrition Paper No 31/1, p. 123

The substance shall also comply with the following:

Primary aromatic amines:

Not more than 100 mg/kg calculated as aniline.

E 101 (ii) Riboflavin-5'-phosphate

Riboflavin-5'-phosphate shall comply with the monograph for riboflavin-5'-phosphate sodium contained in FAO Food and Nutrition Paper No 31/1, p.127, with the following execption:

Assay (content):

not less than 70 % and not more than 75 % of total (free and esterified) riboflavin calculated as riboflavin determined by fluorescence.

The substance shall also comply with the following:

Chemical description:

Riboflavin-5'-phosphate consists mainly of the monosodium salt of the 5'-monophosphate ester of riboflavin dihydrate.

Primary aromatic amines (calculated as aniline):

not more than 70 mg/kg.

ph of a 1 % weight/volume solution:

not less than 5,0 and not more than 6,5.

E 102 Tartrazine

Tartrazine shall comply with the monograph for Tartrazine contained in FAO Food and Nutrition Paper No 31/1, p. 133.

E 104 Quinoline yellow

Quinoline yellow shall comply with the monograph for Quinoline yellow contained in FAO Food and Nutrition Paper No 31/1, p. 117, with the following exceptions:

Limit figure for subsidiary colouring matters should read:

"not more than 1 %" 2-(2-quinolyl)indan-1,3 dione and 2-(2-(6-methylquinolyl))indan-1,3-dione: not more than 4 mg/kg.

E 110 Sunset yellow S

Sunset yellow S shall comply with the monograph for Sunset yellow FCF contained in FAO Food and Nutrition Paper No 31/1, p. 131.

E 120 Cochineal/Carminic acid/Carmines

Carmines of cochineal shall comply with the monograph for Carmines contained in FAO Food and Nutrition Paper No 25, p. 60; Cochineal and Carminic acid shall comply with the monograph for Cochineal and Carminic acid contained in FAO Food and Nutrition Paper No 31/1, p. 63.

E 122 Azorubine

Azorubine shall comply with the monograph for Azorubine contained in FAO Food and Nutrition Paper No 31/1, p. 21.

E 123 Amaranth

Amaranth shall comply with the monograph for Amaranth contained in FAO Food and Nutrition Paper No 31/1, p. 9.

E 124 Ponceau 4R

Ponceau 4R shall comply with the monograph for Ponceau 4R contained in FAO Food and Nutrition Paper No 31/1, p. 115, with the following exceptions:

Assay (content):
not less than 70 % total colouring matters.

Loss on drying at 135 °C:
not more than 30 %.

Chloride and sulphate (calculated as sodium salts):
not more than 30 %.

E 127 Erythrosine

Erythrosine shall comply with the monograph for Erythrosine contained in FAO Food and Nutrition Paper No 31/1, p. 71.

E 128 Red 2G

Red 2G shall comply with the monograph for Red 2G in FAO Food and Nutrition Paper No 31/1, p. 121.

E 129 Allura red AC

Allura red AC shall comply with the monograph for Allura red AC contained in FAO Food and Nutrition Paper No 31/1, p. 3.

E 131 Patent blue V

Patent blue V shall comply with the monograph for Patent blue V contained in FAO Food and Nutrition Paper No 31/1, p. 111.

E 132 Indigotine

Indigotine shall comply with the monograph for Indigotine contained in FAO Food and Nutrition Paper No 31/1, p. 95.

E 133 Brilliant blue FCF

Brilliant blue FCF shall comply with the monograph for Brilliant blue FCF in FAO Food and Nutrition Paper No 31/1, p. 31.

E 140 Chlorophylls and chlorophyllins

(i) Chlorophylls

(ii) Chlorophyllins

(i) Chlorophylls shall comply with the monograph for chlorophylls in FAO Food and Nutrition Paper No 31/1, p. 57, with the following exceptions:

Content (assay):
not less than 10 % of total phaeophytins and complexes of phaeophytins determined and calculated as phaeophytin a, which may be in solution in any type of edible vegetable oil.

$E\ \frac{1\ \%}{1\ cm}$ at 409 nm = not less than 70 (in $CHCl_3$).

Definition:

Chlorophylls are obtained by solvent extraction of chlorophyll from grass, nettles, lucerne or other edible plants, followed by removal of the solvent with or without subsequent removal of magnesium from the complexes. Only the following solvents may be used:

acetone, ethanol, light petroleum, methyl ethyl ketone and dichloromethane. Chlorophylls may also contain other pigments and other substances such as oils, fats and waxes derived from the source material.

Description:

Waxy solids, ranging from olive green to dark green.

The materials shall also comply with the following:

Solvent residues:

acetone ethanol light petroleum methanol methyl ethyl ketone dichloromethane propan-2-ol	Not more than 50 mg/kg singly or in combination.
Ionic copper (as Cu):	Not more than 50 mg/kg related to 10 % total phaeophytins.

(ii) Chlorophyllins

Chemical description:

Chlorophyllins are obtained by the saponification of chlorophyll obtained by solvent extraction from grass, lucerne, other edible plants, e.g. nettle, with or without the addition of copper.

The major colouring principles are normally disodium, dipotassium or sodium potassium 3-(10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl) propionate (chlorophyllin a) and disodium, dipotassium or sodium potassium 3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl) propionate (chlorophyllin b), present either as such or in the form of the magnesium or copper complexes, although monosodium and/or monopotassium salts may also be present, depending on the degree of hydrolysis, and in some products the isocyclic ring may be cleaved with the resultant production of tribasic sodium, potassium or sodium potassium salts. Chlorophyllins also contain other pigments, which in coppered products may be present as the copper derivatives, and other substances such as the sodium or potassium salts of fatty acids, derived directly or indirectly from the source material.

Solvents used are the following: acetone, chloroform, dichloromethane, ethanol, light petroleum, methyl ethyl ketone, methanol and propanol-2-ol.

E 141 Copper complexes of chlorophylls and chlorophyllins

(i) Copper chlorophylls, formed by the replacement of all or part of the magnesium of uncoppered chlorophylls by copper, shall comply with the purity criteria for chlorophylls, with the following exceptions:

Content (assay):

$E\ \frac{1\ \%}{1\ cm}$ at 422 nm = not less than 54 (in $CHCl_3$).

Free ionic copper (as Cu):

not more than 200 mg/kg.

Total copper:

not more than 8 000 mg/kg related to 10 % total phaetophytines.

(ii) Copper complexes of chlorophyllins

Chemical description:

Chlorophyllins are obtained by the saponification of chlorophyll exctracts obtained by solvent extraction from grass, nettle, lucerne, other edible plants with the addition of copper.

The major colouring principles are normally disodium, dipotassium or sodium potassium 3-(10-carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2-vinylphorbin-7-yl) propionate (chlorophyllin a) and diso-

dium, dipotassium or sodium potassium 3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinylphorbin-7-yl) propionate (chlorophyllin b), present in the form of copper complexes, although monosodium and/or monopotassium salts may also be present, depending on the degree of hydrolysis, and in some products the isocyclic ring may be cleaved with the resultant production of tribasic sodium, potassium or sodium potassium salts. Chlorophyllins also contain other pigments which may be present as the copper derivatives, and other substances such as the sodium or potassium salts of fatty acids, derived directly or indirectly from the source material.

Solvents used are the following: acetone, dichloromethane, ethanol, light petroleum, methyl ethyl ketone, methanol and propanol-2-ol.

Free ionic copper (as Cu):

not more than 200 mg/kg.

Total copper:

not more than 8 000 mg/kg.

E 142 Green S

Green S shall comply with the monograph for Green S contained in FAO Food and Nutrition Paper No 31/1, p. 91.

E 150 Caramel

Description:

Caramel colours are dark brown to black liquids or solids, having an odour of burnt sugar and a pleasant, somewhat bitter taste. They are prepared by the controlled heat treatment of carbohydrates (commercially available food-grade nutritive sweeteners which are the monomers, glucose and fructose, and/or polymers thereof (e.g. glucose syrups, sucrose, and/or invert syrups, and dextrose). To promote caramelization, food-grade acids, alkalis and salts may be employed.

The following sulphite compounds are also used in the preparation of caustic sulphite caramel (E 150 b) and sulphite ammonia caramel (E 150 d): sulphurous acid and potassium, sodium and ammonium sulphites and bisulphites.

The following ammonium compounds are also used in the preparation of ammonia caramel (E 150 c) and sulphite ammonia caramel (E 150 d): ammonium hydroxide, carbonate, bicarbonate phosphate and sulphate and, for E 150 d, ammonium sulphite and bisulphite.

Specific requirements for individual caramels

(i) **E 150 a**

Colour bound by DEAE cellulose:

not more than 50 %.

Colour bound by phosphoryl cellulose:

not more than 50 %.

Colour intensity (1):

0,01 to 0,14.

Total nitrogen:

not more than 0,1 % (*).

Total sulphur:

not more than 0,2 % (*).

(ii) **E 150 b**

Colour bound by DEAE cellulose:

more than 50 %.

Colour intensity:

0,05 to 0,13.

Total nitrogen:

not more than 0,3 % (*).

(1) Colour intensity is defined as the absorbance of a 0 to 1 % (w/v) solution of caramel colour solids in water in a 1 cm cell at 610 nm.

(*) Expressed on equivalent colour basis.

Sulphur dioxide:
not more than 0,2 % (*).

Total sulphur:
1,0 to 3,5 % (*).

Sulphur bound by DEAE cellulose (1):
more than 40 %.

Absorbance ratio of colour bound by DEAE cellulose (2):
19 to 34.

Absorbance ratio (A 280/560):
greater than 50.

(iii) **E 150 c**

Colour bound by DEAE cellulose:
more than 50 %.

Colour bound by phosphoryl cellulose:
more than 50 %.

Colour intensity:
0,08 to 0,36.

Ammoniacal nitrogen:
not more than 0,3 % (*).

4-methylimidazole:
not more than 250 mg/kg (*).

2-acetyl-4-tetrahydroxy-butylimidazole:
not more than 25 mg/kg (*).

Total sulphur:
not more than 0,2 % (*).

Total nitrogen:
0,7 to 3,3 % (*).

Absorbance ratio of colour bound by phosphoryl cellulose (3):
13 to 35.

(iv) **E 150 d**

Colour bound by DEAE cellulose:
more than 50 %.

Colour intensity:
0,10 to 0,60.

Ammoniacal nitrogen:
not more than 0,6 % (*).

Sulphur dioxide:
not more than 0,2 % (*).

(*) Expressed on equivalent colour basis.

(1) Sulphur bound by DEAE cellulose is defined as the percentage of decrease in total sulphur content after treatment with DEAE cellulose.

(2) Absorbance ratio of colour bound by DEAE cellulose is defined as the absorbance of the colour bound by DEAE cellulose at 280 nm divided by the absorbance at 560 nm (1 cm cell).

(3) Absorbance ratio of colour bound by phosphoryl cellulose is defined as the absorbance of the colour bound by phosphoryl cellulose at 280 nm divided by the absorbance at 560 nm 1 cm cell).

4-methylimidazole:
not more than 250 mg/kg (*).

Total nitrogen:
0,3 to 1,7 % (*).

Total sulphur:
0,8 to 2,5 % (*).

Nitrogen/sulphur ratio of alcohol precipitate:
0,7 to 2,7.

Absorbance ratio of alcohol precipitate (¹):
8 to 14.

Absorbance ratio (A 280/560):
not more than 50.

E 151 Brilliant black PN

Brilliant black PN shall comply with the monograph for Brilliant black PN contained in FAO Food and Nutrition Paper No 31/1, p. 27, with the following exceptions:

Assay (content):
not less than 70 % total colouring matters.

Loss on drying at 135 °C:
not more than 30 %.

Chloride and sulphate (calculated as sodium salts):
not more than 30 %.

E 153 Vegetable carbon

Vegetable carbon shall comply with the monograph for Carbon blacks contained in FAO Food and Nutrition Paper No 31/1, p. 43.

E 154 Brown FK

Chemical description:
Brown FK consists essentially of a mixture of:

(i) sodium 4-(2,4-diaminophenylazo)benzenesulphonate
(ii) sodium 4-(4,6-diamino-m-tolylazo)benzenesulphonate
(iii) disodium 4,4'-(4,6-diamino-1,3-phenylenebisazo)di(benzenesulphonate)
(iv) disodium 4,4'-(2,4-diamino-1,3-phenylenebisazo)di(benzenesulphonate)
(v) disodium 4,4'-(2,4-diamino-5-methyl-1,3-phenylenebisazo)di(benzenesulphonate)
(vi) trisodium 4,4',4''-(2,4-diaminobenzene-1,3,5-trisazo)tri(benzenesulphonate)

and subsidiary colouring matters, together with sodium chloride and/or sodium sulphate as the principal uncoloured components.

Assay (content):
not less than 70 % of a mixture of (i), (ii), (iii), (iv), (v) and (vi), and subsidiary colouring matters. Furthermore, the proportions of the various components of the colours shall not exceed:

(*) Expressed on equivalent colour basis.
(¹) Absorbance ratio of alcohol precipitate is defined as the absorbance of the precipitate at 280 nm divided by the absorbance at 560 nm (1 cm cell).

(i) 26 %
(ii) 17 %
(iii) 26 %
(iv) 16 %
(v) 20 %
(vi) 16 % } (TLC)

Subsidiary dyes:

not more than 3,5 % (TLC).

Organic compounds other than colouring matters:

Unsulphonated primary aromatic amines other than m-phenylene diamine and 4-methyl-m-phenylene diamine	not more than 0,0070 %.
Sulphanilic acid	not more than 0,7 % (HPLC).
m-phenylene diamine and 4-methyl-m-phenylene diamine	not more than 0,35 % (HPLC).

Water insoluble matter:

not more than 0,2 %.

Matter extractable by diethyl ether:

not more than 0,2 % from an aqueous solution.

Loss on drying at 135 °C:

not more than 30 %.

Chloride and sulphate (calculated as sodium salts):

not more than 30 %.

E 155 Brown HT

Brown HT shall comply with the monograph for Brown HT contained in FAO Food and Nutrition Paper No 31/1, p. 35.

E 160 a (i) Mixed carotenes

Definition:

Mixed carotenes are obtained by hexane extraction of edible vegetables with subsequent removal of the solvent. The main colouring principle is beta-carotene, but alpha- and gamma-carotene may be present.

Mixed carotenes also contain other pigments and other substances such as oils, fats and waxes derived from the source material. It is necessary to add an edible oil (e.g. peanut oil, corn oil, palm oil) immediately after the extraction to stabilize the product. Because the maximum solubility of carotenes in oil is about 1 %, concentrated carotenes are oil suspensions and not solutions. Carotenes are insoluble in water and soluble in hexane, oils and fats.

Content:

Oil suspensions: not less than 5 % expressed as beta-carotene.

Oil solutions: not less than 0,2 % expressed as beta-carotene.

Spectral characteristics:

Maximum absorption at 450 nm in hexane and at 455 nm in cyclohexane.

Solvent Residue:

Hexane
Light petroleum } not more than 25 mg/kg, singly or in combination.

E 160 a (ii) Beta-carotene

Beta-carotene shall comply with the monograph for Beta-carotene-synthetic contained in FAO Food and Nutrition Paper No 31/1, p. 47.

The substance shall also comply with the following:

Volatile matter:

not more than 0,1 % (60 °C; in vacuum).

Phosphorus (as P):

not more than 20 mg/kg.

E 160 (b) Annatto extracts

(i) Solvent extracted bixin and norbixin

Chemical description:

Bixin is prepared by the extraction of the outer coating of the seeds of the annatto tree *(Bixa orellana L.)* with one or more of the following organic solvents: acetone, hexane, or methanol followed by the removal of the solvent.

Norbixin is prepared by hydrolysis by aqueous alkali of the extracted bixin.

Norbixin and bixin may contain other materials extracted from the annatto seed.

Content:

Bixin/Norbixin powders contain not less than 95 % total carotenoids calculated as bixin/norbixin.

The bixin powder contains several coloured components, the major single one being bixin, which may be present in both cis- and trans-forms. Thermal degradation products of bixin may also be present.

The norbixin powder contains the hydrolysis product of bixin, in the form of the sodium or potassium salts as the major colouring principle. Both cis- and trans-forms may be present.

Colour intensity:

$E^{1\,\%}_{502\ nm}$ = 2 870 in chloroform, 1 cm-layer for pure bixin.

$E^{1\,\%}_{482\ nm}$ = 2 870 in 0,1 N sodium hydroxide, 1 cm-layer for pure norbixin.

Residual solvents:

not more than 50 mg/kg singly or in combination.

(ii) Alkali extracted annatto

Chemical description:

Water soluble annatto is prepared by extraction with aqueous alkali (sodium or potassium hydroxide) of the outer coating of the seeds of the annatto tree *(Bixa orellana L.).*

Content:

Water soluble annatto contains norbixin, the hydrolysis product of bixin, in the form of the sodium or potassium salts, as the major colouring principle. Both cis- and trans-forms may be present. Water soluble annatto contains not less than 0,1 % of total carotenoids expressed as norbixin.

Colour intensity:

$E^{1\,\%}_{482\ nm}$ = 2 870 in 0,1 N sodium hydroxide, 1 cm-layer for pure norbixin.

(iii) Oil extracted annatto

Chemical description:

Annatto extracts in oil, as solution or suspension, are prepared by extraction of the outer coating of the seeds of the annatto tree *(Bixa orellana L.)* with food-grade vegetable oil.

Content:

Annatto extract in oil contains several coloured components, the major single one being bixin, which may be present in both cis- and trans-forms. Thermal degradation products of bixin may also be present.

Annatto extract in oil contains not less than 0,1 % of total carotenoids expressed as bixin.

Colour intensity:

$E^{1\,\%}_{502\ nm}$ = 2 870 in chloroform, 1 cm-layer for pure bixin.

E 160 c Paprika extract

Paprika extract shall comply with the monograph for Paprika oleoresin contained in FAO Food and Nutrition Paper No 31/1, p. 105, with the following exceptions:

Definition (chemical description):

Paprika extract is obtained by solvent extraction of paprika, which consists of the ground fruits pods, with or without the seeds, of *Capsicum annuum L.,* and contains the major colouring principles of this spice. The major colouring principles of paprika extracts are capsanthin and capsorubin. A wide variety of other coloured compounds is known to be present. The main flavouring component is capsaicin.

Only the following solvents may be used in the extraction:

acetone,
dichloromethane,
ethanol,
light petroleum,
trichloroethylene.

Residual solvents:

Dichloromethane Trichloroethylene	not more than 30 mg/kg singly or in combination.
Other permitted extraction solvents (acetone, ethyl alcohol, light petroleum)	not more than 50 mg/kg singly or in combination.

The substance shall also comply with the following:

Assay (content):

Total carotenoids:

not less than 9,5 %.

Capsanthin and Capsorubin:

not less than 75 % of total carotenoids.

Capsaicin:

not more than 0,5 %.

Loss on drying at 135 °C:

not more than 0,02 %.

Unsaponifiable matter:

not more than 14 %.

Total fatty acids:

not less than 75 %.

E 160 e Beta-apo-8'-carotenal (C 30)

Beta-apo-8'-carotenal shall comply with the monograph for Beta-apo-8'-carotenal in FAO Food and Nutrition Paper No 31/1, p. 13.

The substance shall also comply with the following:

Volatile matter:

not more than 0,1 % (60 °C vacuum).

Phosphorus (as P):

not more than 20 mg/kg.

E 160 f Ethyl ester of Beta-apo-8'-carotenoic acid (C 30)

Ethyl ester of Beta-apo-8'-carotenoic acid (C 30) shall comply with the monograph for Beta-apo-8'-carotenoic acid ethyl ester in FAO Food and Nutrition Paper No 31/1, p. 17.

The substance shall also comply with the following:

Volatile matter:

not more than 0,1 % (60 °C vacuum).

Phosphorus (as P):

not more than 20 mg/kg.

E 161 Xanthophylls

Chemical description:

Xanthophylls are prepared by physical means and are defined as the 3-hydroxy- and 3,3'-dihydroxy-derivatives of alpha-, beta-, and gamma-carotenes, their naturally occurring mono- and di-epoxides, neoxanthin, neochrome and the fatty acid esters of these compounds present in natural food.

Xanthophylls are obtained by hexane extraction of the food and subsequent removal of the solvent. After removal of the solvent, the product may be mixed with edible vegetable oils. Xanthophylls may contain other substances, such as oils, fats and waxes derived from the source material.

Content:

not less than 1 % total colouring matters.

Residual solvents:

Hexane, Light petroleum } not more than 50 mg/kg, singly or in combination.

E 161 g Canthaxanthin

Canthaxanthin shall comply with the monograph for Canthaxanthin in FAO Food and Nutrition Paper No 31/1, p. 39.

The substance shall also comply with the following:

Volatile matter:

not more than 0,1 % (60 °C vacuum)

Phosphorus (as P):

not more than 20 mg/kg

E 162 Beetroot red

Beetroot red shall comply with the monograph for Beetroot red in FAO Food and Nutrition Paper No 31/1, p. 23, with the following exceptions:

Content (assay) (calculated as betanin):

not less than 1,2 % betanin (in liquid or powder forms).

Beetroot red shall also comply with the following:

Nitrate (as sodium nitrate):

not more than 25 mg/kg product (in liquid or solid forms).

E 163 Anthocyanins

Anthocyanins shall comply with the monograph for Grape skin extract in FAO Food and Nutrition Paper No 31/1, p. 87, with the following exceptions:

Definition:

Anthocyanins are obtained by extraction with water, methanol or ethanol from vegetables or edible fruits. Anthocyanins contain the common components of the source material, namely anthocyanine, tartaric acid, tannins, sugars, minerals, etc., but not necessarily in the same proportion as found in the source material. During the extraction process, food-grade acid or aqueous solution of sulphite may be added as pH regulating agent and stabilizer. During the process, most of the extracted sugars are fermented to alcohol. The extract may be concentrated by vacuum evaporation during which the alcohol is removed.

Sulphur dioxide:

not more than 1 000 mg/kg (liquid extracts; 10 baumé),

not more than 5 000 mg/kg (dried extracts).

The material shall also comply with the following:

Residual solvents (methanol, ethanol):

not more than 50 mg/kg singly or in combination.

E 170 Calcium carbonate

Description:

White crystalline or amorphous powder

Content:

not less than 97 % of $CaCO_3$ on a volatile matter free basis

Volatile matter:

not more than 1 % (determine by drying to constant weight at 105 °C)

Antimony (as Sb)
Copper (as Cu)
Chromium (as Cr)
Zinc (as Zn)
Barium (as Ba)
} not more than 100 mg/kg singly or in combination.

E 171 Titanium dioxide

Titanium dioxide shall comply with the monograph for Titanium dioxide in FAO Food and Nutrition Paper No 31/1, p. 135.

E 172 Iron oxides and hydroxides

Iron oxides and hydroxides shall comply with the monograph for Iron oxides in FAO Food and Nutrition Paper No 31/1, p. 99.

The materials shall also comply with the following:

Loss on ignition:

not more than 15 %.

E 173 Aluminium

Aluminium shall comply with the monograph for Aluminium powder in FAO Food and Nutrition Paper No 31/1, p. 7, with the following exception:

Lead:

not more than 10 mg/kg.

E 174 Silver

Content:

not less than 99,5 % calculated as Ag.

E 175 Gold

Content:

not less than 99,5 % calculated as Au.

E 180 Lithol rubine BK

Lithol rubine BK shall comply with the monograph for Lithol rubine BK in FAO Food and Nutrition Paper No 31/1, p. 101.'

III

(Notices)

COMMISSION

Amendment to notice of invitation to tender for the refund for the export of common wheat to the countries of zones I, II a, III, IV a and b, V, VI, VII and the German Democratic Republic

(85/C 278/05)

(Official Journal of the European Communities No C 130 of 29 May 1985)

Page 11, the text of paragraph 2 under heading I 'Subject', is amended as follows:

'2. The total quantity in respect of which there may be fixed a maximum export refund as provided in Article 5 (1) of Commission Regulation (EEC) No 279/75 (1), as amended by Regulation (EEC) No 2944/78 (2), is approximately 2 500 000 tonnes.'

COMMISSION OF THE EUROPEAN COMMUNITIES

THE RULES GOVERNING MEDICAMENTS IN THE EUROPEAN COMMUNITY

The conditions in which medicinal products for human and veterinary use can be manufactured and marketed within various Member States of the European Communities are regulated by Community rules which are contained in a number of Directives. These texts afford protection on the ground of public health and improve the free movement of medicines. As regards public health, this protection is designed to ensure that medicines are soundly based and of high quality of manufacture.

To facilitate free movement of medicines for human use a Committee for Proprietary Medicinal Products has been set up to ensure close cooperation between the competent authorities of the ten Member States so that decisions made upon applications for marketing authorization are as consistent as possible. A Committee for Veterinary Medicinal Products has also been set up with similar responsibilities in the veterinary sector. Another factor in facilitating free movement of medicines is the suppression of regular controls at the time of importation.

115 pages.

CB-41-84-515-EN-C ISBN 92-825-4531-8

Published in: English, French, German

Price (excluding VAT) in Luxembourg:

BFR 300 IRL 4.90 UKL 4.00 USD 5.50 DKR 55 HFL 17 DRA 595

OFFICE FOR OFFICIAL PUBLICATIONS OF THE EUROPEAN COMMUNITIES
L-2985 Luxembourg

85-18