

DIRECTIVES

COMMISSION DIRECTIVE 2010/67/EU

of 20 October 2010

amending Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁽¹⁾, and in particular Article 30(5) thereof,

After consulting the Scientific Committee on Food and the European Food Safety Authority,

Whereas:

(1) Commission Directive 2008/84/EC of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners⁽²⁾ sets out the purity criteria for the additives mentioned in European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners⁽³⁾.

(2) Under Article 30(4) of Regulation (EC) No 1333/2008 specifications of the food additives covered under paragraphs 1 to 3 of that Article, including additives authorised under Directive 95/2/EC, shall be adopted, in accordance with Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings⁽⁴⁾, at the moment when those food additives are entered in the respective Annexes in accordance with those paragraphs.

(3) Since the lists have not yet been drawn up, and in order to ensure that the modification of the Annexes to Directive 95/2/EC pursuant to Article 31 is effective, and to ensure that additives so authorised comply with safe conditions of use, Directive 2008/84/EC should therefore be amended.

(4) The entry related to carbon dioxide (E 290) should be revised with respect to the concentration level of 'oil content' to take into account Codex Alimentarius specifications drafted by the Joint Expert Committee on Food Additives (JECFA) and the documents of the International Organisation for Standardisation (ISO) (e.g. ISO 6141).

(5) The European Food Safety Authority (hereinafter the Authority) has assessed the information on the safety of extracts of rosemary when used as an antioxidant in foodstuffs. Extracts of rosemary are derived from *Rosmarinus officinalis* L. and contain several compounds which exert antioxidative functions (mainly phenolic acids, flavonoids, diterpenoids and triterpenes). It is considered appropriate to adopt specifications for extracts of rosemary which is authorised as a new food additive for use in foodstuffs under Directive 95/2/EC and assigned E 392 as its E number. Several types of production process are described, using solvent extraction (ethanolic, acetone and hexane) and supercritical carbon dioxide extraction.

(6) Soybean hemicellulose (E 426) was evaluated by the Scientific Committee on Food in 2003⁽⁵⁾ and is currently authorised within the EU under Directive 95/2/EC. A new variety of soybean hemicellulose is now produced and complies with all specifications set out in Directive 2008/84/EC for E 426 except that

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 253, 20.9.2008, p. 1.

⁽³⁾ OJ L 61, 18.3.1995, p. 1.

⁽⁴⁾ OJ L 354, 31.12.2008, p. 1.

⁽⁵⁾ Opinion of the Scientific Committee on Food on Soybean Hemicellulose expressed on 4 April 2003 (SCF/CS/ADD/EMU/185 Final).

ethanol is technologically needed as precipitant for purifying the extract solution of that new variety of soybean hemicellulose. In consequence, the final E 426, which feature differs from a spray dried white powder, may also contain some ethanol as a residue at the maximum concentration of 2 %. Ethanol is authorised by Directive 2009/32/EC of the European Parliament and of the Council ⁽¹⁾ as extraction solvent during the processing of raw materials, foodstuffs, food components, or food ingredients in compliance with good manufacturing practice.

- (7) The Authority assessed the information on the safety of cassia gum as a new food additive acting as gelling agent and thickener and expressed its opinion on 26 September 2006 ⁽²⁾. The Authority found the use of cassia gum as indicated under the conditions specified of no safety concern. It is therefore appropriate to adopt specifications for that new food additive which is assigned E number 427.
- (8) The entry relating to hydroxypropyl cellulose (E 463) should be modified in order to correct an error of the specifications in relation to the assay. Instead of 'Content not less than 80,5 % of hydroxypropoxyl groups', it should read 'Content not more than 80,5 % of hydroxypropoxyl groups'. It is therefore appropriate to update the current specifications.
- (9) The entry relating to hydrogen (E 949) should be corrected so that the concentration levels indicated in the assay and purity sections can be compatible. Consequently, the concentration of nitrogen should be corrected.
- (10) The Authority assessed the information on the safety of the new food additive, polyvinyl alcohol (PVA), as a film-coating agent for food supplements and expressed its opinion on 5 December 2005 ⁽³⁾. The Authority found the use of PVA of no safety concern in the coating of food supplements that are in the form of capsules and tablets. It is therefore appropriate to adopt specifications for polyvinyl alcohol which is assigned E number 1203, and which is authorised as a food additive under Directive 95/2/EC.
- (11) The Authority assessed the information on the safety of six grades of polyethylene glycols (PEG 400, PEG 3000, PEG 3350, PEG 4000, PEG 6000, PEG 8000) as film

coating agents for use in food supplement products and expressed its opinion on 28 November 2006 ⁽⁴⁾. The Authority found the use of those grades of polyethylene glycol as glazing agent in film-coating formulations of no safety concern for food supplement tablets and capsules under the intended conditions of use. All those grades of polyethylene glycols have been assigned a new E number, namely E 1521. It is therefore appropriate to adopt specifications for those six grades of polyethylene glycols and to group them together under a single entry. Consequently, it is necessary to update the current specifications already laid down in Directive 2008/84/EC for polyethylene glycol 6000.

- (12) EFSA assessed the safety of use of an enzyme preparation based on thrombin with fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food and concluded in its opinion on 26 April 2005 that this use of the enzyme preparation when produced as outlined in the opinion is of no safety concern ⁽⁵⁾. However, the European Parliament in its Resolution of 19 May 2010 on the draft Commission Directive amending the Annexes to the European Parliament and Council Directive 95/2/EC on food additives other than colours and sweeteners, considered that the inclusion in Annex IV to Directive 95/2/EC of this enzyme preparation as a food additive for reconstituting food was not compatible with the aim and content of Regulation (EC) No 1333/2008, as it does not meet the general criteria of Article 6 of Regulation (EC) No 1333/2008, especially in paragraph 1(c) of Article 6.
- (13) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius drafted by the JECFA. In particular where appropriate, the specific purity criteria need to be adapted to reflect the limits for individual heavy metals of interest.
- (14) Directive 2008/84/EC should therefore be amended accordingly.
- (15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health, and neither the European Parliament nor the Council has opposed them,

⁽¹⁾ OJ L 141, 6.6.2009, p. 3.

⁽²⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to an application on the use of cassia gum as a food additive, *The EFSA Journal* (2006) 389, 1-16.

⁽³⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyvinyl alcohol as a coating agent for food supplement, *The EFSA Journal* (2005) 294, p. 1.

⁽⁴⁾ Scientific opinion of the Panel on Food Additives, Flavourings, Processing Aids and Material in Contact with Food on a request from the Commission related to the use of polyethylene glycol (PEG) as a film coating agent for use in food supplement products, *The EFSA Journal* (2006) 414, p. 1.

⁽⁵⁾ Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to the use of an enzyme preparation based on thrombin:fibrinogen derived from cattle and/or pigs as a food additive for reconstituting food, *The EFSA Journal* (2005) 214, p. 1.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 2008/84/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 31 March 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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.

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 its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 20 October 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

Annex I to Directive 2008/84/EC is amended as follows:

1. in the section on E 290 Carbon dioxide the subentry on 'Oil content' is replaced by the following:

'Oil content	Not more than 5 mg/kg';
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2. after the section on additive E 385, the following section on E 392 Extracts of rosemary is inserted:

E 392 EXTRACTS OF ROSEMARY

GENERAL SPECIFICATION

Synonym	Extract of rosemary leaf (antioxidant)
Definition	Extracts of rosemary contain several components, which have been proven to exert antioxidative functions. These components belong mainly to the classes of phenolic acids, flavonoids, diterpenoids. Besides the antioxidant compounds, the extracts can also contain triterpenes and organic solvent extractable material specifically defined in the following specification
EINECS	283-291-9
Chemical name	Rosemary extract (<i>Rosmarinus officinalis</i>)
Description	Rosemary leaf extract antioxidant is prepared by extraction of the leaves of <i>Rosmarinus officinalis</i> using a food approved solvent system. Extracts may then be deodorised and decolourised. Extracts may be standardised
Identification	
Reference diterpenes	antioxidative compounds: phenolic Carnosic acid (C ₂₀ H ₂₈ O ₄) and Carnosol (C ₂₀ H ₂₆ O ₄) (which comprise not less than 90 % of the total phenolic diterpenes)
Reference key volatiles	Borneol, Bornyl Acetate, Camphor, 1,8-Cineol, Verbenone
Density	> 0,25 g/ml
Solubility	Insoluble in water
Purity	
Loss on Drying	< 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 2 mg/kg

1. Extracts of rosemary produced from dried rosemary leaves by acetone extraction

Description	Extracts of rosemary are produced from dried rosemary leaves by acetone extraction, filtration, purification and solvent evaporation, followed by drying and sieving to obtain a fine powder or a liquid
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Identification

Content of reference antioxidative compounds	≥ 10 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles — Ratio	(Total % w/w of carnosic acid and carnosol) ≥ 15 (% w/w of reference key volatiles)* (* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, “GC-MSD”)
Residual Solvents	Acetone: not more than 500 mg/kg

2. *Extracts of rosemary prepared by extraction of dried rosemary leaves by means of supercritical carbon dioxide*

Extracts of rosemary produced from dried rosemary leaves extracted by means of supercritical carbon dioxide with a small amount of ethanol as entrainer.

Identification

Content of reference antioxidative compounds	≥ 13 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles — Ratio	(Total % w/w of carnosic acid and carnosol) ≥ 15 (% w/w of reference key volatiles)* (* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, “GC-MSD”)
Residual Solvents	Ethanol: not more than 2 %

3. *Extracts of rosemary prepared from a deodorised ethanolic extract of rosemary*

Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary. The extracts may be further purified, for example by treatment with active carbon and/or molecular distillation. The extracts may be suspended in suitable and approved carriers or spray dried.

Identification

Content of reference antioxidative compounds	≥ 5 % w/w, expressed as the total of carnosic acid and carnosol
Antioxidant/Volatiles — Ratio	(Total % w/w of carnosic acid and carnosol) ≥ 15 (% w/w of reference key volatiles)* (* as a percentage of total volatiles in the extract, measured by Gas Chromatography — Mass Spectrometry Detection, “GC-MSD”)
Residual Solvents	Ethanol: not more than 500 mg/kg

4. *Extracts of rosemary decolourised and deodorised, obtained by a two-step extraction using hexane and ethanol*

Extracts of rosemary which are prepared from a deodorised ethanolic extract of rosemary, undergone a hexane extraction. The extract may be further purified, for example by treatment with active carbon and/or molecular distillation. They may be suspended in suitable and approved carriers or spray dried.

Identification

Content of reference antioxidative compounds	≥ 5 % w/w, expressed as the total of carnosic acid and carnosol
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Antioxidant/Volatiles — Ratio

(Total % w/w of carnosic acid and carnosol) \geq 15
 (% w/w of reference key volatiles)*
 (* as a percentage of total volatiles in the extract,
 measured by Gas Chromatography — Mass Spectrometry
 Detection, “GC-MSD”)

Residual solvents

Hexane: not more than 25 mg/kg
 Ethanol: not more than 500 mg/kg;

3. in the section on E 426 Soybean Hemicellulose:

(a) the entries on ‘Definition’ and ‘Description’ are replaced by the following:

Definition

Soybean Hemicellulose is a refined water-soluble polysaccharide obtained from natural strain soybean fibre by hot water extraction. No organic precipitant shall be used other than ethanol

Description

Free flowing white or yellowish white powder;

(b) in the entry on ‘Purity’, the following subentry is added:

‘Ethanol

Not more than 2 %;

4. after the section on additive E 426, the following section on E 427 Cassia gum is inserted:

E 427 CASSIA GUM**Synonyms****Definition**

Cassia gum is the ground purified endosperm of the seeds of *Cassia tora* and *Cassia obtusifoli* (*Leguminosae*) containing less than 0,05 % of *Cassia occidentalis*. It consists mainly of high molecular weight polysaccharides composed primarily of a linear chain of 1,4- β -D-mannopyranose units linked with 1,6- α -D-galactopyranose units. The ratio of mannose to galactose is about 5:1

In the manufacture the seeds are dehusked and degermed by thermal mechanical treatment followed by milling and screening of the endosperm. The ground endosperm is further purified by extraction with isopropanol

Assay

Not less than 75 % of Galactomannan

Description

Pale yellow to off-white, odourless powder

Identification

Solubility

Insoluble in ethanol. Disperses well in cold water forming a colloidal solution

Gel formation with borate

To an aqueous dispersion of the sample add sufficient sodium borate test solution (TS) to raise the pH to above 9; a gel is formed

Gel formation with xanthan gum	<p>Weigh 1,5 g of the sample and 1,5 g of xanthan gum and blend them. Add this blend (with rapid stirring) into 300 ml water at 80 °C in a 400 ml beaker. Stir until the mixture is dissolved and continue stirring for an extra 30 min after dissolution (maintain the temperature above 60 °C during the stirring process). Discontinue stirring and allow the mixture to cool at room temperature for at least 2 h</p> <p>A firm, viscoelastic gel forms after the temperature drops below 40 °C, but no such gel forms in a 1 % control solution of cassia gum or xanthan gum alone prepared in a similar manner</p>
Viscosity	Less than 500 mPa.s (25 °C, 2h, 1 % solution) corresponding to an average molecular weight of 200 000-300 000 D
Purity	
Acid insoluble matter	Not more than 2,0 %
pH	5,5-8 (1 % aqueous solution)
Crude fat	Not more than 1 %
Proteins	Not more than 7 %
Total ash	Not more than 1,2 %
Loss on drying	Not more than 12 % (5 h, 105 °C)
Total Anthraquinones	Not more than 0,5 mg/kg (detection limit)
Solvent residues	Not more than 750 mg/kg Isopropyl alcohol
Lead	Not more than 1 mg/kg
Microbiological criteria	
Total plate count	Not more than 5 000 colony forming units per gram
Yeast and mould	Not more than 100 colony forming units per gram
<i>Salmonella</i> spp.	Absent in 25 g
E. Coli	Absent in 1 g';

5. in the section on E 463 Hydroxypropyl cellulose, the subentry on 'Assay' is replaced by the following:

'Assay	Content not more than 80,5 % of hydroxypropoxyl groups (-OCH ₂ CHOHCH ₃) equivalent to not more than 4,6 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis';
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6. in the section on E 949 Hydrogen, in entry on 'Purity', the subentry on 'Nitrogen' is replaced by the following:

'Nitrogen	Not more than 0,07 % v/v';
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7. after the section on additive E 1201, the following section is inserted:

E 1203 POLYVINYL ALCOHOL

Synonyms	Vinyl alcohol polymer, PVOH
Definition	Polyvinyl alcohol is a synthetic resin prepared by the polymerisation of vinyl acetate, followed by partial hydrolysis of the ester in the presence of an alkaline catalyst. The physical characteristics of the product depend on the degree of polymerisation and the degree of hydrolysis
Chemical name	Ethenol homopolymer
Chemical formula	$(C_2H_3OR)_n$ where R = H or COCH ₃
Description	Odourless, tasteless, translucent, white or cream-coloured granular powder
Identification	
Solubility	Soluble in water; sparingly soluble in ethanol
Precipitation reaction	Dissolve 0,25 g of the sample in 5 ml of water with warming and let the solution cool to room temperature. The addition of 10 ml of ethanol to this solution leads to a white, turbid or flocculent precipitate
Colour reaction	Dissolve 0,01 g of the sample in 100 ml of water with warming and let the solution cool to room temperature. A blue colour is produced when adding (to 5 ml solution) one drop of iodine test solution (TS) and a few drops of boric acid solution Dissolve 0,5 g of the sample in 10 ml of water with warming and let the solution cool to room temperature. A dark red to blue colour is produced after adding one drop of iodine TS to 5 ml of solution
Viscosity	4,8 to 5,8 mPa.s (4 % solution at 20 °C) corresponding to an average molecular weight of 26 000-30 000 D
Purity	
Water insoluble matter	Not more than 0,1 %
Ester value	Between 125 and 153 mg KOH/g
Degree of hydrolysis	86,5 to 89,0 %
Acid value	Not more than 3,0
Solvent residues	Not more than 1,0 % Methanol, 1,0 % Methyl acetate
pH	5,0 to 6,5 (4 % solution)
Loss on drying	Not more than 5,0 % (105 °C, 3 H)
Residue in ignition	Not more than 1,0 %
Lead	Not more than 2,0 mg/kg;

8. the section on 'Polyethylene glycol 6000' is replaced by the following:

E 1521 POLYETHYLENE GLYCOLS

Synonyms	PEG, Macrogol, Polyethylene oxide
Definition	Addition polymers of ethylene oxide and water usually designated by a number roughly corresponding to the molecular weight
Chemical name	alpha-Hydro-omega-hydroxypoly (oxy-1,2-ethanediol)
Chemical formula	$\text{HOCH}_2 - (\text{CH}_2 - \text{O} - \text{CH}_2)_n - \text{CH}_2\text{OH}$
Average molecular weight	380 to 9 000 D
Assay	PEG 400: Not less than 95 % and not more than 105 % PEG 3000: Not less than 90 % and not more than 110 % PEG 3350: Not less than 90 % and not more than 110 % PEG 4000: Not less than 90 % and not more than 110 % PEG 6000: Not less than 90 % and not more than 110 % PEG 8000: Not less than 87,5 % and not more than 112,5 %
Description	PEG 400 is a clear, viscous, colourless or almost colourless hygroscopic liquid PEG 3000, PEG 3350, PEG 4000, PEG 6000 and PEG 8000 are white or almost white solids with a waxy or paraffin-like appearance
Identification	
Melting point	PEG 400: 4-8 °C PEG 3000: 50-56 °C PEG 3350: 53-57 °C PEG 4000: 53-59 °C PEG 6000: 55-61 °C PEG 8000: 55-62 °C
Viscosity	PEG 400: 105 to 130 mPa.s at 20 °C PEG 3000: 75 to 100 mPa.s at 20 °C PEG 3350: 83 to 120 mPa.s at 20 °C PEG 4000: 110 to 170 mPa.s at 20 °C PEG 6000: 200 to 270 mPa.s at 20 °C PEG 8000: 260 to 510 mPa.s at 20 °C For polyethylene glycols having a average molecular weight greater than 400, the viscosity is determined on a 50 per cent m/m solution of the candidate substance in water

Solubility	<p>PEG 400 is miscible with water, very soluble in acetone, in alcohol and in methylene chloride, practically insoluble in fatty oils and in mineral oils</p> <p>PEG 3000 and PEG 3350: very soluble in water and in methylene chloride, very slightly soluble in alcohol, practically insoluble in fatty oils and in mineral oils</p> <p>PEG 4000, PEG 6000 and PEG 8000: very soluble in water and in methylene chloride, practically insoluble in alcohol and in fatty oils and in mineral oils</p>
Purity	
Acidity or alkalinity	<p>Dissolve 5,0 g in 50 ml of carbon dioxide-free water and add 0,15 ml of bromothymol blue solution. The solution is yellow or green. Not more than 0,1 ml of 0,1 M sodium hydroxide is required to change the colour of the indicator to blue</p>
Hydroxyl value	<p>PEG 400: 264-300</p> <p>PEG 3000: 34-42</p> <p>PEG 3350: 30-38</p> <p>PEG 4000: 25-32</p> <p>PEG 6000: 16-22</p> <p>PEG 8000: 12-16</p>
Sulphated ash	<p>Not more than 0,2 %</p>
1,4-Dioxane	<p>Not more than 10 mg/kg</p>
Ethylene oxide	<p>Not more than 0,2 mg/kg</p>
Ethylene glycol and diethylene glycol	<p>Total not more than 0,25 % w/w individually or in combination</p>
Lead	<p>Not more than 1 mg/kg'.</p>
