



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 2 September 2013

13128/13

DENLEG 98

COVER NOTE

from: European Commission

date of receipt: 22 August 2013

to: Secretariat General of the Council

No Cion doc.: D027808/03

Subject: COMMISSION REGULATION (EU) No .../..of XXX amending and correcting Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards certain food additives

Delegations will find attached Commission document D027808/03.

Encl.: D027808/03



Brussels, **XXX**
SANCO/10784/2013 Rev. 2
(POOL/E3/2013/10784/10784R2-
EN.doc) D027808/03
[...](2013) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending and correcting Annexes II and III to Regulation (EC) No 1333/2008 of the
European Parliament and of the Council and the Annex to Commission Regulation (EU)
No 231/2012 as regards certain food additives**

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of XXX

amending and correcting Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards certain food additives

(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 additives¹, and in particular Articles 10(3), 14 and 30(5) thereof,

Having regard to 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 flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food additives, food enzymes, flavourings, nutrients and their conditions of use.
- (3) Commission Regulation (EU) No 231/2012 of 9 March 2012 lays down specifications for food additives³ listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (4) Those lists may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (5) When updating the specifications it is necessary to take into account the specifications and analytical techniques for food additives as set out in the Joint FAO/WHO Expert Committee on Food Additives' specifications adopted by the Codex Alimentarius Commission and also the International Numbering System for Food Additives, i.e., INS name⁴.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ OJ L 83, 22.03.2012, p. 1.

⁴ International Numbering System for Food Additives (INS).

- (6) The currently authorised food colour 'Brilliant Black BN, Black PN' (E 151) should be renamed as 'Brilliant Black PN' in the Union list of food additives approved for use in foods and their conditions of use and in the specifications for this additive for the purpose of clarity and in order to align it with its registered name in the INS.
- (7) At present, the definition of the food additive Algal Carotenes (E 160a (iv)) in the specifications reads 'Mixed carotenes may also be produced from strains of the algae *Dunaliella salina*, grown in large saline lakes located in Whyalla, South Australia. (...)' referring to a specific location where the algae are grown, namely, Whyalla. However, in the last years, global demand on algal carotenes has increased and further saline lakes have been established in Australia and in other countries. There is no mention or any restriction about the location(s) where *Dunaliella salina* is grown in the current Joint FAO/WHO Expert Committee on Food Additives' specifications for algal carotenes⁵ and the European Food Safety Authority's opinion on the re-evaluation of mixed carotenes (E 160a (i)) and beta-carotene (E 160a (ii)) as a food additive⁶. Therefore, in order to avoid market disruption, the description of Algal Carotenes (E 160a (iv)) in the specifications should be amended.
- (8) Regulation (EU) No 231/2012 contains errors in the specifications for Calcium Bisulphite (E 227) and Potassium Bisulphite (E 228). Those errors should be corrected.
- (9) Regulation (EU) No 231/2012 lays down specifications also for Microcrystalline Cellulose (E 460(i)) which indicate that the synonym for this food additive is Cellulose gel. Since the Codex Alimentarius adopted a dual name for Microcrystalline Cellulose (E 460(i)), its designated INS name is 'Microcrystalline cellulose (Cellulose gel)'. Taking into account previous practice⁷ and in order to ensure consistency, and to avoid any disruption in trade, the dual name of Microcrystalline Cellulose, Cellulose Gel should be adopted for the food additive (E 460(i)). Accordingly, the name 'Cellulose gel' should be removed from the entry 'Synonyms' in the specifications for that food additive and its name should be amended accordingly in Annex II to Regulation (EC) No 1333/2008.
- (10) The food additive 'Carboxy methyl cellulose, Sodium carboxy methyl cellulose, cellulose gum' (E 466) should be renamed as 'Sodium carboxy methyl cellulose, Cellulose gum' in the Union list of food additives set out in Annexes II and III to Regulation (EC) No 1333/2008 and in the specifications for this additive for the purpose of clarity and in order to align it with its registered name in the INS.
- (11) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annexes II and III to Regulation (EC)

⁵ Monograph 4 (2007) on CAROTENES (Algae) available at <http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-114.pdf>

⁶ EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of Mixed Carotenes (E 160a (i)) and beta-Carotene (E 160a (ii)) as a food additive. EFSA Journal 2012; 10(3):2593.

⁷ The proposed amendment is in line with other similar cases, such as Sodium carboxymethyl cellulose (E 466), Cross-linked sodium carboxymethyl cellulose (E 468) and Enzymatically hydrolysed carboxymethyl cellulose (E 469), to which dual names have been attributed.

No 1333/2008, except if the updates in question are not liable to have an effect on human health. Since the updates in the Union lists referred to above are not liable to have an effect on human health, it is not necessary to seek the opinion of the Authority.

- (12) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended and corrected accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 1333/2008 are amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

The food additives 'Brilliant Black BN, Black PN' (E 151) or 'Carboxy methyl cellulose, Sodium carboxy methyl cellulose, Cellulose gum' (E 466) and foods containing those food additives, labelled or placed on the market up to twenty four months after the entry into force of this Regulation and which do not comply with the requirements of this Regulation, may be marketed until the stocks are exhausted.

Article 4

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
José Manuel BARROSO

ANNEX I

A. Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part A, table 3, the entry for food additive E 151 is replaced by the following:

'E 151	Brilliant Black PN'
--------	---------------------

(2) In Part B:

(a) in point 1 'Colours', the entry for food additive E 151 is replaced by the following:

'E 151	Brilliant Black PN'
--------	---------------------

(b) in point 3 'Additives other than colours and sweeteners', the entry for food additive E 466 is replaced by the following:

'E 466	Sodium carboxy methyl cellulose, Cellulose gum'
--------	---

(3) In Part C:

(a) in Group III: Food colours with combined maximum limit, the entry for food additive E 151 is replaced by the following:

'E 151	Brilliant Black PN'
--------	---------------------

(b) in Group I, the entry for food additive E 466 is replaced by the following:

'E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i> '
--------	--	------------------------

(4) In Part E:

(a) in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', the entry for food additive E 151 is replaced by the following:

'	E 151	Brilliant Black PN	100	(35)	only fish paste and crustacean paste'
---	-------	--------------------	-----	------	---------------------------------------

(b) in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', the entry for food additive E 151 is replaced by the following:

'	E 151	Brilliant Black PN	250	(36)	only precooked crustacean '
---	-------	--------------------	-----	------	-----------------------------

(c) in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', the entry for food additive E 151 is replaced by the following:

'	E 151	Brilliant Black PN	100	(37)	only smoked fish'
---	-------	--------------------	-----	------	-------------------

(d) in food category 11.4.1 'Table-top sweeteners in liquid form', the entry for food additive E 460 (i) is replaced by the following:

'	E 460 (i)	Microcrystalline Cellulose, Cellulose gel	<i>quantum satis</i>		'
---	-----------	---	----------------------	--	---

(e) in food category 11.4.3 'Table-top sweeteners in tablets', the entry for food additive E 460 (i) is replaced by the following:

'	E 460 (i)	Microcrystalline Cellulose, Cellulose gel	<i>quantum satis</i>		'
---	-----------	---	----------------------	--	---

(f) in food category 01.6.1 ‘Unflavoured pasteurised cream (excluding reduced fat creams)’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>		'
---	-------	---	--------------------------	--	---

(g) in food category 01.6.2 ‘Unflavoured live fermented cream products and substitute products with a fat content of less than 20 %’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>		'
---	-------	---	--------------------------	--	---

(h) in food category 11.4.1 ‘Table-top sweeteners in liquid form’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>		'
---	-------	---	--------------------------	--	---

(i) in food category 11.4.2 ‘Table-top sweeteners in powder form’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>		'
---	-------	---	--------------------------	--	---

(j) in food category 11.4.3 ‘Table-top sweeteners in tablets’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>		'
---	-------	---	--------------------------	--	---

(k) in food category 13.1.5.1 ‘Dietary foods for infants for special medical purposes and special formulae for infants’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	10 000		From birth onwards in products for the dietary management of metabolic disorders'
---	-------	---	--------	--	---

(l) in food category 13.1.5.2 ‘Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	10 000		From birth onwards in products for the dietary management of metabolic disorders'
---	-------	---	--------	--	---

(m) in food category 14.1.3 ‘Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products’, the entry for food additive E 466 is replaced by the following:

'	E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>		only traditional Swedish and Finnish fruit syrups from citrus'
---	-------	---	----------------------	--	--

B. Annex III to Regulation (EC) No 1333/2008 is amended as follows:

(1) In Part 1, the entry for food additive E 466 is replaced by the following:

'E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>	All food additives'
--------	--	----------------------	---------------------

(2) In Part 3, the entry for food additive E 466 is replaced by the following:

'E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>	<i>quantum satis</i>	<i>quantum satis</i>	Yes'
--------	---	----------------------	----------------------	----------------------	------

(3) In Part 5, Section A, the entry for food additive E 466 is replaced by the following:

'E 466	Sodium carboxy methyl cellulose, Cellulose gum	<i>quantum satis</i>	All nutrients	Yes'
--------	---	----------------------	---------------	------

(4) In Part 5, Section B, the entry for food additive E 466 is replaced by the following:

'E 466	Sodium carboxy methyl cellulose, Cellulose gum	For uses in nutrient preparations under the condition that the maximum level in foods mentioned in point 13.1 of Part E of Annex II is not exceeded	All nutrients	Dietary foods for infants and young children for special medical purposes as defined in Directive 1999/21/EC'
--------	---	---	---------------	---

(5) In Part 6, table 1, the entry for food additive E 466 is replaced by the following:

'E 466	Sodium carboxy methyl cellulose, Cellulose gum'
--------	---

ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) In the entry for E 160a (iv) Algal Carotenes, the specification as regards definition is replaced by the following:

'Definition	Mixed carotenes may also be produced from strains of the algae <i>Dunaliella salina</i> . 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.'
--------------------	---

(2) The entry for E 151 Brilliant Black BN, Black PN, is amended as follows:

(a) the heading is replaced by the following:

'E 151 BRILLIANT BLACK PN'

(b) the specification as regards definition is replaced by the following:

'Definition	Brilliant Black PN consists essentially of tetrasodium-4-acetamido-5- hydroxy-6-[7-sulfonato-4-(4-sulfonatophenylazo)-1-naphthylazo] naphthalene-1,7-disulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. Brilliant Black PN is described as the sodium salt.
--------------------	---

	The calcium and the potassium salt are also permitted.'
--	---

(3) In the entry for E 227 Calcium Bisulphite, the heading is replaced by the following:

'E 227 CALCIUM HYDROGEN SULPHITE'
--

(4) In the entry for E 228 Potassium Bisulphite, the heading is replaced by the following:

'E 228 POTASSIUM HYDROGEN SULPHITE'
--

(5) The entry for E 460(i) Microcrystalline Cellulose is amended as follows:

(a) the heading is replaced by the following:

'E 460 (i) MICROCRYSTALLINE CELLULOSE, CELLULOSE GEL'
--

(b) the specification as regards synonyms is replaced by the following:

'Synonyms'	
-------------------	--

(6) The entry for E 466 Sodium Carboxy Methyl Cellulose, Carboxy Methyl Cellulose, Cellulose Gum is amended as follows:

(a) the heading is replaced by the following:

'E 466 SODIUM CARBOXY METHYL CELLULOSE, CELLULOSE GUM'

(b) the specification as regards synonyms is replaced by the following:

'Synonyms	NaCMC; Sodium CMC'
------------------	--------------------

(c) the specification as regards definition is replaced by the following:

'Definition	Sodium carboxy methyl cellulose is the partial sodium salt of a carboxymethyl ether of cellulose, the cellulose being obtained directly from strains of fibrous plant material'
--------------------	---