USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 5/15/2015
GAIN Report Number: IN5063

India

Post: New Delhi

FSSAI Updates Standards for Carboxymethyl Cellulose

Report Categories:
Sanitary/Phytosanitary/Food Safety
FAIRS Subject Report
Exporter Guide

Approved By:
Jonn Slette
Prepared By:
Radha Mani

Report Highlights:

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) amended the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 and Food Safety and Standards (Packaging and Labeling) Regulations, 2011, pertaining to standards and labeling requirements for carboxymethyl cellulose.

Executive Summary:

FSSAI published Food Safety and Standards (Food Product Standards and Food Additives) and Amendment Regulations, 2014, and updated its standards for carboxymethyl cellulose, and natural food coloring products. FSSAI also updated its (Packaging and Labeling) Amendment Regulations, 2014, for carboxymethyl cellulose. The GOI notified these changes to the World Trade Organization (WTO), and on April 23, 2015, and the draft regulations were published on WTO website. FSSAI is currently accepting public comments for both the amendments and will continue to accept comments through June 22, 2015.

Post notes the following discrepancies in the FSSAI notification:

i. The amendment, though published in 2015, is titled as "Amendment Regulations, 2014"
ii. Clause (49), which was added to Sub-regulation 2.4.5. in this notification, should actually be Clause (50) as (49) was already added in an earlier FSSAI notification wherein requirements and restrictions for nutritional ingredient labels for trehalose, plant stanol ester, and oligofructose in specified food products were updated (GAIN Report IN5047).

General Information:

DISCLAIMER: The information contained in this report was retrieved from the Government of India (GOI) and WTO websites: http://www.fssai.gov.in/ and www.wto.org. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

Amendments as listed in the FSSAI notification are given below:

1. In Chapter 2, a new clause (49) has been added to Sub-regulation 2.4.5 relating to 'Specific requirements/restrictions on manner of labeling' and it states:

   "49. Every package of ready to serve beverages using carboxymethyl cellulose shall bear the quantity of carboxymethyl cellulose used and fruit content therein"

2. In Chapter 3, various sub-clauses with a proviso have been added to Clause 2 of Regulation 3.1.2 relating to 'Coloring Matter' and they are as follows:

   (h) Anthocyanins
   (i) Copper Cholorophyllin
   (j) Natural Carotenes
   (k) Paprika
   (l) Carthamus
   (m) Lutein
   Provided that no natural color shall be allowed in infant foods.

3. In Sub-regulation 3.2.1, various clauses have been added after Clause 15 relating to 'Standards of food additives 'and they are pasted below.

"(16) **Anthocyanins:**

(i) **Grape Skin Extract.**-Purplish-red liquid, lump, powder or paste, having a slight characteristic odour and isobtained by aqueous extraction of grape skin or marc after the juice has been expressed from it; contains the common components of grape juice, namely, anthocyanine, tartaric acid, tannins, sugar, minerals, etc., but not in same proportions as found in grape juice.

Synonyms	Enociania, Eno; INS No.163 (ii)
Chemical names	The principal colouring matters are anthocyanins, glucosides of anthocyanidins (2-phentlbenzopyrylium salts) such as peonidin, malvidin, delphinidin, and petunidin.
Empirical formula	Peonidin: $C_{16}H_{13}O_6X$
	Malvidin: $C_{17}H_{15}O_7X$
	Delphinidin: $C_{15}H_{11}O_7X$
	Petunidin: $C_{16}H_{13}O_7X$
	X: acid moiety
Solubility	Soluble in water
Spectrophotometery	AtpH3 the absorbance maximum is about 525 nm.

Colour reaction:	Add 0.1 g of the sample to 50 ml of water and shake thoroughly. Filter if necessary. The solution shows red to purplish-red colour and it turns to blue or dark green on the addition of sodium hydroxide TS.
Purity	Sulfurdioxide: Not more than 0.005% per 1 colour value.
	Basic colouring matters Add 1 g of the sample to 100 ml sodium hydroxide solution (1 in 100) and shake well. Take 30 ml of this solution and extract with 15 ml of ether. Extract this ether extract twice with each 5 ml of dilute acetic acid TS. The acetic acid extract is colourless.
	Other acidic colouring matters:
	Add 1 ml of ammonia TS and 10 ml of water to 1 g of the sample and following the directions Chromatography place 0.002 ml of the solution on the chromatographic sheet and dry it. Use a mixture of pyridine and ammonia TS (2:1 by volume) as developing solvent and stop the development when the solvent front reaches about 15 cm height from the point where the sample solution was placed. No spot is observed at the solvent front after drying under daylight. If any spot is observed, it should be decolourized when sprayed with a solution of stannous chloride in hydrochloric acid (2 in 5).
	Arsenic: Not more than 3mg/kg.
	Lead: Not more than 2 mg/kg.

(ii) **Blackcurrant extract.** - Blackcurrant extract is obtained from blackcurrant pomace by aqueous extraction. The main coloring principles are four anthocyanins (cyaniding 3-rutinoside, delphinidin 3-rutinoside, cyaniding 3-glucoside, delphinidine 3-glucoside).

Purplish-red liquid, paste or powder having a slight characterstic odour.

Chemical names	I. Cyaniding 3-rutinoside,
	II. Delphinidin 3-rutinoside,
	III. Cyaniding 3-glucoside,
	IV. Delphinidine 3-glucoside
Empirical formula	I. $[C_{27}H_{31}O_{15}]^+ X^-$
	II. $[C_{27}H_{31}O_{16}]^+ X^-$
	III. $[C_{21}H2_1O_{11}]^+ X^-$
	IV. $[C_{21}H_{31}O_{12}]^+ X^-$
	X: counter ion
Solubility	Soluble in water and ethanol.
Spectrophotometery	AtpH3 the absorbance maximum is about 520 nm.
Colour reaction	Add 0.1 g of the sample to 50 ml of water and shake thoroughly. Filter if necessary. The solution shows red to purplish-red colour and it turns to blue or dark green on the addition of sodium hydroxide TS.
Purity	Sulfurdioxide: Not more than 50 mg/kg for each unit of color intensity.
	Basic colouring matter Add 1 g of the sample to 100 ml of 1% sodium hydroxide solution and shake well. Extract 30 ml of this solution with 15 ml ether. Extract the ether solution twice with 5 ml dilute acetic acid TS. The acetic acid extract is colourless.
	Other acidic colouring matters. Add 1 ml of ammonia TS and 10 ml of water to 1 g of the sample. Following the directions in Chromatography (FNP 5) place 2 µl of the solution on the chromatographic sheet and dry it. Use a mixture of pyridine and ammonia TS (2:1 by volume) as developing solvent and stop the development when the solvent front reaches about 15 cm height from the point where the sample solution was placed. No spot is observed in daylight at the solvent front after drying. If any spot is observed, it should be decolourized when sprayed with a solution of 40% stannous chloride in hydrochloric acid.
	Lead: Not more than 2 mg/kg

(iii) **Beet Red.**-Obtained from the roots of red beets (Beta vulgaris L var rubra) as press juice or by aqueous extraction of shredded beet roots; composed of different pigments all belonging to the class betalaine; main colouring principle

consists of betacyanins (red) of which betanine accounts for 75-95%; minor amounts of betaxanthine (yellow) and degradation products of betalaines (light brown) may be present; Red or dark red liquid, paste, powder or solid.

Synonyms:	Beetroot Red; INS No. 162.
Chemical names:	[S-(R*,R*)-4-[2-[2-Carboxy-5-(ß-D-glucopyranosyloxy)-2,3-dihydro-6-hydroxy-1H-indol-1-yl)ethenyl]-2,3-dihydro-2,6-pyridine-dicarboxylic acid; 1-[2-(2,6-dicarboxy-1,2,3,4-tetrahydro-4-pyridylidene ethylidene]-5-β-D-glucopyrano-syloxy)-6-hydroxyinodolium-2-carboxylate.
Empirical formula:	Betanine: $C_{24}H_{26}N_2O_{13}$
Solubility (Vol. 4):	Soluble in or miscible with water; insoluble in or immiscible with ethanol
Colour reaction:	Addition of an aqueous 10% w/v sodium hydroxide solution to an aqueous solution of the sample successively changes the colour from red to reddish violet to yellow.
Spectrophotometry	Betanine in water at pH 5.4 has an absorbance maximum at about 530 nm and at pH 8.9 exhibits a broadened maximum at about 545 nm.
Thin layer chromatography:	Passes test.
Purity:	Nitrate: Not more than 2 g nitrate anion/g of red colour (as calculated from assay)
	Arsenic (Vol. 4) Not more than 3 mg/kg (Method II)
	Lead: Not more than 2 mg/kg
	Basic colouring: To 1 g of the sample add 100 ml of 1% sodium hydroxide solution, and mix well. Extract 30 ml of this solution with 15 ml of diethyl ether. When extracted wash the ether layer twice with 5 ml of dilute acetic acid TS; the dilute acetic acid layer does not produce a colour.
	Other acidic colouring matters: To 1 g of the sample add 1 ml of ammonia TS and 8 ml of water, and shake well. Discard an oily layer when separated. Proceed as directed under Determination by Paper Chromatography (Ascending chromatography), using 2 µl of the solution as the sample solution, and a mixture of pyridine and ammonia TS (2:1 by volume) as the developing solvent. Stop the development when the solvent front has advanced about 15 cm from the point of application. No spot is observed at the solvent front after drying under daylight, or, if any spot is observed, it shall be decolourized when sprayed with a solution of stannous chloride (2 parts of stannous chloride by weight in 5 parts of water).

(17) **Copper Cholorophyllin (Chlorophyllins, copper complexes Sodium and Potassium salts).**-Dark green to blue/black powder or dark green solution.

Synonyms	Sodium copper chlorophyllin, potassium copper chlorophyllin, C.I. (1975) No. 75815, INS No. 141(ii)
Chemical names	The major colouring principles in their acid forms are 3-(10-Carboxylato-4-ethyl-1,3,5,8-tetramethyl-9-oxo-2 vinylphorbin-7-yl)propionate, copper complex (Copper chlorophyllin a) 3-(10-carboxylato-4-ethyl-3-formyl-1,5,8-trimethyl-9-oxo-2-vinyl-phorbin-7-yl)propionate copper complex (Copper chlorophyllin b) Depending on the degree of hydrolysis the cyclopentenyl ring may be cleaved with the resultant production of a third carboxyl function.
Empirical formula	Copper chlorophyllin a (acid form): $C_{34}H_{32}CuN_{405}$
	Copper chlorophyllin b (acid form): $C_{34}H_{30}CuN_{406}$
Formula Weight:	Copper chlorophyllin a: 640.20.
	Copper chlorophyllin b: 654.18.
Solubility	Soluble in water; very slightly soluble in lower alcohols and ketones and diethyl ether; insoluble in chloroalkanes, hydrocarbons and fixed oils
Test for copper:	Dissolve the sulfated ash of the sample (using 1 g of sample, Method I) in 10 ml of dilute hydrochloric acid TS by heating on a water bath. Filter if the solution is not clear, and dilute to 10 ml with water. Use this solution as the test preparation for the following tests.
	To 5 ml of the test preparation add ammonia TS to make the solution alkaline. Blue colour should appear.
	To 5 ml of the above test preparation add 0.5 ml of a 1 in 1000 sodium diethyldithiocarbamate solution. A brown precipitate should be formed.

Test for sodium:	Passes test
Test for potassium	Passes test
Spectrophotometery	A (1%, 1 cm) of the sample, dried at 100° for 1 h, at 405 nm in pH 7.5 phosphate buffer is not less than 540.
Purity	Basic dyes: The ether layer should be no darker than pale green. Residual solvents (Vol. 4): Acetone, methanol, ethanol, propan-2-ol, hexane: Not more than 50 mg/kg, singly or in combination Dichloromethane: Not more than 10 mg/kg Free ionizable copper: Not more than 200 mg/kg. Total copper: Not more than 8% of the total copper phaeophytins. Arsenic (Vol.4): Not more than 3 mg/kg. Lead (Vol. 4): Not more than 5 mg/kg.

(18) **Natural Carotenes (β- Carotene from Blakeslea Trispora).-**Obtained by a fermentation process using the two sexual mating types (+) and (-) of the fungus Blakeslea trispora. The colour is isolated from the biomass by solvent extraction and crystallised.Red to brownish-red crystals or crystalline powder.

Synonyms:	CI Food Orange 5; INS No. 160a(iii)
Chemical names:	β-carotene, β,β-carotene
Empirical formula:	$C_{40}H_{56}$
Formula Weight:	536.88.
Solubility:	Insoluble in water; practically insoluble in ethanol, slightly soluble in vegetable oil.
UV/VIS absorption:	Determine the absorbance of the diluted sample solution used in the Method of Assay at 455 nm and 483 nm. The ratio is between 1.14 and 1.19. Determine the absorbance of the diluted sample solution used in the Method of Assay at 455 nm and 340 nm. The ratio is not lower than 0.75.
Carotenoid:	The colour of a solution of the sample in acetone disappears after successive addition of a 5% solution of sodium nitrite and 0.5 M of sulfuric acid.
Purity:	Sulfated ash: Not more than 0.2% Carotenoids other than β-carotene: Not more than 3.0% of total colouring matters Residual Solvent: Ethanol: Not more than 0.8% singly or in combination. Ethyl acetate: Not more than 0.8% singly or in combination. Isopropanol: Not more than 0.1% Isobutyl acetate: Not more than 1.0% Lead: Not more than 2 mg/kg

(19) **Paprika.-**Paprika extract is obtained by solvent extraction of the dried ground fruit pods of Capsicum annuum. The major colouring compounds are capsanthin and capsorubin. Other coloured compounds, such as other carotenoids are also present. The balance of the extracted material is lipidic in nature and varies depending on the primary extraction solvent. Commercial preparations may be diluted and Standardized with respect to colour content using refined vegetable oil. Only methanol, ethanol, 2-propanol, acetone, hexane, ethyl acetate and supercritical carbon dioxide may be used as solvents in the extraction. Dark-red viscous liquid.

Synonyms:	INS No. 160c, Capsanthin, Capsorubin
Chemical names:	Capsanthin: (3R, 3'S, 5'R)-3,3'-dihydroxy-β,κ-carotene-6-one Capsorubin: (3S, 3'S, 5R, 5'R)-3,3'-dihydroxy-κ,κ-carotene-6,6'-dione
Empirical formula:	Capsanthin: $C_{40}H_{56}O_3$ Capsorubin: $C_{40}H_{56}O_4$
Formula weight:	Capsanthin: 584.85 Capsorubin: 600.85.
Solubility:	Practically insoluble in water, soluble in acetone
Spectrophotometry :	Maximum absorption in acetone at about 462 nm and in hexane at about 470 nm.
Colour reaction:	To one drop of sample add 2-3 drops of chloroform and one drop of sulfuric acid. A deep blue colour is produced.
High Performance Liquid Chromatography (HPLC):	Passes test.
Purity:	Residual solvents: Ethyl acetate, methanol, ethanol, acetone, 2-propanol, hexane: Not more than 50 mg/kg either singly or in combination Arsenic: Not more than 3 mg/kg. Lead: Not more than 2 mg/kg.

(20) **Carthamus (Carthamus Yellow).**-Carthamus Yellow, a flavonoid, is obtained by extracting the corolla (petals) of Carthamus tinctorius L. with water or slightly acidified water and drying the extract. The principal colouring matters are safflomin A (hydroxysafflor yellow A) and safflomine B (safflor yellow B). Besides the colour pigments carthamus yellow consists of sugars, salts and/or proteins naturally occurring in the source materials. Food grade materials such as dextrin may be added as carriers for manufacturing dry, powdered items of commerce.Yellow to dark brown crystals, paste, powder or liquid with a faint characteristic odour.

Synonyms:	Safflower yellow, CI Natural Yellow 5
Empirical formula:	I. $C_{27}H_{32}O_{16}$ (Safflomin A). II. $C_{48}H_{54}O_{27}$ (Safflomin B).
Formula weight:	I. 612.5 (Safflomin A). II. 1062 (Safflomin B).
Solubility:	Very soluble in water, practically insoluble in ether and ethanol
Spectrophotometry:	A solution of the sample in citric acid/disodium hydrogen phosphate buffer solution (pH 5.0) is yellow and shows an absorption maximum at 400-408 nm.
Colour reaction:	Make the solution of the sample in water alkaline by 10% sodium hydroxide solution; the colour changes from yellow to orange-yellow.
Purity:	Synthetic dyes Basic dyes: To 1 g of the sample add 100 ml of 1% sodium hydroxide solution, and mix well. Extract 30 ml of this solution with 15 ml of ether. Then extract the ether layer twice with dilute acetic acid (5 ml); the dilute acetic acid layer does not contain any colour.

Acidic dyes: To 1 g of the sample add 1 ml of ammonia TS and 8 ml of water, and shake well. Discard an oily layer when separated. Proceed as directed under Paper Chromatography (Ascending Chromatography) using 20 µl of the solution as the sample solution, and a mixture of pyridine and ammonia TS (2:1 by volume) as the developing solvent. Stop the development when the solvent front has advanced about 15 cm from the point of application. No spot is observed at the solvent front after drying under daylight. If any spot is observed, it should be decolourized when sprayed with a solution of stannous chloride in hydrochloric acid (2 in 5).

Lead: Not more than 5 mg/kg.

(21) **Lutein** (Lutein from *Tagetes Erecta*).-Lutein from Tagetes erecta L. is a purified extract of xanthophylls obtained from marigold oleoresin. The oleoresin is prepared from hexane extracts of marigold (Tagetes erecta L) flowers, saponified with potassium hydroxide in either methanol or propylene glycol. The resulting crystalline material contains lutein, and minor components including other carotenoids and waxes. A free-flowing, orange-red powder

Synonyms:	Vegetable lutein; vegetable luteol; Bo-Xan (lutein)
Chemical names:	3R,3'R,6'R-β,ε-carotene-3,3'-diol; all-trans-lutein; 4',5'-didehydro-5',6'-dihydro-beta,beta-carotene-3,3'-diol (lutein)
Empirical formula:	$C_{40}H_{56}O_2$ (lutein)
Formula weight:	568.88 (lutein)
Solubility:	Insoluble in water, soluble in hexane
Spectrophotometry:	A chloroform/ethanol (1:9) solution shows maximum absorbance at ca. 445 nm
Melting range:	177 to 178° C.
Test for carotenoids:	The colour of a solution of the sample in acetone disappears after successive addition of a 5% solution of sodium nitrite and 0.5 M of sulfuric acid.
Purity:	Moisture: Not more than 1.0%. Ash: Not more than 1.0%. Zeaxanthin: Not more than 9.0% Lead: Not more than 3 mg/kg. Hexane: Not more than 50 mg/kg. Methanol: Not more than 10 mg/kg. Propylene glycol: Not more than 1000 mg/kg. Waxes: Not more than 14.0%.

(c) In Appendix A, relating to list of food additives,-

(i) In Table 1, for serial number G in item (a), after sub-item (11) and the entries relating thereto, the following item and entries shall be inserted, namely:—

"1.	2.	3	4
12.	Anthocyanins.	-	GMP
13.	Copper Cholorophyllin	-	GMP
14.	Natural Carotenes	-	GMP
15.	Paprika.	-	GMP
16.	Carthamus.	-	GMP

17.	Lutein	-	GMP"

(ii) in Table 3,-

(a) in serial number16, in column number(5), the following entry shall be inserted, namely,—

"Carboxy methyl cellulose-GMP".

(b) in serial numbers 1,2,3,4,5,6,7,9,12,13,14,15,16,17,18,21,25,27,29,31 in column (3), the following entries shall be inserted, namely,—

"Natural Colours (Singly or in combination): Anthocyanins-GMP, Copper Cholorophyllin –GMP, Natural Carotenes-GMP, Paprika-GMP,Carthamus-GMP, Lutein-GMP".

(iii) in Table 5, in serial number E, after item 3, the following item number and entries shall be inserted, namely:—

"1	2	3	4	5
4. Anthocyanins.	GMP (Singly or in combination	GMP (Singly or in combination	GMP (Singly or in combination	GMP(Singly or in combination
5. Copper Cholorophyllin				
6. Natural Carotenes				
7. Paprika.				
8. Carthamus.				
9. Lutein				

(iv) in Table 6, in serial number E, after item 11, the following item and entries shall be inserted, namely:-

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
E (a)																	
12	Anthocyanins.																
13	Copper Cholorophyllin																
14	Natural Carotenes																
15	Paprika.																
16	Carthamus.																
17	Lutein																

GMP

GMP

1	2	19	20	21	22
E (a)					
12	Anthocyanins.				
13	Copper Cholorophyllin				
14	Natural Carotenes				
15	Paprika.				
16	Carthamus.				
17	Lutein				

GMP

(v) in Table 7, in serial number C, after item 11, the following serial numbers and entries shall be inserted, namely:—

"1	2	4	7	12	24
12	Anthocyanins.	GMP	GMP	GMP	GMP
13	Copper Cholorophyllin	GMP	GMP	GMP	GMP
14	Natural Carotenes	GMP	GMP	GMP	GMP
15	Paprika.	GMP	GMP	GMP	GMP
16	Carthamus.	GMP	GMP	GMP	GMP
17	Lutein	GMP	GMP	GMP	GMP"

(vi) in Table 8, in serial number D, after item 11, the following serial numbers and entries shall be inserted, namely—

"1	2	4	6	7	13
D (a)					
12	Anthocyanins.	GMP	GMP	GMP	GMP
13	Copper Cholorophyllin	GMP	GMP	GMP	GMP
14	Natural Carotenes	GMP	GMP	GMP	GMP
15	Paprika.	GMP	GMP	GMP	GMP
16	Carthamus.	GMP	GMP	GMP	GMP
17	Lutein	GMP	GMP	GMP	GMP"

(vii) in Table 9, in serial number D, after item 11, the following item and entries shall be inserted, namely:—

"1	2	3	5	6	9	10	14
D (a)							
12	Anthocyanins.	GMP	GMP	GMP	GMP	GMP	GMP
13	Copper Cholorophyllin	GMP	GMP	GMP	GMP	GMP	GMP
14	Natural Carotenes	GMP	GMP	GMP	GMP	GMP	GMP
15	Paprika.	GMP	GMP	GMP	GMP	GMP	GMP
16	Carthamus.	GMP	GMP	GMP	GMP	GMP	GMP
17	Lutein	GMP	GMP	GMP	GMP	GMP	GMP"

(viii) in Table 10, in serial number E, after item 11, following item and entries shall be inserted, namely:—

"1	2.	3.	4.	5.	7.	9.	10.	11.	12.	13.
E (a)										
12	Anthocyanins.	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP
13	Copper Cholorophyllin	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP
14	Natural Carotenes	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP
15	Paprika.	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP
16	Carthamus.	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP
17	Lutein	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP	GMP"

(i) F.No. 4/15015/30/2011, dated 7th June, 2013.
(ii) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
(iii) F.No. 5/15015/30/2012, dated 12th July, 2013.

Comments should be sent to:

Mr. P. Karthikeyan
Assistant Director
SPS Enquiry Point
Food Safety and Standards Authority of India (FSSAI)
FDA Bhawan, Kotla Road
New Delhi – 110 002
Email: baranip@yahoo.com

FSSAI's notification is available on FSSAI's website: http://www.fssai.gov.in/

Final details on the draft regulations:

Publication Date on the FSSAI website: April 7, 2015
Date of Implementation: To be determined
WTO Notification Number: G/SPS/N/IND/102
WTO Notification Date: April 23, 2015
Final Date for Comments: June 22, 2015
Products affected: Fruit and vegetable juice based drinks