

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Voluntary Public

Date: 4/14/2015

GAIN Report Number: IN5046

India

Post: New Delhi

FSSAI Publishes Amendments to Standards and Additives Regulations

Report Categories:

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

Dairy and Products

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](#), to include additional changes for standards of food additives for infant foods, cereals, dairy products, and some processed foods

Executive Summary:

FSSAI published the Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2015, and amended standards for (i) infant foods; (ii) cereal and cereal products; and (iii) processed foods. The amendments are based on feedback received following the public comment period from draft regulations published on May 16, 2013 ([IN3092](#)). (NOTE: although the amendments are listed as officially published on May 16, 2013, there were not actually posted on FSSAI's website until August 1, 2013.) To date, the most recent 2015 amended regulations have not been notified to the World Trade Organization (WTO).

General Information:

DISCLAIMER: The information contained in this report was retrieved from FSSAI's website <http://www.fssai.gov.in/>. The Office of Agricultural Affairs and/or the U.S. Government make no claim of accuracy or authenticity.

Background:

On August 1, 2013, FSSAI notified (see 'note' above in parenthesis) draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations, 2013. The amendments pertain to Chapters 2 and 3 of the [Food Safety and Standards \(Food Product Standards and Food Additives\) Regulations, 2011](#), and included updates to regulations 2.1.9, 2.4.1, 2.4.2, and 3.1.17, which regulate standards for infant foods, cereals and cereal products, and processed foods. A 60-day public comment period was established for these amendments, which expired on September 5, 2013. The most recent amendments take the public comment feedback into account.

Please refer to GAIN report [IN3092](#) for additional information. The full text of the amendments as given in the FSSAI's notification published on March 23, 2015 is attached below and is also available on FSSAI's website: <http://www.fssai.gov.in/>.

Details of Notification: F.No.1-83F/Sci.Pan-Noti/FSSAI-2012

- Publication Date: March 23, 2015
- Date of Implementation: Immediate
- WTO Notification Date: Not notified as of April 15, 2015

Products affected: All infant foods, cereal and cereal foods and processed foods

Agency in Charge: Food Safety and Standards Authority of India, Ministry of Health and Family Welfare, GOI.

NOTIFICATION

New Delhi, the 17th February, 2015

F. No. 1-83F/Sci. Pan- Noti/FSSAI-2012.—Whereas the draft of the Food Safety and Standards (Food Products Standards and Food Additives) (Amendment) Regulations, 2013, were published as required under sub-section (1) of Section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number No. 1-83/Sci. Pan-Noti/FSSAI-2012, dated the 16th May, 2013 in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 14th July, 2013;

And whereas the objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (e) of sub-section (2) of Section 92 read with Section 16 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, namely:-

Regulations

1. (1) These regulations may be called the Food Safety and Standards (Food Product Standards and Food Additives) (Amendment) Regulations, 2015.
- (2) They shall come into force on the date of their publication in the Official Gazette
2. In Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 (hereinafter referred to as the said regulations), -
 - A. in regulation 2.1.9 relating to "DAIRY PRODUCTS AND ANALOGUES", under regulation 2.1-
 - (i) after the heading "FOODS FOR INFANT NUTRITION", the sub-heading "Infant Milk Substitutes" shall be inserted;
 - (ii) in sub-regulation 2 relating to infant formula, after the second proviso, the following proviso shall be inserted, namely:

"Provided also that the lactose free or lactose and sucrose free or sucrose free infant milk substitutes shall conform to the following requirements, except the requirements of milk protein and milk fat, in the following manner, namely:—

 - (a) total protein, per cent. by weight shall not be less than 10.0 per cent and not more than 16 percent.;
 - (b) total fat, per cent by weight shall not be less than 18.0 per cent; and
 - (c) the lactose in the product claimed to be lactose free shall not exceed 0.05 per cent";
 - (iii) in clause 3 before the words "milk cereal based complementary food", the sub-heading "Infant Foods" shall be inserted;
 - (iv) in clause 4 relating to processed cereal based complementary food, at the end, the following proviso shall be inserted, namely:—

'Provided that the processed cereal based complementary foods for use in specific conditions, where protein needs to be restricted and where other cereals like wheat, soya, legumes and milk cannot be used, such processed cereal based complementary foods shall be prepared with single cereal like rice or ragi, which shall have the minimum protein content of 6-9 per cent, such products shall be conspicuously labeled, "Processed Mono Cereal Based Complementary Food for use in specific conditions under medical guidance only.';

856 GD/15-3

B. in regulation 2.4.1, for sub-regulation 2 relating to Fortified atta, the following shall be substituted, namely:
 "2. Fortified atta means the product obtained by adding one or more of the following nutrients to atta, namely:

S. No	Nutrient	Level of fortification per Kg of atta (Not more than)
1.	Calcium- Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;	1500mg
2.	Iron- (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate, electrolytic iron, ferrous fumarate; (b) Sodium Iron (III) Ethylene Diamine tetra Acetate, Trihydrate (Sodium Ferredetate- Na Fe EDTA)	60mg 25mg
3.	Zinc- Zinc Sulphate	30mg
4.	Vitamin A- Retinyl acetate, Retinylpalmitate, Retinylpropionate;	1500 µg RE
5.	Ascorbic Acid (Vitamin C) – Ascorbic acid, sodium ascorbate, calcium ascorbate, ascorbyl- 6-palmitate;	100 mg
6.	Thiamine (Vitamin B1) – Thiamine hydrochloride, Thiamine mononitrate;	3.5mg
7.	Riboflavin (Vitamin B2) – Riboflavin, Riboflavin 5'-Phosphate sodium;	4.0mg
8.	Niacin – Nicotinamide, nicotinic acid;	45mg
9.	Pyridoxine (Vitamin B6) – Pyridoxine hydrochloride;	5.0mg
10.	Folic acid- Folic acid;	250µg
11.	Vitamin B12- Cyanocobalamine, hydroxycobalamine;	2.5µg
12.	Vitamin D- Cholecalciferol, Ergocalciferol	1000 IU

Note: It shall be free from any extraneous matter including rodent hair and excreta.”;

C. in regulation 2.4.2, for sub-regulation 2 relating to Fortified maida, the following shall be substituted, namely:—
 "2. Fortified maida means the product obtained by adding one or more of the following nutrients to maida, namely:—

S. No	Nutrient	Level of fortification per Kg of Maida (Not more than)
1.	Calcium- Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic;	1500mg
2.	Iron- (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate, electrolytic iron, ferrous fumarate; (b) Sodium Iron (III) Ethylene Diamine tetra Acetate, Trihydrate (Sodium Ferredetate- Na Fe EDTA)	60mg 25mg
3.	Zinc- Zinc Sulphate	30mg
4.	Vitamin A- Retinyl acetate, Retinylpalmitate, Retinyl propionate;	1500 µg RE
5.	Ascorbic Acid (Vitamin C) – Ascorbic acid, sodium ascorbate, calcium ascorbate, ascorbyl- 6-palmitate;	100 mg
6.	Thiamine (Vitamin B1) – Thiamine hydrochloride, Thiamine mononitrate;	3.5mg
7.	Riboflavin (Vitamin B2) – Riboflavin, Riboflavin 5'- Phosphate sodium;	4.0mg
8.	Niacin – Nicotinamide, nicotinic acid;	45mg
9.	Pyridoxine (Vitamin B6) – Pyridoxine hydrochloride;	5.0mg
10.	Folic acid- Folic acid;	250µg

S. No	Nutrient	Level of fortification per Kg of Maida (Not more than)
11.	Vitamin B12- Cyanocobalamine, hydroxycobalamin;	2.5µg
12	Vitamin D- Cholecalciferol, Ergocalciferol	1000 IU

Note : It shall be free from any extraneous matter including rodent hair and excreta.”;

D. in regulation 3.1.17 after the table, the following shall be inserted, namely:—“Use of food ingredients in different foods-

The following food products may contain the food ingredients as specified below in addition to those permitted under these regulations:

- (i) **Oligofructose** may be added at not more than ten per cent of the product, in the following products, subject to label declaration under sub-regulation 43 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011:—

Dairy products like: yoghurt, mousse, spreads, dairy based drinks (milkshakes, yoghurt drink), cheese, pudding, cream and ice-cream; frozen desserts like non dairy ice, sorbet and fruit ice, frozen yoghurt, flakes and ready-to-eat dry breakfast cereals, chocolate and sweets; and carbohydrate based and milk product based sweets like halwa, mysore pak, boondi laddu, jalebi, khoyaburfi, peda, gulab jamun, rasogolla and similar milk product based sweets sold by any name; cooked sausages, ham and meat spreads;

- (ii) **Phyto or Plant stanol esters** may be added to the following products so as to allow users to easily restrict their consumption to maximum 3gm per day through the use of either one portion containing maximum 3 gm or three portions containing 1gm and it shall be added subject to the table declaration under sub-regulation 48 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011:—

(I) *Fat spread, milk products, milk based fruit drink, fermented milk products, soy and rice drink, cheese products, yoghurt products, spice sauces, salad dressings, juices and nectars.*

- (II) *Products containing Phyto or Plant Stanols be sold in single portions containing either maximum 3 g or 'maximum 1 g of phyto or/ plant Stanols, calculated as free phyto or plant Stanols, and if they do not contain so, there should be a clear indication of what constitutes a standard portion of the food, expressed in g or ml, and of the amount of phyto or plant Stanols, calculated as free phyto or plant Stanols, contained in such a portion;*

- (iii) **Trehalose** may be added as an ingredient in the following foods, subject to label declaration under sub-regulation 49 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011:—

(i)	Biscuits, bread, cakes, breakfast cereals	0.5-10.0 per cent
(ii)	Carbonated water, thermally processed fruits, fruit juices, fruit nectars, fruit beverages, fruit squashes, jam, jelly, fruit cheese, marmalade, dairy based drinks, milk powder	0.5-20.0 per cent
(iii)	carbohydrate- based and milk product based sweets like gulab jamun, rasogolla, peda, khoya burfi	0.5-20.0 per cent
(iv)	Macroni products, noodles, pasta	0.5-5.0 per cent
(v)	Sweets and confectionery, candies and icings	5.0-7.5 per cent
(vi)	Savouries and snacks	0.5-1.0 per cent

- (iv) **Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Ferredetate-Na Fe EDTA)** may be added as an ingredient in the following foods:-

Ready to serve beverages, carbonated fruit drinks and fruit nectars – Not More than 155ppm”

YUDHVIR SINGH MALIK, Chief Executive Officer
[ADVT.-III/4/Exty./187-O/14]

Foot Note: The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number No. 2-15015/30/2010 dated the 1st August, 2011 and subsequently amended vide notifications numbers.

- (i) F.No. P.15014/1/2011-PFA/FSSAI, dated 27th June, 2013.
(ii) F.No. 5/15015/30/2012, dated 12th July, 2013.
(iii) F.No. 4/15015/30/2011, dated the 7th June, 2013.
(iv) F.No. P.15025/262/13-PA/FSSAI dated the 5th December, 2014