

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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Voluntary \_ Public

**Date:** 8/8/2013

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## India

**Post:** New Delhi

### More Amendments in Food Products Standards and Additives Regulations

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

Food Processing Ingredients

Grain and Feed

Dairy and Products

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**Report Highlights:**

The Food Safety and Standards Authority of India (FSSAI) has amended the [FSS \(Food Products Standards and Food Additives\) Regulations, 2011](#) further to reflect changes in the standards for food additives relating to foods for infant nutrition, cereals and cereal products, dairy products and some processed foods. The amended regulation has not been notified to the World Trade Organization. The deadline for comments is September 5, 2013.

## **General Information:**

**DISCLAIMER:** The information contained in this report was retrieved from the Government of India website <http://www.fssai.gov.in/>. The U.S. Government makes no claim of accuracy or authenticity.

## **Introduction:**

On August 1, 2013, The Food Safety and Standards Authority of India (FSSAI) published Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2013. The amendments relate to Chapter 2 and 3 of the [FSS \(Food Products Standards and Food Additives\) Regulations, 2011](#) and include additions to regulations 2.1.9, 2.4.1, 2.4.2, and 3.1.17 relating to standards for (i) infant nutrition foods; (ii) cereal and cereal products; and (iii) food additives. The [Food Safety and Standards \(Food Products Standards and Food Additives\) Amendment Regulations, 2013](#), have not been notified to the World Trade Organization. Stakeholders are invited to submit comments/suggestions by September 5, 2013.

Comments/suggestions should be addressed to:

**The Chief Executive Officer**  
**Food Safety and Standards Authority of India**  
**Food and Drug Administration Bhawan**  
**Kotla Road, New Delhi - 110 002**  
**Email: [nutra.regulation.fssai@gmail.com](mailto:nutra.regulation.fssai@gmail.com)**

The details of the amendments are given below.

## **Regulation 2.1.9 – Foods for Infant Nutrition**

(i) Sub-heading ‘Infant Milk Substitutes’ has been inserted after the heading ‘Foods for Infant Nutrition.’

(ii) In sub-regulation 2 relating to infant formula, a new proviso shall be added after the second proviso which reads as:

“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, percent by weight shall not be less than 10.0 and not more than 16 percent;
- (b) Total fat, percent by weight shall not be less than 18.0; and
- (c) The lactose in the product claimed to be lactose free shall not exceed 0.05 percent

(iii) In sub-regulation 3 relating to milk-cereal based complementary food, the heading “Infant Foods” has been inserted.

(iv) The following proviso shall be inserted in sub-regulation 4 relating to processed cereal based

complementary food:

‘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 percent. Such products shall be conspicuously labeled, “Processed Mon Cereal Based Complementary Food for use in specific conditions under medical guidance only.”

#### Regulation 2.4.1 – *Atta*

A new table has been inserted to provide the nutrient level of fortification per kilogram of *atta* in detail.

S. No.	Nutrient	Level of fortification per Kg of <i>atta</i> (Not less than)
(1)	(2)	(3)
1.	<b>Calcium-</b> Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic.	900mg
2.	<b>Iron-</b> (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;  (b) <i>Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Ferredetate- Na Fe EDTA)</i>	60mg  200mg
3.	<b>Vitamin A-</b> Retinyl acetate, Retinyl palmitate, Retinyl propionate.	1400 µg RE
4.	<b>Ascorbic Acid (Vitamin C) –</b> Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl- 6-palmitate.	90 mg
5.	<b>Thiamine (Vitamin B1) –</b> Thiamine chloride hydrochloride, Thiamine mononitrate.	2.7mg
6.	<b>Riboflavin (Vitamin B2) –</b> Riboflavin, Riboflavin 5'-Phosphate sodium.	3.2mg
7.	<b>Niacin –</b> Nicotinamide, Nicotinic acid.	36mg
8.	<b>Pyridoxine (Vitamin B6) –</b> Pyridoxine hydrochloride.	4.5mg
9.	<b>Folic acid-</b> Folic acid.	300 µg
10.	<b>Vitamin B12-</b> Cyanocobalamine, Hydroxycobalamin.	2.5 µg

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

#### Regulation 2.4.2 – *Maida*

A new table has been inserted to provide the nutrient level of fortification per kilogram of *maida* in

detail.

S. No	Nutrient	Level of fortification per Kg of maida ( Not less than)
1.	<b>Calcium-</b> Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic.	900mg
2.	<b>Iron-</b> (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;  (b) <i>Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Feredetate- Na Fe EDTA)</i>	60mg  200 mg
3.	<b>Vitamin A-</b> Retinyl acetate, Retinyl palmitate, Retinyl propionate.	1400 µg RE
4.	<b>Ascorbic Acid (Vitamin C) –</b> Ascorbic acid, Sodium ascorbate, Calcium ascorbate, ascorhyl-6-palmitate.	90 mg
5.	<b>Thiamine (Vitamin B1) -</b> Thiamine chloride hydrochloride, Thiamine mononitrate.	2.7mg
6.	<b>Riboflavin (Vitamin B2) –</b> Riboflavin, Riboflavin 5'- Phosphate sodium.	3.2mg
7.	<b>Niacin –</b> Nicotinamide, Nicotinic acid.	36mg
8.	<b>Pyridoxine (Vitamin B6) -</b> Pyridoxine hydrochloride.	4.5mg
9.	<b>Folic acid-</b> Folic acid.	300 µg
10.	<b>Vitamin B12-</b> Cyanocobalamine, Hydroxycobalamin.	1.5 µg

It shall be free from any extraneous matter including rodent hair and excreta."

### Regulation 3.1.17 – Other Substances to be used in specified limits

After the table specifying the limits on the use of food additives, the following shall be inserted:

#### “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 the Regulations:

- (i) Oligofructose may be added at not more than ten percent of the products, 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 Labeling) Regulation, 2011:  
Dairy products like: yoghurt, mousee, 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,

khoya burfi, 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 3 grams per day through the use of either one portion containing maximum 3 gram or three portions containing 1 gram 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 Labeling) Regulations, 2011:

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

Products containing Phyto or Plant stanols be sold in single portions containing either maximum 3 grams or maximum 1 gram of phyto/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 has been added as an ingredient for the following foods, subject to label declaration under sub-regulation 49 of regulation 2.4.5 of the Food Safety and Standards (Packaging and Labeling) Regulations, 2011.

(i)	Biscuits, bread, cakes, breakfast cereals	0.5-10%
(ii)	Carbonated water, thermally processed fruits, fruit juices, fruit nectars, fruit beverages, fruit squashes, jam, jelly, fruit cheese, marmalade, dairy based drinks.	0.5-20%
(iii)	Carbohydrate- based and milk product based sweets like gulab jamun, rosogolla, peda , khoya burfi.	0.5-20%
(iv)	Macroni products, noodles, pasta.	0.5-5%
(v)	Sweets and confectionery, candies and icings.	5.0-75%

- (iv) Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Feredetate – Na Fe EDTA) has been added as an ingredient in the following foods:

Ready to serve beverages, carbonated fruit drink and fruit nectars	} Not more than 155 ppm.”.
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The full text of the amendment as given in the notification is attached below and can also be accessed on the [FSSAI](http://fssai.gov.in) website.

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

- **Publication Date:** May 16, 2013

- **Date of Notification made available to public:** August 1, 2013
- **Date of implementation:** October 1, 2013
- **WTO Notification Date:** Not notified

**Products Affected:** All food products

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

## MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

### NOTIFICATION

New Delhi, the 16th May, 2013.

**No. 1-83/Sci. Pan- Noti/FSSAI-2012.**—The following draft of certain regulations to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India, with the previous approval of the Central Government, proposes to make, in exercise of the powers conferred by clause (e) of sub-section (2) of section 92 read with sub-section (2) of section 16 of the Food Safety and Standards Act, 2006, is hereby published as required by sub-section (1) of section 92 of the said Act, for the information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of a period of sixty days from the date on which the copies of the Official Gazette in which this notification is published are made available to the public;

Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi-110 002;

The objections and suggestions, which may be received from any person with respect to the said draft regulations before the expiry of the period specified above, shall be considered by the aforesaid Authority.

#### Draft Regulations

- (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2013.
- (2) They shall come into force on the date of their final publication in the Official Gazette.
- In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011,—
  - in regulation 2.1.9 –
    - after the heading “FOODS FOR INFANT NUTRITION”, the sub-heading “**Infant Milk Substitutes**” shall be inserted;
    - 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:—***

      - total protein, percent, by weight shall not be less than 10.0 and not more than 16 percent;
      - total fat, percent by weight shall not be less than 18.0; and
      - the lactose in the product claimed to be lactose free shall not exceed 0.05 percent.”;
  - in sub-regulation 3 relating to milkcereal based complementary food, the heading “**Infant Foods**” shall be inserted;



- (iv) in sub-regulation 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.”;

- 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 less than)
(1)	(2)	(3)
1.	<b>Calcium-</b> Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic.	900mg
2.	<b>Iron-</b> (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;  (b) <i>Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Ferredetate- Na Fe EDTA)</i>	60mg       <b>200mg</b>
3.	<b>Vitamin A-</b> Retinyl acetate, Retinyl palmitate, Retinyl propionate.	1400 µg RE
4.	<b>Ascorbic Acid (Vitamin C) –</b> Ascorbic acid, Sodium ascorbate, Calcium ascorbate, Ascorbyl- 6-palmitate.	90 mg
5.	<b>Thiamine (Vitamin B1) –</b> Thiamine chloride hydrochloride, Thiamine mononitrate.	2.7mg
6.	<b>Riboflavin (Vitamin B2) –</b> Riboflavin, Riboflavin 5'- Phosphate sodium.	3.2mg
7.	<b>Niacin –</b> Nicotinamide, Nicotinic acid.	36mg
8.	<b>Pyridoxine (Vitamin B6) –</b> Pyridoxine hydrochloride.	4.5mg
9.	<b>Folic acid-</b> Folic acid.	300 µg
10.	<b>Vitamin B12-</b> Cyanocobalamine, Hydroxycobalamin.	2.5 µg

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 less than)
1.	<b>Calcium-</b> Calcium carbonate, Calcium chloride, Calcium citrate, Calcium phosphate monobasic, Calcium phosphate dibasic, Calcium phosphate tribasic.	900mg
2.	<b>Iron-</b> (a) Ferrous citrate, Ferrous lactate, Ferrous sulphate, Ferric pyrophosphate;  (b) <i>Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Feredetate- Na Fe EDTA)</i>	60mg  200 mg
3.	<b>Vitamin A-</b> Retinyl acetate, Retinyl palmitate, Retinyl propionate.	1400 µg RE
4.	<b>Ascorbic Acid (Vitamin C) -</b> Ascorbic acid, Sodium ascorbate, Calcium ascorbate, ascorbyl-6-palmitate.	90 mg
5.	<b>Thiamine (Vitamin B1) -</b> Thiamine chloride hydrochloride, Thiamine mononitrate.	2.7mg
6.	<b>Riboflavin (Vitamin B2) -</b> Riboflavin, Riboflavin 5'- Phosphate sodium.	3.2mg
7.	<b>Niacin -</b> Nicotinamide, Nicotinic acid.	36mg
8.	<b>Pyridoxine (Vitamin B6) -</b> Pyridoxine hydrochloride.	4.5mg
9.	<b>Folic acid-</b> Folic acid.	300 µg
10.	<b>Vitamin B12-</b> Cyanocobalamine, Hydroxycobalamine.	1.5 µg

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, khoya burfi, 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:—

*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.*



*Products containing Phyto or Plant stanols be sold in single portions containing either maximum 3 g or maximum 1 g of phyto/ 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%
(ii)	Carbonated water, thermally processed fruits, fruit juices, fruit nectars, fruit beverages, fruit squashes, jam, jelly, fruit cheese, marmalade, dairy based drinks.	0.5-20%
(iii)	Carbohydrate- based and milk product based sweets like gulab jamun, rosogolla, peda , khoya burfi.	0.5-20%
(iv)	Macroni products, noodles, pasta.	0.5-5%
(v)	Sweets and confectionery, candies and icings.	5.0-75%

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

Ready to serve beverages,  
carbonated fruit drink and fruit nectars



Not more than 155 ppm.”.

R. K. JAIN, Chief Executive Officer  
[ ADVT III/4/Exty./187-O/13]

**Foot note: —** The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number 2-15015/30//2010 dated the 1st August, 2011.