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Draft Amendments on Standards and Labeling Regulations

Report Categories:

FAIRS Subject Report

Sanitary/Phytosanitary/Food Safety

Exporter Guide

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Report Highlights:

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) published draft regulations which update (i) dairy products and analogues of infant nutrition; and (ii) artificial sweeteners. The GOI is seeking public comments for these draft regulations and has established April 6, 2015, as the deadline for the public comment period.

Executive Summary:

FSSAI published [Draft Food Product Standards cum Packaging and Labeling \(Amendment\) Regulations, 2015](#), relating to limits of isomaltulose, high fiber dextrin, arachidonic acid (ARA) and docosahexaenoic acid (DHA) in various infant food products. The amendment also includes requirements and restrictions relating to the manner of labeling of these food products and a requirement for the source of ingredients to be non-genetically modified. To date, these draft regulations have not been notified to the World Trade Organization (WTO). However, FSSAI is seeking public comments from interested stakeholders through April 6, 2015.

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 makes no claim of accuracy or authenticity.

Amendments as listed in the FSSAI notification are given below:

1. In Chapter 2, Sub-regulation 2.1.9 of the Food Product Standards, a new paragraph has been inserted into Clause 2, which pertains to infant formula. The amended paragraph now states:

“It may contain algal and fungal oil as sources of DHA and ARA from crypthecodium cohnii and mortiella alpine, respectively at the level of 17 milligram (mg) per 100 Kilo calories (Kcal) (equivalent to 0.3 per cent of total fatty acids of DHA) and ARA as ratio of ARA:DHA as 2:1.”

2. In Sub-regulation 3.1., which pertains to artificial sweeteners, paragraph (1) has been amended and now states:

“Artificial sweeteners mentioned in column 2 of the table below, may be used only in the food articles mentioned in column 3 and in quantities not exceeding the limits mentioned in column 4 and as per provision contained in these regulations and Appendices and shall bear the label declarations as provided in Regulation 2.4.5 (24, 25, 26, 27, 28, 29 and 50) of the Food Safety and Standards (Packaging and Labeling) Regulations, 2011.”

3. In Chapter 3, an additional sweetener has been added to the table which lists maximum limits for artificial sweeteners. This addition, which is listed as number VI, is as follows:

S.No.	Name of Artificial Sweetener	Article of Food	[Maximum limit of Artificial Sweetener
“VI	Isomaltulose	Confectionery products*	50 percent (max) of the total sugar with adversely affecting the stability of the product.”

*Confectionery products do not include ice lollies or edible ices.

4. In Sub-regulation 3.1.6 relating to use of carboxymethyl cellulose in various foods, an additional

clause has been inserted and now states:

“Use of Dietary Fiber (Dextrin-soluble fiber) in various foods

Dietary Fiber (Dextrin) may be used in the following food products in the level mentioned in column (3) of the table given below and shall bear the label declaration as provided in the regulation 2.4.5 (51) of the Food Safety and Standards (Packaging and Labeling) Regulations, 2011, and the source of the ingredients (wheat/maize) should be non-genetically modified (GM).

S.No.	Article of Food	Minimum Level (Source of dietary fiber)
1.	Flakes and ready to eat breakfast cereals	3g/100g or 1.5g/100 kcal
2.	Noodles and pasta	3g/100g or 1.5g/100 kcal
3.	Salad dressing or toppings and spreads	3g/100g or 1.5g/100 kcal
4.	Table top fiber as filler or carrier and cereals	3g/100g or 1.5g/100 kcal
5.	Other snack food or savories	3g/100g or 1.5g/100 kcal
6.	Bakery products including biscuit, cookies, bread, cakes mix and pastries	3g/100g or 1.5g/100 kcal

Provided that if in above products it is intended to make claims on high source of dietary fiber, such products shall contain not less than 3g/100g or 1.5g/100Kcal and not more than 6g/100g or 3g/100Kcal.”

- In Appendix A of the Food Standards and Additives Regulations, which includes a list of food additives, isomaltrose has been added to Table 2 as an additional artificial sweetener, as noted below:

1	2	3	4	5	6	7	8	9	10	11	12
	Isomaltulose	-	-	-	-	-	50 percent max of the total sugar without adversely affecting the stability of the product.	50 percent max of the total sugar without adversely affecting the stability of the product.	50 percent max of the total sugar without adversely affecting the stability of the product.	-	50 percent max of the total sugar without adversely affecting the stability of the product.

- In the Food Safety and Standards (Packaging and Labeling) Regulations, 2011, the following shall be inserted in sub-regulation 2.4.5 after sub-clause (49). This amendment relates to specific requirements/restrictions vis-à-vis labeling.

“(50) Every package of food product containing Isomaltulose shall bear the following declarations:

Contains Isomaltulose------(calories)

(51) Every package of flakes and ready to eat dry breakfast cereals, noodles, pasta, salad dressings/toppings and spreads; table top fiber as filler or carrier, cereals and other snack food/savories and bakery products including biscuits, cookies, bread, cake mix and pastries containing added Dietary Fiber (Dextrin-soluble fiber) shall bear the following declarations:

Contains Dietary Fiber (Dextrin)------(Source of soluble dietary fiber)

Public comments, in the format pasted below, should be sent to:

Chief Executive Officer
Food Safety and Standards Authority of India
Food and Drug Administration Bhawan, Kotla Road
New Delhi – 110002
Email: regulation@fssai.gov.in

FSSAI's notification is attached at the end of this report and is also available on FSSAI's website:
<http://www.fssai.gov.in/>.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 11th December, 2014

No. 3-14F/Notification (Nutraceuticals)/FSSAI-2013.—The following draft of certain regulations further to amend the Food Safety and Standards (Food Product 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 (34 of 2006), is hereby published as required by sub section (1) of the said section for information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulations will be taken into consideration after the expiry of a period of sixty days from the date on which 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. (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2014.
(2) They shall come into force on the date of their final 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), in regulation 2.1 relating to dairy products and analogues,-
 - (a) in sub- regulation 2.1.9 relating to foods for infant nutrition,—
 - (i) in clause 2 relating to infant formula, after the first paragraph, the following paragraph shall be inserted, namely:—

“It may contain algal and fungal oil as sources of Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA) from *Cryptocodium cohnii* and *Mortierella alpina*, respectively at the level of 17mg per 100 Kcal (equivalent to 0.3 per cent. of total fatty acids of DHA) and ARA as ratio of ARA:DHA as 2:1.”;
 - (ii) in clause 5 relating to follow-up formula–Complementary food, after the first paragraph, the following paragraph shall be inserted, namely:—

“It may contain algal and fungal oil as sources of Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA) from *Cryptocodium cohnii* and *Mortierella alpina* respectively at the level of 17mg per 100 Kcal (equivalent to 0.3 per cent of Total Fatty acids of DHA) and ARA as ratio of ARA: DHA as 2:1.”
3. In the said regulations, in regulation 3.1 relating to Food Additives, –
 - (I) in sub-regulation 3.1.3 relating to artificial sweeteners, in paragraph (1) relating to use and sale of artificial sweeteners ,—
 - (a) for the words, figures and brackets “the regulation 2.4.5 (24, 25, 26, 27, 28 & 29)”, the words, figures and brackets “the regulation 2.4.5 (24, 25, 26, 27, 28, 29 and 50)” shall be substituted;
 - (b) in the table after serial number V and the entries relating thereto, the following serial number and the entries shall be inserted, namely:—

1	2	3	4
“VI	Isomaltulose	Confectionery products*	50 per cent (max) of the total sugar with adversely affecting the stability of the product.”;

*Confectionery products does not include ice lollies or edible ices.

(II) in sub regulation 3.1.6, after clause (12) relating to use of Carboxymethyl Cellulose in various foods, the following clause shall be inserted, namely:—

“(13) Use of Dietary Fibre (Dextrin-soluble fibre) in various foods

Dietary Fibre (Dextrin) may be used in the following food products in the level mentioned in column (3) of the table given below and shall bear the label declaration as provided in the regulation 2.4.5 (51) of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, and the source of the ingredients (wheat/maize) should be non-genetically modified (GM).

Sl. No. (1)	Article of food (2)	Minimum Level (Source of dietary fibre) (3)
1	Flakes and ready to eat dry breakfast cereals	3g/100g or 1.5 g/100kcal
2	Noodles and pasta	3g/100g or 1.5 g/100kcal
3	Salad dressing or toppings and spreads	3g/100g or 1.5 g/100kcal
4	Table top fibre as filler or carrier and cereals	3g/100g or 1.5 g/100kcal
5	Other snack food or savouries	3g/100g or 1.5 g/100kcal
6	Bakery products including biscuit, cookies, bread, cakes mix and pastries	3g/100g or 1.5 g/100kcal

Provided that if in above products it is intended to make claims on high Source of dietary fibre, such products shall contain not less than 3g/100g or 1.5g/100Kcal and not more than 6g/100g or 3g/100Kcal.”.

4. In said regulations, in Appendix A relating to list of food additives, in Table 2, in serial number E, after item number 4 relating to Sucralose and the entries relating thereto, the following item number and the entries shall be inserted, namely:—

1	2	3	4	5	6	7	8	9	10	11	12
“5	Isomaltulose	-	-	-	-	-	50 per cent max of the total sugar without adversely affecting the stability of the product.	50 per cent max of the total sugar without adversely affecting the stability of the product.	50 per cent max of the total sugar without adversely affecting the stability of the product.	-	50 per cent max of the total sugar without adversely affecting the stability of the product”.

YUDHVIR SINGH MALIK, Chief Executive Officer

[ADVT-III/4/Exty./1870/14/(226)]

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.

NOTIFICATION

New Delhi, the 11th December, 2014

No. 3-14P/Notification (Nutraceuticals)/FSSAI-2013.—The following draft of certain regulations further to amend the Food Safety and Standards (Packaging and labelling) 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 (k) of sub-section (2) of Section 92 read with sub-section (1) of Section 23 of the Food Safety and Standards Act, 2006 (34 of 2006), is hereby published as required by sub section (1) of the said section for information of all persons likely to be affected thereby; and notice is hereby given that the said draft regulations will be taken into consideration after the expiry of a period of sixty days from the date on which 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 (Packaging and labelling) (Amendment) Regulations, 2014.
(2) They shall come into force on the date of their final publication in the Official Gazette.
- In Food Safety and Standards (Packaging and Labelling) Regulations, 2011 (hereinafter referred to as the said regulations), in regulation 2.4 relating to specific requirement/restriction on manner of labelling, in sub regulation 2.4.5, after sub-clause (49), the following shall be inserted, namely:—
“(50) Every package of food product containing Isomaltulose shall bear the following declarations, namely:—

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THE GAZETTE OF INDIA : EXTRAORDINARY

[PART III—SEC. 4]

Contains Isomaltulose----- (calories)

- (51) Every Package of flakes and ready to eat dry breakfast cereals, noodles, pasta, salad dressings/toppings and spreads; table top fibre as filler or carrier, cereals and other snack food/savouries and bakery products including biscuits, cookies, bread, cake mix and pastries containing added Dietary Fibre (Dextrin-soluble fibre) shall bear the following declarations, namely:—

Contains Dietary Fibre (Dextrin)----- (Source of soluble Dietary fibre)

YUDHVIR SINGH MALIK, Chief Executive Officer

[ADVT-III/4/Exty./1870/14/(226)]

Foot note: The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 notification No. 2-15015/30/2010 dated 1st August, 2011 and lastly amended vide notification No. 4/15015/30/2011, dated 7th June, 2013.

Subject: Draft Food Safety and Standards (Food Products Standards and Additives) (Amendment) Regulations, 2014 and Food Safety and Standards (Packaging and labelling) (Amendment) Regulations, 2014 with respect to limits of Isomaltulose, High fibre Dextrin, ARA and DHA in various food products. [Amendment in the food safety and Standards (Food Products standard: and Food additives) Regulation, 2011]

FORMAT FOR SENDING THE COMMENTS AND SUGGESTIONS

Sl. No.	Name and Address of the organisation/person, contact number and E-mail.	Relevant section in the draft notification on which comments are being provided	Comments/suggestion	Rationale	Remarks, if any

Date:

Place:

Name and signature