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Final Amendment on Food Product Standards and Labeling Regulations

Report Categories:

Sanitary/Phytosanitary/Food Safety

Exporter Guide

Food and Agricultural Import Regulations and Standards - Narrative

Dairy and Products

Food Processing Ingredients

Oilseeds and Products

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Report Highlights:

On July 25, 2016, the Government of India's (GOIs) Food Safety and Standards Authority of India (FSSAI) published notifications to amend the Food Products Standards and Packaging and Labeling Regulations, 2011. The amendments are specific to fatty acids, dietary fiber, packaging, and labeling related to plant sterols, isomaltulose, and high-fiber dextrin in various food products.

General Information:

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

FSSAI notified its (i) Food Safety and Standards (Food Product Standards and Food Additives) Fourth Amendment Regulations, 2016, regarding the use of arachidonic acid (ARA), cocosahexaenoic acid (DHA), isomaltulose, and high fiber dextrin in various food products; and (ii) Food Safety and Standards (Packaging and Labeling) Third Amendment Regulations, 2016, regarding the use of plant sterols (phytosterols), isomaltulose, and high fibre dextrin. Both amendments are finalized and effective as of the date of publication in the official Gazette, i.e., July 13, 2016.

The full text of both the amendments published by FSSAI on July 27 is provided below and is also available on their website: <http://www.fssai.gov.in/>.

Details of Notification: 3-14F/Notification (Nutraceuticals)/FSSAI-2013

- Publication Date in the Official Gazette: July 13, 2016
- Date of Implementation: Immediate

Products affected: Infant formula foods, confectionery, bakery products, lozenges, chewing/bubble gum, chocolates, fat spread, milk products, milk based fruit drink, soy and rice drinks, cheese products, spice sauces, salad dressings, juices, nectars, edible oils.

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 13th July, 2016

No. 3-14F/Notification (Nutraceuticals) /FSSAI-2013.—Whereas the draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2014 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. 3-14F/ Notification(Nutraceuticals)/FSSAI-2013, dated the 11th December, 2014 in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from persons likely to be affected thereby, before the expiry of period of sixty days from the date on which the copies of the 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 6th February, 2015;

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) **Short title and commencement.**- (1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Fourth Amendment Regulations, 2016.

(2) They shall come into force on the date of their publication in the Official Gazette.

- 2) (A) In Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 (hereinafter referred to as the said regulations), in regulation 2.1, in sub-regulation 2.1.9,-

(i) in clause 2, 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 *Cryptocodinium cohnii*, *Mortierella alpina*, *Schizochytrium* sp., and *Ulkenia* sp. at the level of maximum 0.5 per cent. DHA of total fatty acids and ratio of ARA: DHA as 1:1 minimum:

Provided that DHA content shall not be less than 0.2 per cent. of total fatty acids, if a claim related to the addition of DHA is made.”;

(ii) in clause 5, 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 *Cryptocodinium cohnii*, *Mortierella alpina*, *Schizochytrium* sp., and *Ulkenia* sp. at the level of maximum 0.5 per cent. DHA of total fatty acids and ratio of ARA:DHA as 1:1 minimum :

Provided that DHA content shall not be less than 0.2 per cent. of total fatty acids, if a claim related to the addition of DHA is made.”.

- (B) In the said regulations, in regulation 2.7, -

(i) in sub-regulation 2.7.1, after Sl. No. (xxv), the following Sl. No. shall be inserted, namely:-

“(xxvi) Isomaltulose at 50 per cent. (Max) of the total sugars without adversely affecting the stability of the product”;

(ii) in sub-regulation 2.7.2, after Sl. No. (xvii), the following Sl. No. shall be inserted, namely:-

“(xviii) Isomaltulose at 50 per cent. (Max) of the total sugars without adversely affecting the stability of the product”;

(iii) in sub-regulation 2.7.3, after Sl. No. (h), the following Sl. No. shall be inserted, namely:-

“(i) Isomaltulose at 50 per cent. (Max) of the total sugars without adversely affecting the stability of the product”;

(iv) in sub-regulation 2.7.4, after the first paragraph, the following paragraph shall be inserted, namely:-

“The product may contain Isomaltulose at 50 per cent. (Max) of the total sugars without adversely affecting the stability of the product.”;

- (v) in sub-regulation 2.7.5, after the second paragraph, the following paragraph shall be inserted at the end, namely:-

“The ice lollies or edible ices and ice candy may contain Isomaltulose at 50 per cent. (max) of the total sugars without adversely affecting the stability of the product.”.

- (C) In the said regulations, in regulation 2.11, after sub-regulation 2.11.7, the following sub-regulation shall be inserted, namely -

“2.11.8: Dietary Fibre (Dextrin – soluble fibre) means glucose polymer of natural origin obtained by dextrinification, i.e. dry roasting acidified starch under specific conditions and further purified. The average degree of polymerization of Dietary Fibre (Dextrin – soluble fibre) is from 12-25 compared to several thousand for starch. Unlike starches and maltodextrins, which contain only “digestible” α - (1, 4) and α - (1, 6) glucosidic linkages, Dietary Fibre (Dextrin – soluble fibre) also shall contain “indigestible” α - and β - linkages.

Dietary Fibre (Dextrin-soluble fibre) may be used in the following food products at the level of Good Manufacturing Practices (GMP). It shall bear the label declaration as provided in serial number (54) of sub-regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, and the source of the ingredients (wheat/maize) shall be Non- Genetically Modified (GM):

Sl. No. (1)	Article of food (2)
1.	Flakes and ready-to-eat dry breakfast cereals
2.	Noodles and pasta
3.	Salad dressing or toppings and spreads
4.	Table top fibre as filler or carrier and cereals
5.	Other snack food or savouries
6.	Bakery products including biscuit, cookies, bread, cakes mix and pastries
7.	Other products where dextrin is allowed under these regulations.

Provided that in above products if it is intended to make claims on source of dietary fibre, it shall not contain less than 3g/100g or 1.5g/100Kcal:

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

PAWAN AGARWAL, Chief Executive Officer

[ADVT.-III/4/Exty./171]

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

- (i) F. No. 4/15015/30/2011, dated the 7th June, 2013;
- (ii) F. No. P.15014/1/2011-PFA/FSSAI, dated the 27th June, 2013;
- (iii) F. No. 5/15015/30/2012, dated the 12th July, 2013;
- (iv) F. No. P.15025/262/13-PA/FSSAI dated the 5th December, 2014;
- (v) F. No.1-83F/Sci.Pan-Noti/FSSAI-2012 dated the 17th February, 2015;
- (vi) F. No. 4/15015/30/2011, dated the 4th August, 2015;
- (vii) F. No. P. 15025/263/13-PA/FSSAI, dated the 4th November, 2015;
- (viii) F. No. P.15025/264/13-PA/FSSAI, dated the 4th November, 2015;
- (ix) F. No. 7/15015/30/2012, dated the 13th November, 2015;

- (x) F. No. P.15025/208/2013-PA/FSSAI, dated the 13th November, 2015;
- (xi) F. No P.15025/261/2013-PA/FSSAI, dated the 13th November, 2015 and
- (xii) F. No.1-10(1)/Standards/SP(Fish and Fisheries Products)/FSSAI-2013, dated the 11th January, 2016
- (xiii) No. 3-16/ Specified Foods/Notification(Food Additive)/FSSAI-2014 dated the 3rd May, 2016.
- (xiv) F. No. 15-03/Enf/FSSAI/2014, dated 14th June, 2016.

NOTIFICATION

New Delhi, the 13th July, 2016

No. 3-14P/Notification(Nutraceuticals)/FSSAI-2013.—Whereas the draft Food Safety and Standards (Packaging and labeling) (Amendment) Regulations, 2014 and the draft of the Food Safety and Standards (Packaging and labelling) (Amendment) Regulations, 2015 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. 3-14P/ Notification(Nutraceuticals)/FSSAI-2013, dated the 11th December, 2014 and F. No. 3-17/Phytosterol/Notification(Labelling)/FSSAI-2014, dated the 30th July, 2015 respectively in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of sixty days from the date on which the copies of the Gazette containing the said notifications were made available to the public;

And whereas the copies of the said Gazette were made available to the public on the 6th February, 2015 and 28th August, 2015 respectively;

And whereas 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 (k) 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 (Packaging and Labeling) Regulations, 2011, namely:-

Regulations

2. **Short title and commencement.**- (1) These regulations may be called the Food Safety and Standards (Packaging and labelling) Third Amendment Regulations, 2016.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In Food Safety and Standards (Packaging and labelling) Regulations, 2011, in regulation 2.4, in sub-regulation 2.4.5, after serial number (52), the following serial numbers shall be inserted, namely:-

“(53) Every package of food product containing Isomaltulose shall bear the following declaration, namely:-

Contains Isomaltulose----- (calories)

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

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

(55) Fat spread, milk products, milk based fruit drink, fermented milk products, soy and rice drinks, cheese products, yoghurt products, spice sauces, salad dressings, juices and nectars, edible oils, and bakery products containing plant sterol shall contain the following declarations, namely:-

- Contains Plant Sterol (as Phytosterols) ---g/100g or 100ml.
- Patients on cholesterol lowering medication should use the product under medical supervision
- May not be nutritionally appropriate for pregnant and lactating women and children under the age of five years.
- CONSUMPTION OF MORE THAN 3g/DAY, TOTAL OF STEROL, STANOLS, OR COMBINATION THEREOF, SHOULD BE AVOIDED"

PAWAN AGARWAL, Chief Executive Officer

[ADVT.-III/4/Exty./171]

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

- i) F. No. 4/15015/30/2011, dated the 7th June, 2013;
- ii) F.No. P 15014/1/2011-PFA/FSSAI, dated the 27th June, 2013;
- iii) F. No. 1-83L/Sci. Pan- Noti/FSSAI-2012, dated the 17th February, 2015;
- iv) No. 3-16/ Specified Foods/Notification(Food Labelling)/FSSAI-2014, dated 3rd May, 2016 and
- v) F. No. 1(94)2015/Notification P&L/Enf/FSSAI, dated 25th May, 2016.