

USDA Foreign Agricultural Service

# GAIN Report

Global Agricultural Information Network

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**Date:** 9/16/2015

**GAIN Report Number:** IN5118

## India

**Post:** New Delhi

### Amendments in Regulations Relating to Phytosterols

**Report Categories:**

Sanitary/Phytosanitary/Food Safety

Exporter Guide

FAIRS Subject Report

Dairy and Products

Beverages

Oilseeds and Products

Honey

Food Processing Ingredients

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**Report Highlights:**

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) published [draft regulations](#) regarding the use of plant sterol (phytosterols) as a food ingredient in certain food products. The GOI is accepting public comments for these draft regulations and has established October 28, 2015, as the deadline for the public comment period.

## Executive Summary:

FSSAI published [Draft Food Product Standards cum Packaging and Labeling \(Amendment\) Regulations, 2015](#), regarding the use of plant sterol (phytosterols) as a food ingredient in yellow fat spreads, milk products, milk based fruit drinks, fermented milk products, cheeses, salad dressings, juices and nectars, edible oils, and baked products such as breads. The amendment further updates requirements and restrictions regarding the labeling of these food products containing plant sterols. To date, these draft regulations have not been notified to the World Trade Organization (WTO). However, FSSAI will accept public comments from interested stakeholders through October 28, 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 make no claim of accuracy or authenticity.

Amendments as listed in the FSSAI notification are given below:

1. In Chapter 2 of the Food Safety and Standards (Packaging and Labeling) Regulation, 2011, a new clause (54) was inserted in sub-Regulation 2.4.5 relating to 'Specific Labeling Requirements of other Products'. The new clause will read as follows:

“54. Yellow fat spread, milk products, milk based fruit drinks, fermented milk products, cheese, salad dressings, juices and nectars, edible oils, baked products (bread) containing plant sterol shall contain the following declarations, namely:

- Contains Plant Sterol Esters (as Plant Sterols)---gm/100 gm or 100 ml.
- 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. PER DAY, TOTAL OF STEROL, STANOLS OR COMBINATION THEREFOF SHALL BE AVOIDED

2. In chapter 3 of the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011, sub-regulation 3.1.17 relating to ‘Other Substances to be used in Specified Limits’, an additional clause (v) shall be inserted after the clause (iv) relating to ‘Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Feredetate-Na Fe EDTA)’. The new clause (v) shall read as follows:

“(v) : **Use of Plant sterol (Phytosterols) as food ingredients.**—(a) The Phyto or Plant sterol from non Genetically Modified (GM) source may be used in the following categories of food products with their use at the level of 0-40mg/kg of body weight—

*Yellow fat spread, milk products, milk based fruit drink, fermented milk products, cheese, salad dressings, juices and nectars, edible oils, baked products (bread).*

Products containing Phyto or Plant Sterols be sold in single portions containing either maximum 3 g or maximum 1 g of phyto/ plant Sterols, calculated as free phyto or plant Sterols. 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 Sterol, calculated as free phyto or plant Sterol, contained in such a portion. In all events, the composition and labelling of products should be such as to allow users to easily restrict their consumption to maximum 3g/day of phytosterols through the use of either one portion containing maximum 3g, or three portions containing maximum 1g.

(b) The products referred to in sub-clause (a) shall not exceed the Acceptable Daily Intake (ADI) for Phytosterols and shall contain the label declarations as provided in the clause 54 of sub-regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011”.

Public comments must be formatted as per pasted below and 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](mailto: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/>.

## NOTIFICATION

New Delhi, the 30th July, 2015

**F. No. 3-17/Phytosterol/Notification(Food Additive)/FSSAI-2014:**—The following draft of certain regulations, further to amend the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, which the Food Safety and Standards Authority of India proposes to make with the previous approval of the Central Government, in exercise of the powers conferred by sub-section (1) and 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 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, duly supported by the scientific evidence, 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;

[ भाग III—खण्ड 4 ]

भारत का राजपत्र : असाधारण

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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 Product Standards and Food Additives) (Amendment) Regulations, 2015.  
(2) They shall come into force with effect from the ensuing 1<sup>st</sup> January or 1<sup>st</sup> July of the year, as the case may be, subject to minimum of 180 days from the date of final notification of these regulations in the Official Gazette.
- In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in regulation in chapter 3 under 'Substances Added to Food' 3.1 relating to 'Food Additives' in sub-regulation 3.1.17 relating to 'Other substances to be used in Specified limits', after the clause (iv) relating to 'Sodium Iron (III) Ethylene Diamine tetra acetate, Trihydrate (Sodium Ferredetate-Na Fe EDTA)', the following clause shall be inserted, namely:—

“(v) : **Use of Plant sterol (Phytosterols) as food ingredients.**—(a) The Phyto or Plant sterol from non Genetically Modified (GM) source may be used in the following categories of food products with their use at the level of 0-40mg/kg of body weight—

*Yellow fat spread, milk products, milk based fruit drink, fermented milk products, cheese, salad dressings, juices and nectars, edible oils, baked products (bread).*

Products containing Phyto or Plant Sterols be sold in single portions containing either maximum 3 g or maximum 1 g of phyto/ plant Sterols, calculated as free phyto or plant Sterols. 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 Sterol, calculated as free phyto or plant Sterol, contained in such a portion. In all events, the composition and labelling of products should be such as to allow users to easily restrict their consumption to maximum 3g/day of phytosterols through the use of either one portion containing maximum 3g, or three portions containing maximum 1g.

(b) The products referred to in sub-clause (a) shall not exceed the Acceptable Daily Intake (ADI) for Phytosterols and shall contain the label declarations as provided in the clause 54 of sub-regulation 2.4.5 of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011”.

YUDHVIR SINGH MALIK, Chief Executive Officer

[ADVT. III/4/Exty./187-O/2015 (150)]

**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 1<sup>st</sup> August, 2010 and subsequently amended vide notification numbers:

- F.No. 4/15015/30/2011, dated the 7<sup>th</sup> June, 2013.
- F.No. P.15014/1/2011-PFA/FSSAI, dated the 27<sup>th</sup> June, 2013
- F.No. 5/15015/30/2012, dated the 12<sup>th</sup> July, 2013 and
- F.No. P.15025/262/13-PA/FSSAI, dated the 5<sup>th</sup> December, 2014
- F.No. 1-83F/Sci. Pan-Noti/FSSAI-2012, dated the 17.02.2015.

Subject: Draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2015 and Food Safety and Standards (Packaging and labelling) Amendment Regulation, 2015 dated 30.07.2015 with respect to the use of Phytosterols as Food Ingredient. [Amendment in the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011: Regulation 3.1.17] and [Amendment in the Food Safety and Standards (Packaging and labelling) Regulation, 2011: Regulation 2.4.5].

FORMAT FOR SENDING THE COMMENTS/ SUGGESTIONS

Sr. 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/ suggestions	Rationale	Remarks

Date:

Place:

Name and Signature