

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-110002;

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 Product Standards and Food Additives) (Amendment) Regulations, 2015.

(2) They shall come into force with effect from the ensuing 1st January or 1st 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.
2. 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 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”.

Sd/-
(Yudhvir Singh Malik)
Chief Executive Officer

F. No.3-17/Phytosterol/Notification (Food Additive)/FSSAI -2014
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Issued by:
Ministry of Health and Family Welfare
(Food Safety and Standards Authority of India)
New Delhi

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 1st August, 2010 and subsequently amended vide 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 and
- (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 17.02.2015.