

F. No.1-94/FSSAI/SP(Claims and Advertisement)/2017

Food Safety and Standards Authority of India

(A statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)

FDA Bhawan, Kotla Road, New Delhi-110002

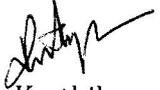
The 28th June, 2019

Subject: Direction under Section 16 (5) of Food Safety and Standards Act, 2006 regarding operationalisation of Food Safety and Standards (Advertising and Claims) Amendment Regulations, 2019.

Reference is drawn to Notification No. 1-94/FSSAI/SP(Claims and Advertisement)/2017 dated 19th November, 2018 published in the Gazette of India.

2. Representations from various stakeholders were received mentioning the difficulties in complying with these regulations and the same were placed before Scientific Panel on Labelling and Claims/Advertisements. After due consideration of representations received from various stakeholders, Scientific Panel has recommended some modification to these regulations.
3. The recommendations of Scientific Panel are being included in the Food Safety and Standards (Advertising and Claims) Regulations, 2018 as an amendment, but the same is likely to take time while following the due process of notification. Pending the final notification of the amendment regulations, it has been decided to operationalise these amendment regulations, enclosed herewith, with immediate effect keeping in mind the consumer interest and the need for fair practices in food business operation.
4. The Food Safety and Standards (Advertising and Claims) Regulations, 2018 together with the above mentioned operationalised amendment regulation shall be followed by food business operators. However, the enforcement of these regulations shall commence after the 6 months from the date of issuance of this direction or after final notification of the proposed amendment in the Gazette of India, whichever is later.
5. Further, in the event of any changes in the operationalised amendment regulations at the time of finalisation, further transition time would be given for those changes only, if required.

6. This issues with the approval of the Competent Authority in exercise of the power vested under Section 18 (2) (d) read with Section 16 (5) of the Food Safety and Standards Act, 2006.


(P. Karthikeyan)

Deputy Director (Regulations & Codex)

To

1. All Food Safety Commissioner.
2. All Authorised Officer, FSSAI.
3. All Central Designated Offices of FSSAI.

Copy for information to:

1. PPS to Chairperson, FSSAI,
2. PS to CEO, FSSAI,
3. All Directors, FSSAI

Notice for operationalisation of Food Safety and Standards (Advertising and Claims) Amendment Regulations, 2019.

1. The Food Safety and Standards Authority of India, hereby makes the following regulations operational with immediate effect. The enforcement of these regulations shall commence after the 6 months from the date of issuance of this direction or after final notification in the Gazette of India, whichever is later.

2. In the Food Safety and Standards (Advertising and Claims) Regulations, 2018 (herein after refer as said regulations), -

(A) in regulations 4,

(a) for sub-regulation (5), the following shall be substituted, namely:-

“(5) Reduction of disease risk claims shall specify the number of servings of the food per day for the claimed benefit.”;

(b) for sub-regulation (7), the following shall be substituted, namely:-

“(7) Where the meaning of a trade mark, brand name or fancy name containing adjectives such as “natural”, “fresh”, “pure”, “original”, “traditional”, “authentic”, “genuine”, “real”, appearing in the labelling, presentation or advertising of a food is such that it is likely to mislead consumer as to the nature of the food, in such cases a disclaimer in not less than 1.5mm size in case of pack size under 100sq. cm and not less than 3mm size in case of pack size above 100 sq. cm shall be given at appropriate place on the label stating that –

“*This is only a brand name or trade mark and does not represent its true nature”.”;

(B) in regulations 5,

(a) for sub-regulation (3), the following shall be substituted, namely:-

“(3) When a nutrient content or any synonymous claim is made for the nutrients indicated in schedule-I, it shall be made in accordance with the conditions specified in Schedule I, provided flexibility in the wording of a nutrition claim is as per Schedule II, or the use of any other word if they are in accordance with conditions specified in Schedule I and the meaning of the claim is not altered.”;

(b) in sub-regulation (4), for clause (a) and (b), the following shall be substituted, namely:-

(a) “(a) at least thirty per cent. in the energy value or nutrient content except micronutrient
.;(b) at least ten per cent. of recommended dietary allowances per 100 g or 100ml, for claims about micronutrients other than sodium.”;

(c) for sub-regulation (6), the following shall be substituted, namely:-

“(6) The equivalence claims in form of phrases such as "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "source" of that nutrient, and the labeled food, on per 100g or 100ml, is an equivalent, source of that nutrient or where the food nutrient is at the same level as the naturally occurring reference food nutrient , the same shall be indicated on the label and through Nutritional information(e.g., "as much fiber as an apple," and "contains the same amount of vitamin C as glass of orange juice.”);

(C) in regulations 6,

(a) for sub-regulation (2), the following shall be substituted, namely:-

“(2) Non-addition of Sodium salts.- Claims regarding the non-addition of sodium salts to a food, including “no added salt”, may be made if the following conditions are met, namely:-

- (a) The food contains no added sodium salts, including but not limited to sodium chloride, sodium tripolyphosphate;
- (b) The food contains no ingredients that contain added sodium salts including but not limited to sauces, pickles, pepperoni, soya sauce, salted fish, fish sauce; and
- (c) The food contains no ingredients that contain sodium salts that are used to substitute for added salt, including but not limited to seaweed.”;

(b) for sub-regulation (3), the following shall be substituted, namely:-

“(3) Non-Addition of additives.- Claims regarding the non-addition of additives including functional classes of additives as specified in Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 to a food, may be made -according to the following conditions, unless otherwise provided in any other Regulations:

- (a) has not been added to the food or removed from food at the time of manufacture;
 - (b) is not contained in any ingredient of the food except where it is naturally present;
 - (c) is one which is allowed to be added in particular products as specified in Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011; and
 - (d) has not been substituted by another additive giving the food equivalent characteristics.”;
- (D) in regulation 14,
- (a) for sub-regulation (3), at the end of the sentence, for the words “issue of the letter” the following words shall be substituted, namely:-

“date of receipt of letter seeking clarification.”;

(b) in sub-regulation (5), at the end of the sentence, for the words “after issuance of letter” the following words shall be substituted, namely:-

“from the date of receipt of notice of the suggested improvement of the claim from the Food Authority.”;

(E) For “SCHEDULE – I” the following shall be substituted, namely:-

SCHEDULE – I

[See regulation 5 (3) and (4) and regulation 7 (1)(b)]

Nutrient Content Claim

A claim that a food containing the nutrient mentioned in column (2) is likely to have the Content as mentioned in column (3) or has the same meaning for the consumer may be made subject to the conditions as mentioned in column (4) below:

(1)	(2)	(3)	(4)
Sl. No	Nutrient/ component*	Claim	Conditions
1.		Low	Not more than 40 kcal per 100 g for solids 20 kcal per 100 ml for liquids.
		Free	Not more than 4 kcal per 100 ml for liquids.
2.	Fat	Low	Not more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100ml for liquids.
		Free	Not more than 0.5 g of fat per 100 g for solids or 100 ml for liquids.
3.	Cholesterol	Low	Not more than 20 mg cholesterol per 100 g for solids and 1.5 g saturated fat per 100 g for solids or 10 mg per 100 ml for liquids and 0.75 g of saturated fat per 100 ml for liquids and in either case must provide not more than 10% of energy from saturated fat.
		Free	Not more than 5 mg cholesterol per 100g for solids or 100 ml for liquids. Additionally the food shall contain no more than 1.5 g saturated fat per 100 g for solids or 0.75 g of saturated fat per 100 ml for liquids and in either case must provide not more than 10% of energy from saturated fat.
4.	Saturated fat	Low	Not more than 1.5g per 100 g for solids or 0.75 g per 100 ml for liquids and in either case must provide not more than 10% of energy from saturated fat.
		Free	Saturated fatty acids do not exceed 0.1 g per 100 g or 100 ml of food.
5.	Unsaturated fat	High	At least 70% of the fatty acids present in the product are derive from unsaturated fat under the condition that

(1)	(2)	(3)	(4)
Sl. No	Nutrient/ component*	Claim	Conditions
			unsaturated fat provides more than 20% of energy of the product
6.	Trans fat	Free	The food contains less than 0.2g trans fat per 100 g or 100ml of food Provided that for edible oils/fats: 1 g per 100 g/ml of edible oils/fats
7.	MUFA	High in MUFA	Shall only be made where at least 45% of the total fatty acids present in the product are derived from mono unsaturated fat and under the condition that monounsaturated fat provides more than 20% of energy of the product
8.	PUFA	High in PUFA	Shall only be made where at least 45% of the total fatty acids present in the product are derived from poly unsaturated fat and under the condition that polyunsaturated fat provides more than 20% of energy of the product
9.	Omega 3 fatty acids	Source	The product contains: at least 0.3g alpha-linolenic acid per 100 g and/or per 100kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and/or per 100kcal
		High	The product contains: at least 0.6 g alpha-linolenic acid per 100g and/or per 100kcal, or at least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and/or per 100kcal
10.	Sugars	Low	The product contains not more than 5 g of sugars per 100 g for solids or 2.5 g of sugars per 100 ml for liquids.
		Free	The product contains not more than 0.5 g of sugars per 100 g for solids or 100 ml for liquids.
11.	Protein	Source	10% of RDA per 100 g for solids 5% of RDA per 100 ml for liquids or 5% of RDA per 100 kcal
		Rich / High	20% of RDA per 100 g for solids 10% of RDA per 100 ml for liquids or 10% of RDA per 100 kcal
12.	Vitamin(s) and/or Mineral(s)	Source	The food provides at least 15% of RDA of the vitamin/mineral per 100g for solids or 7.5% of RDA of the vitamin/mineral per 100 ml for liquids

(1)	(2)	(3)	(4)
Sl. No	Nutrient/ component*	Claim	Conditions
		High	The food provides at least 30% of RDA per 100 g for solids or 15% of RDA per 100 ml for liquids
13.	Sodium	Low	Product contains not more than 0.12 g of sodium per 100 g for solids or 100 ml for liquids.
		Very low	Product contains not more than 0.04 g of sodium per 100 g for solids or 100 ml for liquids.
		Sodium free	Product contains not more than 0.005g of sodium per 100 g for solids or 100 ml for liquids.
14.	Dietary fibre	Source	Product contains at least 3 g of fibre per 100 g or 1.5 g per 100kcal or 100 ml
		High Or Rich	The product contains at least 6 g per 100 g or 3 g per 100 kcal or 100 ml
15.	Probiotics	Source	Product contains $\geq 10^8$ CFU in the recommended serving size per day
16.	Glycemic index (GI)**	Low GI	GI value below 55 A food's GI indicates the rate at which the carbohydrate in the food is broken down into glucose and absorbed from the gut into the blood
17	Docosahexaenoic acid (DHA)	Source	Product contains at least 40 mg of DHA per 100 g and per 100 kcal.
18	Lactose	Free	Lactose content in the product shall not exceed 0.05 per cent.
19	Gluten	Free	Gluten content in the product shall not exceed 20 mg/kg.

*A food which, by its nature, free from the nutrient/component shall not qualify for claiming free of that nutrient/component.

**GI is defined as the relation of the incremental area under the blood-glucose response curve (Incremental Area Under Curve, IAUC) of a tested meal containing 50 g of digestible carbohydrates and the average incremental area under blood-glucose response curve of a reference food. Acceptable Reference foods are 1) anhydrous glucose powder (50 g), 2) Dextrose (glucose monohydrate, 55 g), 3) commercial solution used for oral glucose tolerance test containing glucose (50g) and 4) white bread or other specific carbohydrate food of consistent composition and GI.”

Note 1: Nutrient content claims for food products falling under health supplement categories shall be governed by Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.

Note2: 1 kcal = 4.2 kJ

$\% \text{ energy from the nutrient} = \frac{\text{Grams of nutrient per 100g of product} \times \text{Conversion factor for nutrient}}{\text{Total Energy per 100g of product}} \times 100$
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(F) For “SCHEDULE –II” the following shall be substituted, namely:-

SCHEDULE – II
[See regulation 5(3)]
Synonyms which may be used for claims defined in these regulations

Free	Low	Reduced	High	Increased	Source
Zero, No, Without, Negligible Source	Little, few (for calories), contains a small amount of, low source of, Lite, Light	Lower, Lesser, fewer (for calories),	More, Rich	, Higher, Enhanced	Provides, Contains

(G) For “SCHEDULE –III” the following shall be substituted, namely:-

SCHEDULE – III

[See regulation 7 (3)]

Reduction of disease risk claims			
SI. No.	Nutrient/Food-Health Relationship	Conditions for claim	Claim Statement
1	Calcium or Calcium and Vitamin D and osteoporosis	<ul style="list-style-type: none"> ○ the food is a source or high in calcium or in calcium and vitamin D and ○ a statement that the beneficial effect is obtained with a daily recommended intake (RDA) 	Adequate Calcium (or Calcium and Vitamin D) intake throughout life, through a balanced diet are essential for bone health and to reduce the risk of osteoporosis
2	Sodium and Hypertension	<p>A food which</p> <ul style="list-style-type: none"> ○ is low in sodium (0.12g sodium/100g or 100ml) ○ a statement that the beneficial effect is obtained with a low sodium diet. 	Diets low in sodium may help in reducing the risk of high blood pressure.
3	Dietary saturated fat and blood cholesterol	<ul style="list-style-type: none"> ○ low saturated fat ○ a statement that the beneficial effect is obtained with a diet low in fat, saturated fat and physical activity 	<i>Diets low in saturated fat contributes to reduction of blood cholesterol levels.</i>
4	Potassium and risk of high blood pressure	<p>the food is a good source of potassium and is</p> <ul style="list-style-type: none"> ⊖ low in sodium ○ low in total fat and saturated fat. 	Diets containing good sources of potassium and low in sodium, fat and saturated fat may help reduce the risk of high blood pressure.
5	Alpha – linolenic acid(ALA) and blood cholesterol level	<ul style="list-style-type: none"> ○ the food contains at least 1g of omega-3 fatty acids per 100g or 100ml or 100kcal. ○ statement that the beneficial effect is obtained with daily intake of 2g of ALA 	Alpha – linolenic acid (ALA) contributes to the maintenance of normal blood cholesterol levels.
6	Soluble Dietary Fibre and blood cholesterol	<ul style="list-style-type: none"> ○ soluble dietary fibre from food sources including but not limited to oats, barley, millets or mixtures thereof ○ contains at least 1g per serving ○ statement that the beneficial effect is obtained with daily intake of 3g of soluble dietary fibre. 	<i>Soluble dietary fibre taken as part of a diet contributes to reduction of blood cholesterol levels.</i>

7	Phytosterol or stanol and blood cholesterol	food with phytosterol or stanol <ul style="list-style-type: none"> ○ contains at least 1g plant sterols or stanols per serving and ○ a statement that the beneficial effect is obtained with a daily intake of up to 3g per day. 	Foods containing plant sterols or stanols (as applicable) containing at least 1g of plant sterols or stanols eaten twice a day with meals for a daily intake of up to 3g <i>contributes to reduction of blood cholesterol levels.</i>
8	Beta-glucans(oats, barley) and blood glucose	<ul style="list-style-type: none"> ○ the food is oats and/or barley, ○ contains at least 4g beta-glucans for each 30g of available carbohydrates in the quantified portion ○ statement that it is taken as part of the meal. 	Beta- glucans from oats or barley when taken as part of a meal may help in reduction of rise in blood glucose after that meal.

(H) in SCHEDULE – V,

(a) in the table, at serial number 2, against the entry “Fresh” in column 2, in clause (a), the words “If such processing also leads to extension in the shelf-life of the product the term “fresh” shall not be used.” shall be omitted.;

(b) in the table, at serial number 3, against the entry “Pure” in column 2, clause (c), shall be omitted.;