

Voluntary Report – Voluntary - Public Distribution

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Report Name: The FSSAI's 2021 Draft Amendments to the Advertising and Claims Regulation now Published as a Final Amendment

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Report Highlights:

On December 13, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) published notification No. Std/EC/T(NSF-01) (Appendix I) in the Gazette of India: Extraordinary. The notification was subsequently published on the FSSAI (food safety authority) website on December 14, 2022. This new FSSAI notification refers to amendments made in the Food Safety and Standards (Advertising and Claims) Regulations (2018). Amendments include a general principle for claims, nutrition claims, non-addition claims, and modified versions of Schedule -I on Nutrient Content Claims, Schedule-II on synonyms used for claims, and Schedule-III on reduction of disease risk claims.

DISCLAIMER: The information contained in this report was retrieved from the Food Safety and Standards Authority of India’s (FSSAI) website <http://www.fssai.gov.in>. The Foreign Agricultural Service (FAS) Office of Agricultural Affairs at the U.S. Embassy in New Delhi, USDA, and/or the U.S. government make no claim of accuracy or authenticity. The Government of India has not officially endorsed this report. Import approval for any product is subject to local rules and regulations as interpreted by Indian officials at the time of product entry. [Note: Use Google Chrome to access the links that do not open in Microsoft Edge. Indian host sites will geo-block site access on a rolling basis].

GENERAL INFORMATION:

On December 13, 2022, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) published notification **No. Std/EC/T(NSF-01)** (see: Appendix I) in the Gazette of India: Extraordinary. The notification was subsequently published on the FSSAI website on December 14, 2022. This new FSSAI notification refers to amendments made in the Food Safety and Standards (Advertising and Claims) Regulations (2018). Amendments include a general principle for claims, nutrition claims, non-addition claims, and modified versions of Schedule -I regarding Nutrient Content Claims, Schedule-II on synonyms used for claims, and Schedule-III on the reduction of disease risk claims.

FAS New Delhi (Post), in comparing the just published final amendment with the earlier draft amendment published on December 27, 2021, finds that the newly issued amendment includes provisions for certain sub-regulations and the Schedule I, II and III have been modified. Post strongly advises interested stakeholders to thoroughly read the entire text of the published final amendment pasted below in this report as Appendix I. The full text of the Food Safety and Standards (Advertising and Claims) Second Amendment Regulations (2022) is also accessible on the FSSAI’s website located at:

https://fssai.gov.in/upload/notifications/2022/12/63998e33c2ad6Gazette_Notification_Amendment_14_12_2022.pdf. World Trade Organization members had been previously invited to comment on the draft amendment.¹ All other information remains the same.

¹ See, USDA GAIN: “India’s FSSAI Publishes Draft Amendments for Advertising and Claims Regulations,” [IN2022-0003](https://www.gain.gov/india/2022/0003).

**APPENDIX I: FOOD SAFETY AND STANDARDS (ADVERTISING AND CLAIMS)
SECOND AMENDMENT REGULATIONS (2022)**

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

NOTIFICATION

New Delhi, the 13th December, 2022

No. Std/SP-08/A-1.2019/N-03.—Whereas the draft of certain rules further to amend the Food Safety and Standards (Advertising and Claims) Regulations, 2018, 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 F.No. Std/SP-08/A-1.2020/N-03, dated the 27th December, 2021, in the Gazette of India, Extraordinary, Part III, section 4, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of the period of sixty days from the date on which the copies of the Official 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 **31st December, 2021**;

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 clauses (k) and (v) of sub-section (2) of section 92 and clause (h) of sub-section (2) of section 16 read with the sections 23 and section 24 of the Food Safety and

Standards Act, 2006 (34 of 2006), the Food Safety and Standards Authority of India hereby makes the following regulations further to amend the Food Safety and Standards (Advertising and Claims) Regulations, 2018, namely: -

1. (1) These regulations may be called the Food Safety and Standards (Advertising and Claims) Second Amendment Regulations, 2022.

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

2. In the Food Safety and Standards (Advertising and Claims) Regulations, 2018 (hereinafter referred to as the said regulations), in regulation 4, -

(a) for sub-regulation (5), the following sub-regulation 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 sub-regulation 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 the consumer as to the nature of the food, in such cases a disclaimer shall be mentioned prominently on the front of pack of the label stating that –

“*This is only a brand name or trademark, or fancy name and does not represent its true nature; (relevant one may be chosen as applicable)” :

Provided that the font size of the above disclaimer shall not be less than 1.5 mm for principal display panel up to 100 cm², not less than 2 mm for principal display panel between 100-200 cm² and not less 3 mm in case of principal display panel above 200 cm².

3. In the said regulations, in regulations 5, -

(a) for sub-regulation (3), the following sub-regulation 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 the said Schedule, 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 clauses (a) and (b), the following shall be substituted, namely: -

“(a) at least thirty per cent. in the energy value or macronutrients content;

(b) at least ten per cent. of the recommended dietary allowances per 100 g or 100 ml, for claims about micronutrients other than sodium;

(c) at least twenty-five per cent. in case of sodium, or the equivalent value for salt:

Provided that in case of salt when sold as such, then ten per cent. difference shall be acceptable.”;

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

“(6) The equivalence claims in the 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 100 g or 100 ml, 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 fibre as an apple,” and “contains the same amount of vitamin C as glass of orange juice.”).

4. In the said regulations, in regulations 6, -

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

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

(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 the 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.”.

5. In the said regulations, in regulation 14, -

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

“(3) The food business operator or the marketer shall submit the information sought for within thirty days from the date of receipt of letter seeking clarification.”;

(b) in sub-regulation (5), for the words “after issuance of letter” occurring at the end, the words “from the date of receipt of notice of the suggested improvement of the claim from the Food Authority.” shall be substituted.

6. In the said regulations, for Schedules– I, II and III, the following Schedules shall be substituted, namely:

“SCHEDULE – I

[See regulation 5 (3) 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) in the table below:

Sl. No	Nutrient or component	Claim	Conditions
(1)	(2)	(3)	(4)
1.	Energy or Calorie	Low	Not more than 40 kcal per 100 g for solids, or 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 100 ml 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 100 g 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 1.5 g 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 for solids or 100 ml for liquids.
5.	Unsaturated fat	High	At least 70 per cent. of the fatty acids present in the product are derived from unsaturated fat under the condition that unsaturated fat provides more than 20 per cent. of energy of the product
6.	Trans fat	Free	The food contains less than 0.2 g trans fat per 100 g for solids or 100 ml for liquids. Provided that for edible oils/fats: 1 g per 100 g or 100 ml of edible oils or fats
7.	Monounsaturated Fatty Acids	High	Shall only be made where at least 45 per cent. of the total fatty acids present in the product are derived from monounsaturated fat and under the condition that monounsaturated fat provides more than 20 per cent. of energy of the product
8.	Polyunsaturated Fatty Acids	High	Shall only be made where at least 45 per cent. of the total fatty acids present in the product are derived from polyunsaturated fat and under the condition that polyunsaturated fat provides more than 20 per cent. of energy of the product
9.	Omega 3 fatty acids	Source	The product contains - at least 0.3 g alpha-linolenic acid per 100 g or per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g or per 100 kcal
		High	The product contains: at least 0.6 g alpha-linolenic acid per 100 g or per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g or per 100 kcal
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 per cent. of Recommended Dietary Allowance per 100 g for solids 5 per cent. of Recommended Dietary Allowance per 100 ml for liquids, or 5 per cent. of Recommended Dietary Allowance per 100 kcal, or 10 per cent. of Recommended Dietary Allowance per serving
		Rich High	20 per cent. of Recommended Dietary Allowance per 100 g for solids 10 per cent. of Recommended Dietary Allowance per 100 ml for liquids, or 10 per cent. of Recommended Dietary Allowance per 100 kcal, or 20 per cent. of Recommended Dietary Allowance per serving
12.	Vitamin(s) or Mineral(s)	Source	The food provides at least - 15 per cent. of Recommended Dietary Allowance of the vitamin or mineral per 100 g for solids; or 7.5 per cent. of Recommended Dietary Allowance of the vitamin or mineral per 100 ml for liquids; or 5 per cent. of Recommended Dietary Allowance per 100 kcal; or 15 per cent. of Recommended Dietary Allowance per serving
		High	The food provides at least - 30 per cent. of Recommended Dietary Allowance per 100 g for solids; or 15 per cent. of Recommended Dietary Allowance per 100 ml for liquids; or 10 per cent. of Recommended Dietary Allowance per 100 kcal; or 30 per cent. of Recommended Dietary Allowance per serving

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 0.005 g 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 for solids; or 1.5 g of fibre per 100 ml for liquids; or 1.5 g of fibre per 100 kcal.
		High or Rich	The product contains at least - 6 g of fibre per 100 g for solids; or 3 g of fibre per 100 ml for liquids; or 3 g of fibre per 100 kcal.
15.	Probiotics	Source	Product contains $\geq 10^8$ Colony Forming Unit 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 or per 100 kcal.
18.	Lactose	Free	Lactose content in the product shall not exceed 0.1 per cent.
19.	Gluten	Free	Gluten content in the product shall not exceed 20 mg/kg.

*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 taken by the same subject. 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 (50 g); 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.

Note 2: 1 kcal = 4.2 kJ

$$\% \text{ energy from the nutrient} = \frac{\text{Grams of nutrient per 100 g of product} \times \text{Conversion factor for nutrient}}{\text{Total Energy per 100 g of product}} \times 100$$

SCHEDULE – II

[See regulation 5(3)]

Synonyms which may be used for claims defined in these regulations

Free (1)	Low (2)	Reduced (3)	High (4)	Increased (5)	Source (6)
Zero, No, Without, Negligible Source	Little, few (for calories), contains a small amount of, low source of, Lite, Light	Lower, Lesser, fewer (for calories)	Rich	More, Higher, Enhanced	Provides, Contains.

SCHEDULE – III

[See regulation 7 (3)]

Reduction of disease risk claims

The claim statements provided below may be used on labels and/or advertisements.

SI. No. (1)	Nutrient or Food-Health Relationship (2)	Conditions for claim (3)	Claim Statement (4)
1	Calcium or Calcium and Vitamin D and osteoporosis	(i) The food is a source or high in calcium or in calcium and vitamin D; and (ii) 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	A food which - (i) is low in sodium (0.12 g sodium/100 g or 100 ml); and (ii) 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	(i) low saturated fat; and (ii) a statement that the beneficial effect is obtained with a diet low in fat, saturated fat and physical activity	Diets low in saturated fat contributes to reduction of blood cholesterol levels.
4	Potassium and risk of high blood pressure	The food is a good source of potassium and is - (i) low in sodium; and (ii) 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	(i) The food contains at least 1 g of omega-3 fatty acids per 100 g or 100 ml or 100 kcal; and (ii) a statement that the beneficial effect is obtained with daily intake of 2 g of ALA	Alpha – linolenic acid (ALA) contributes to the maintenance of normal blood cholesterol levels.
6	Soluble Dietary Fibre and blood cholesterol	(i) Soluble dietary fibre from food sources including but not limited to oats, barley, millets or mixtures thereof; (ii) contains at least 1 g per serving; and (iii) statement that the beneficial effect is obtained with daily intake of 3 g of soluble dietary fibre.	Soluble dietary fibre taken as part of a diet contributes to reduction of blood cholesterol levels.
7	Phytosterol or stanol and blood cholesterol	Food with phytosterol or stanol - (i) contains at least 1 g plant sterols or stanols per serving; and (ii) a statement that the beneficial effect is obtained with a daily intake of up to 3 g 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 3 g contributes to reduction of blood cholesterol levels.
8	Beta-glucans (oats, barley) and blood glucose	(i) The food is oats or barley; (ii) contains at least 4 g beta-glucans for each 30 g of	Beta- glucans from oats or barley when taken as part of a

		(iii) available carbohydrates in the quantified portion; and a statement that it is taken as part of the meal.	meal may help in reduction of rise in blood glucose after that meal.
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Note: Food Business Operators may choose to use same or similar terms in the claim statements as provided in this Schedule while ensuring that the intent and meaning of the claim is not changed.”.

7. In the said regulations, in SCHEDULE – IV, in the table, against serial number 4 relating to “Folate and Folic Acid” in column (3) under the sub-heading “Claims”, for the words “Folate & Folic acid is important for foetal development and blood formation”, the words “Folate and Folic Acid is important for blood formation” shall be substituted.

8. In the said regulations, in SCHEDULE – V, in the table, -

- (a) against serial number 2 relating to 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) against serial number 3 relating to the entry “Pure”, in column 2, clause (c) shall be omitted.

S. GOPALAKRISHNAN, Chief Executive Officer

[ADVT.-III/4/Exty./462/2022-23]

Attachments:

No Attachments.