

Food Safety and Standards (Advertising and Claims) Regulations, 2018

1. Short title and commencement- (1) These regulations may be called the Food Safety and Standards (Advertising and Claims) Regulations, 2018.

(2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations by 1st July, 2019.

2. Definitions – (1) In these regulations unless the context otherwise requires, -

- (a) “Act” means the Food Safety and Standards Act, 2006 (34 of 2006);
- (b) “advertisement” means any audio or visual publicity, representation or pronouncement made by means of any light, sound, smoke, gas, print, electronic media, internet or website and includes through any notice, circular, label, wrapper, or other documents;
- (c) “balanced diet” means a diet containing all essential (macro and micro) nutrients in optimum quantities and in appropriate proportions that meet the requirements;
- (d) “claim” means any representation which is printed, oral, audio or visual and states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or otherwise;
- (e) “dietary fiber” means carbohydrate polymers with a degree of polymerisation (DP) not lower than three, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and the same consists of one or more of-
 - (i) edible carbohydrate polymers naturally occurring in the food as consumed;
 - (ii) carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means;
 - (iii) synthetic carbohydrate polymers;
- (f) “equivalence claims” means claims that attempt to promote the equality in value, amount and importance of one food attribute to another;
- (g) “fat” means total lipids including saturated fat, monounsaturated fat, polyunsaturated fat and trans fat.

Explanation.- for the purposes of this clause,-

- (i) “saturated fats” means fatty acids without double bonds;
 - (ii) “monounsaturated fats” means fatty acids with one cis double bond;
 - (iii) “polyunsaturated fats” means fatty acids with cis-cis methylene interrupted double bonds; and
 - (iv) “trans fat” means all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration;
- (h) “health claim” means any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health, which includes the following, namely:-
- (i) “nutrient function claim” is that which describes the physiological role of the nutrient in growth, development and normal functions of the body;
Example: Nutrient ‘A’ - naming a physiological role of nutrient ‘A’ in the body in maintenance of health and promotion of normal growth and development. (Food X is a rich source of or high in nutrient ‘A’);
 - (ii) “other function claim” that describes the specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet or normal functions or biological activities of the body, which relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.
Example: Substance A naming the effect of substance A on improving or modifying physiological function or biological activity, associated with health (Food Y contains X grams of substance ‘A’).;

(iii) “reduction of disease risk claims” refers to claims that state, suggest or imply that consumption of such foods or food constituents, in the context of total diet, reduce the risk of developing a disease or health related condition.

Explanation.- for the purpose of this sub-clause, “reduction of disease risk” means significantly altering major risk factors, for a disease or health related condition as diseases have multiple risk factors and altering one of these risk factors may or may not have a beneficial effect and the presentation of risk reduction claim must ensure, for example, by use of appropriate language and reference to other risk factors, that consumers do not interpret them as prevention claims.

Examples:

(a) *A healthful diet low in nutrient or substance ‘A’ may reduce the risk of disease D. Food X is low in nutrient or substance ‘A’;*

(b) *A healthful diet rich in nutrient or substance ‘A’ may reduce the risk of disease D. Food X is rich in nutrient or substance ‘A’;*

- (i) “marketer” refers to persons or companies, including advertisers, and direct marketers, including e-platforms who or on whose behalf marketing communications are published for the purpose of promoting their products or influencing consumer behaviour;
- (j) “marketing communications” includes advertising as well as other techniques, such as promotions, sponsorships and direct marketing, and shall be interpreted broadly to mean any communications produced directly by or on behalf of marketers intended primarily to promote products or to influence consumer behaviour;
- (k) “nutrient” means a constituent of food, which-
 - (i) provides energy ; or
 - (ii) has specific metabolic or physiological functions; or
 - (iii) is needed for growth and development and maintenance of healthy life;
- (l) “nutrition claim” means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins, minerals and other permitted listed nutrients and nutrition claims may include the following:
 - (i) “nutrient content claim” is a nutrition claim that directly or indirectly describes the level of a nutrient contained in a food. (Examples: contains or source of; high in; rich in; low in, etc.);
 - (ii) “nutrient comparative claim” is a claim that compares the nutrient levels or energy value of two or more foods. (Examples: reduced; less than; fewer; increased; more than, etc.);
- (m) “non-addition claim” means any claim that an ingredient or additive has not been added to a food, either directly or indirectly and the ingredient or additive is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food;
- (n) “recommended dietary allowances” means the average daily dietary nutrient intake level sufficient to meet the nutrient requirement of nearly all (97 to 98 per cent.) healthy individuals in a particular life stage and gender group.

Explanations.- For the purposes of this clause, recommended dietary allowances values as provided in current Indian Council of Medical Research Nutrient Requirements and Recommended Dietary Allowances for Indians shall be applicable and if Indian recommended dietary allowances is not available for any nutrient then values provided in Codex or World Health Organization guidelines shall be applicable;
- (o) “sugars” means all monosaccharides (glucose, fructose, etc.) and disaccharides (maltose, sucrose, lactose, etc.).

(2) All other words and expressions used herein and not defined, but defined in the Act, rules or regulations made thereunder, shall have the meanings assigned to them in the Act, rules or regulations, respectively.

3. Food business operator and marketers to follow general principles.- Every food business operator and marketer while advertising and publishing or disseminating marketing communication meant for promotion or sale of any article of food including labelling claims shall comply with the following general principles:

Provided that advertisements and claims in respect of food meant for infants shall be in accordance with the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 (41 of 1992) Act).

4. General principles.-

(1) Claims must be truthful, unambiguous, meaningful, not misleading and help consumers to comprehend the information provided.

(2) Claims shall not encourage or condone excess consumption of a particular food.

(3) Claims shall not state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients as required by the body.

(4) Where the claim benefit is related to or dependent on the method of preparation of the food the same shall be provided on the label.

(5) Claims shall specify the number of servings of the food per day for the claimed benefit.

(6) The claim that a food has certain nutritional or health attributes shall be scientifically substantiated by validated methods of characterising or quantifying the ingredient or substance that is the basis for the claim.

(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”, etc., 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 3mm size 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”.

(8) All disclaimers related to a claim shall be conspicuous and legible.

(9) Notwithstanding the mandatory declaration of Food Safety and Standards Authority of India logo and license number as per Food Safety and Standards (Packaging and Labelling) Regulations, 2011, no claim or promotion of sale, supply, use and consumption of articles of foods shall be made using Food Safety and Standards Authority of India logo and license number.

(10) Advertisements shall also not undermine the importance of healthy lifestyles.

(11) Advertisements for food or beverages shall not be promoted or portrayed as a meal replacement unless otherwise specifically permitted as a meal replacement under any other Regulations made under Food Safety and Standards Act, 2006 (34 of 2006)

(12) Claims in advertisements shall be consistent with information on the label of the food or beverage.

(13) No advertisement shall be made for food products which is deceptive to the consumers.

(14) Every declaration which is required to be made on advertisements under these regulations shall be conspicuous and legible.

5. Nutrition claims.-

(1) Nutrition claims may be.-

(a) nutrient content claim; or

(b) nutrient comparative claim

(2) The following do not constitute nutrition claims, namely:-

(a) the mention of substances in the list of ingredients;

(b) the mention of nutrients as a mandatory part of nutrition labelling;

(c) quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by Food Safety and Standards Act, 2006 (34 of 2006) and the rules and regulations made thereunder.

(3) Nutrient content or nutrient comparative claim or any synonymous claim 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.

(4) Where a nutrient comparative claim is made, the foods shall be different versions of the same food or similar foods being compared and shall be easily identifiable and the relative difference of the claimed parameter between the compared foods is-

(a) at least twenty-five per cent. in the energy value or nutrient content and a minimum absolute difference equivalent to the figure defined as "low" or as a "source" in Schedule I, for claims about energy or macronutrients and sodium respectively.

(b) at least ten per cent. of recommended dietary allowances, for claims about micronutrients other than sodium.

(5) In addition, where a comparative claim is made, the identity of the foods being compared and the amount of difference expressed as a percentage, fraction or an absolute amount shall be given in close proximity to the claim.

(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 (e.g., "as much fiber as an apple," and "contains the same amount of vitamin C as glass of orange juice.")

6. Non-addition claims.-

(1) Non-addition of sugars.- (a) Claims regarding the non-addition of sugars to a food may be made if the following conditions are met, namely:-

(i) no sugars of any type have been added to the food (Examples: sucrose, glucose, honey, molasses, corn syrup, etc.);

(ii) the food contains no ingredients that contain sugars as an ingredient (Examples: jams, jellies, sweetened chocolate, sweetened fruit pieces, etc.);

(iii) the food contains no ingredients containing sugars that substitute for added sugars (Examples: non-reconstituted concentrated fruit juice, dried fruit paste, etc.); and

(iv) the sugars content of the food itself has not been increased above the amount contributed by the ingredients by some other means (Example: the use of enzymes to hydrolyse starches to release sugars).

(b) Claims regarding the non-addition of sugars to a food may also be made, where sugars are naturally present in the food, and in such case the following indication shall also appear on the label.

‘CONTAINS NATURALLY OCCURRING SUGARS’.

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

(a) The food contains no added salt (sodium chloride); and

(b) The food contains no ingredients that contain added salt (sodium chloride) including but not limited to sauces, pickles, pepperoni, soya sauce, salted fish, fish sauce.

(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 if that the additive for which claim is made-

(a) has not been added to the food;

(b) is not contained in any ingredient of the food;

(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

(4) Additional conditions for non-addition claims.- The additional conditions or disclaimer statements may be used with non-addition claims to assist consumer understanding of the claims provided that the disclaimer statements shall be conspicuous and legible.

7. Health claims.- (1) Health claims shall comply with the following conditions and declarations, namely:-

- (a) the health claim must consist of two parts, namely:-
 - (i) information on the physiological role of the nutrient or substance or an accepted diet- health relationship; and
 - (ii) information on the composition of the product relevant to the physiological role of the nutrient or substance or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food;
- (b) if the claimed benefit is attributed to a constituent in the food, for which a recommended dietary allowance value is established, the food in question shall be-
 - (i) a source of or high in the constituent, in accordance with conditions specified in Schedule I, in the case where increased consumption is recommended; or,
 - (ii) low in, reduced in or free of the constituent, in accordance with conditions specified in Schedule I, in the case where reduced consumption is recommended;
- (c) a statement of the quantity of a nutrient or a substance that is the subject of the claim, per 100g or 100ml or per pack (single consumption pack) of the food;
- (d) where applicable, target group shall be mentioned or where a certain contraindication exists, advice to vulnerable groups on consumption or avoidance of the food shall be made available;
- (e) directions for use of the food to obtain the claimed benefit in the context of the diet and other lifestyle factors where appropriate;
- (f) maximum safe intake of the food or the constituent, if necessary.

(2) Nutrient function claims and other function claims may be made based on current relevant scientific substantiation and to provide sufficient evidence on the type of claimed effect and the relationship to health as recognised by generally accepted scientific review of the data and the scientific substantiation shall be reviewed by food business operator as new knowledge becomes available and claims updated accordingly.

¹[(2A) Claims including nutrient function claims for edible vegetable oils may be made as provided in Schedule – IIA.]

(3) No reduction of disease risk claims shall be made that is not in accordance with the conditions specified in Schedule III.

(4) Food articles that are fortified as per Food Safety and Standards (Fortification of Foods) Regulations, 2018 may make health claims as provided in Schedule IV and flexibility in the wordings of the claim statement is acceptable, if the meaning of the claim is not altered.

(5) Where a claimed health benefit is attributed directly to the product, it shall be based on statistically significant results from well-designed human intervention studies, conducted by or under guidance of established research institutions, in line with the principles of GCP (Good Clinical Practices) and peer reviewed or published in a peer reviewed reputed scientific journal.

8. Claims related to dietary guidelines or healthy diets.- (1) claims may be made related to a “healthy diet” or any synonymous term referring to the pattern of eating as per current Indian Council of Medical Research Dietary Guidelines for Indians and the label shall carry a statement relating the food to the pattern of eating described thereof.

(2) Foods, which are described as part of a healthy diet, balanced diet shall not be based on selective consideration of one or more aspects of the food and shall also satisfy the criteria for other major nutrients related to the current Indian Council of Medical Research Nutrient Requirements and Recommended Dietary Allowances for Indians and Indian Council of Medical Research Dietary Guidelines for Indians, based on scientific evidence.

(3) Foods shall not be described as “healthy” or be represented in a manner that implies that a food in and of itself will impart health.

(4) Flexibility in the wordings is acceptable, if the claims remain faithful to the pattern of eating outlined in the current Indian Council of Medical Research Nutrient Requirements and Recommended Dietary Allowances for Indians and Indian Council of Medical Research Dietary Guidelines for Indians.

9. Conditional Claims.- (1) a claim may be made where a food is by its nature high or low or free of a specific nutrient provided the name of the nutrient or substance is preceded by the words 'natural or naturally' in the claim statement.

Explanation: "a naturally low (naming a nutrient or substance) food" or "a naturally (naming the nutrient or the substance) free food".

(2) claims containing adjectives such as "natural", "fresh", "pure", "original", "traditional", "Authentic", "Genuine", "Real", etc. , when used, shall be in accordance with conditions laid down in Schedule V and the claims containing words or phrases like "home-made", "home cooked", etc., which may give an erroneous impression to the consumer shall not be used.

10. Prohibited claims.- (1) no claims shall be made which refer to the suitability of the food for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition unless specifically permitted under any other regulations made under Food Safety and Standards Act, 2006 (34 of 2006).

(2) There shall not appear in the label of any package, containing food for sale the words "recommended by the medical or nutrition or health professionals" or any words which imply or suggest that the food is recommended, prescribed, or approved by medical practitioners or approved for medical purpose.

(3) No product shall claim the term "added nutrients", if such nutrients have been added merely to compensate the nutrients lost or removed during processing of the food

(4) Foods for special dietary uses or foods for special medical purposes shall not carry a claim unless specifically permitted under any other regulations made under Food Safety and Standards Act, 2006 (34 of 2006).

(5) Claims which do give rise to doubt or suspicion about the safety of similar food or which may arouse fear shall not be made.

(6) No health claims shall be made for foods that contain nutrients or constituents in quantity that increase the risk of disease or an adverse health-related condition.

(7) No advertisements or claims for articles of foods shall be made by any food business operator that undermines the products of any other manufacturer for the purpose of promoting their products or influencing consumer behavior.

11. Approval of claims.- The food business operator or marketer shall seek prior approval from the Food Authority for reduction of disease risk claims other than those that are defined and for which criteria are laid out under these regulations or any other regulations made under the Food Safety and Standards Act, 2006 (34 of 2006).

12. Procedure for approval of claims.- (1) The food business operator shall submit an application along with applicable fees as prescribed by Food Safety and Standards Authority of India consisting of the following information, namely:-

(i) Claim to be made;

(ii) Name of ingredient, nutrient or substance on the basis of which the claim is to be made;

(iii) Validated Method of analysis of ingredient or substance for which the claim is to be made;

(iv) Scientific information or materials substantiating the claim;

(v) How is the claim clear and meaningful and help consumers to comprehend the information provided;

(vi) Well-designed human intervention studies in case of health claims conducted by or under guidance of established research institutions; and

(vii) Any other useful information.

(2) The food authority itself or may appoint an agency or panel to carry out preliminary scrutiny of the application submitted by food business operators or marketers for approval of their claims.

(3) On scrutiny, deficiencies, if any, shall be informed to applicant within ninety days from the date of receipt of application and the applicant shall provide the information required by the food authority within thirty days of the receipt of the communication, failing which the application shall be rejected without any further reference.

(4) The fees paid by the applicant for recognition shall not be refunded under any circumstances.

(5) After scrutiny, the Food Authority may pass a speaking order either for approval or rejection of concerned claims and may also suggest an amendment for the concerned claim.

(6) The amended claim referred to in sub-regulations (5) may be submitted to the Food Authority within thirty days for reconsideration.

(7) In case of rejection, the food business operator or marketer shall not use that claim in their advertising and marketing communication in respect of articles of food offered for sale or for promotion of sale, supply, use or consumption.

13. Redressal of non-compliance.- (1) Any person who advertises or is a party to the publication of any advertisement or claims not complying with this regulation shall be penalised as per section 53 of Food Safety and Standards Act, 2006 (34 of 2006).

14. Procedure for redressal of non-compliance.- (1) The misleading claims shall be referred to the food authority or the Food Authority may on its own motion take on file any misleading claim and the Food Authority may itself analyse or may appoint an agency or panel to analyse such misleading claims.

(2) In case the agency or Food Authority requires information from the food business operator or marketer, the food authority will seek clarification failing which action shall be initiated as per sub-regulation (1) of regulation 13.

(3) the food business operator or the marketer shall submit the information sought for within thirty days from the issue of the letter.

(4) After scrutiny of the submitted information, the officer nominated by the Authority shall pass a speaking order within ninety days either for acceptance or rejection of submitted clarification on misleading claims.

(5) The Food Authority may also suggest an improvement for the concerned claim and the improved claim shall be intimated to the Food Authority within forty- five days after issuance of letter.

15. Corrective advertisement.- If an advertisement is found to be in violation of the provisions of these regulations, the Food Authority may, by order, require the concerned food business operator or advertiser to stop it immediately and to issue corrective advertisement within thirty days through the same medium for neutralising the effect of such advertisement.

SCHEDULE – I

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

NUTRITION CLAIMS

A claim that a food containing the nutrient mentioned in column (2) is likely to have the benefits 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.	Energy/Calorie	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 1.5 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 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 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

(1)	(2)	(3)	(4)
Sl. No	Nutrient/ component	Claim	Conditions
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 per 100kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal
		High	The product contains: at least 0.6 g alpha-linolenic acid per 100g and per 100kcal, or at least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and 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	¹ [Source]	10% of RDA per 100 g for solids 5% of RDA per 100 ml for liquids or 5% of RDA per 100 kcal
		¹ [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
		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
		High Or Rich	The product contains at least 6 g per 100 g or 3 g per 100 kcal

(1)	(2)	(3)	(4)
Sl. No	Nutrient/ component	Claim	Conditions
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 and expressed as a per cent of the response to the same amount of carbohydrate from a standard food, white bread

Note: 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.

1 kcal = 4.2 kJ

* To make these claims the specific nutrient in the food must provide the minimum amount of energy specified.

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

SCHEDULE – II

[See regulation 5(3)]

Synonyms which may be used for claims defined in these regulations

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

¹[SCHEDULE – IIA

List of Claims for Edible Vegetable Oils

[See regulation 7(2A)]

The claim statements provided below may be used on labels or advertisements, as the case may be:

The terms used in this Schedule such as Rich, Contains shall be in accordance with conditions specified in Schedules-I :

Provided that Food Business Operators may choose to use same or similar terms in the claim statements as provided in this Schedule while ensuring no change in the intent and meaning of the claim.

SI. No.	Edible Vegetable Oil	Claims
1.	Coconut Oil	<ul style="list-style-type: none"> Contains medium chain fatty acids that are easily metabolized.
2.	Corn Oil	<ul style="list-style-type: none"> Rich in Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA, linoleic acid); Linoleic acid is an essential fatty acid that helps to maintain normal blood cholesterol levels.
3.	Cottonseed Oil	<ul style="list-style-type: none"> Rich in Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA, linoleic acid); Linoleic acid is an essential fatty acid that helps to maintain normal blood cholesterol levels; Contains Tocopherols which are natural antioxidant.
4.	Groundnut Oil	<ul style="list-style-type: none"> Contains Mono Unsaturated Fatty Acid (MUFA) and Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA) that helps lowering of cholesterol; Contains Tocopherols which are natural antioxidant.
5.	Linseed/Flax Seed Oil	<ul style="list-style-type: none"> Rich in Omega-3 Poly Unsaturated Fatty Acid (Omega-3 PUFA, Alpha linolenic acid); Alpha linolenic acid is an essential fatty acid that contributes to the maintenance of normal blood cholesterol levels.
6.	Mustard/Rapeseed Oil (Low Erucic)	<ul style="list-style-type: none"> Rich in Mono Unsaturated Fatty Acid (MUFA) that helps to maintain blood cholesterol levels; Contains Omega-3 Poly Unsaturated Fatty Acid (Omega-3 PUFA, Alpha linolenic acid); Alpha linolenic acid is an essential fatty acid that contributes to the maintenance of normal blood cholesterol levels.
7.	Mustard Oil	<ul style="list-style-type: none"> Contains Omega-3 Poly Unsaturated Fatty Acid (Omega-3 PUFA) Alpha linolenic acid is an essential fatty acid that contributes to the maintenance of normal blood cholesterol levels Contains Tocopherols which are natural antioxidant.
8.	Olive Oil/Olive Pomace Oil/Extra virgin Olive oil	<ul style="list-style-type: none"> Rich in Mono Unsaturated Fatty Acid (MUFA) that helps to maintain blood cholesterol levels; Contains polyphenols which are natural antioxidant.
9.	Safflower Oil	<ul style="list-style-type: none"> Rich in Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA, linoleic acid) Linoleic acid is an essential fatty acid that helps to maintain normal blood cholesterol levels.
10.	Palm Kernel Oil	<ul style="list-style-type: none"> Contains medium chain fatty acids that are easily metabolized
11.	Palmolein Oil	<ul style="list-style-type: none"> Contains Tocopherols and Tocotrienols which are natural antioxidant
12.	Rice Bran Oil	<ul style="list-style-type: none"> Contains MUFA and Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA)that helps lowering of cholesterol Contains Oryzanol, Tocopherols and Tocotrienols which are natural antioxidants

		<ul style="list-style-type: none"> • Oryzanol has antioxidant property and reduces high blood cholesterol
13.	Sesame Oil	<ul style="list-style-type: none"> • Contains equal proportions of MUFA (oleic acid) and Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA, Linoleic acid) that helps lowering of cholesterol • Contains lignans which are natural antioxidants. • Contains Tocopherols which are natural antioxidant
14.	Soybean Oil	<ul style="list-style-type: none"> • Contains Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA, linoleic acid) and Omega-3 Poly Unsaturated Fatty Acid (Omega-3 PUFA, alpha linolenic acid) in appropriate proportions suggested by RDA guidelines of ICMR • Linoleic acid is an essential fatty acid that helps to maintain normal blood cholesterol levels • Alpha linolenic acid is an essential fatty acid that contributes to the maintenance of normal blood cholesterol levels • Contains Tocopherols which are natural antioxidant
15.	Sunflower Oil	<ul style="list-style-type: none"> • Rich in Omega-6 Poly Unsaturated Fatty Acid (Omega-6 PUFA, linoleic acid) • Linoleic acid is an essential fatty acid that helps to maintain normal blood cholesterol levels • Contains Tocopherols which are natural antioxidant.]

SCHEDULE – III

[See regulation 7 (3)]

HEALTH CLAIMS	
Introductory note:	<p><i>Health claims are structured on the following criteria:</i></p> <ol style="list-style-type: none"> 1. <i>Health claims are always to be stated as part of a balanced diet.</i> 2. <i>To obtain the claimed benefit two conditions are to be complied with</i> <ol style="list-style-type: none"> a. <i>A specified amount of the nutrient/ingredient per serving of the food for example 1 g 'X' nutrient)</i> b. <i>A statement that in order to obtain the claimed benefits, the daily intake of the nutrient/ingredient (for example 3g of 'X' nutrient) should be taken either from the same food or any other food that provides the beneficial nutrient/ingredient.</i> 3. <i>The health claims regarding vitamins and minerals – a statement regarding the RDA for the specific vitamin and mineral shall be given. Where no RDA is established by ICMR, the RDA provided in Codex/WHO guidelines shall be applicable.</i> 4. <i>The claim statements provided below may be used on labels and/or advertisements. Provided further that Food Business Operators may choose to use same or similar terms in the claim statements as provide in the schedule under this regulation while ensuring that the intent and meaning of the claim is not changed.</i>

Sl. 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 level	<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 	Diets low in saturated fat contributes to the maintenance of normal blood cholesterol levels.
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 lipid profile	<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. 	Soluble Dietary Fibre taken as part of a diet may help in the maintenance of normal lipid profile.
7	Phytosterol or stanol and lipid profile	<p>food with phytosterol or stanol</p> <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 may help in improving the lipid profile.
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.

SCHEDULE – IV
[See regulation 7 (4)]
Health Claims for Fortified Food Articles

Sl. No.	Nutrients	Claims
1.	Vitamin A	Vitamin A helps against night blindness.
2.	Vitamin D	Vitamin D supports strong bones.
3.	Vitamin B12	Vitamin B12 is important for maintaining normal functioning of Nervous system and blood formation.
4.	Folate & Folic acid	Folate & Folic acid is important for foetal development and blood formation.
5.	Iron	Iron fights Anemia.
6.	Iodine	Iodine is required for normal growth, thyroid and brain function.
7.	Zinc	Zinc supports a healthy immune system.
8.	Thiamine	Thiamine is required for normal nerve and heart function.
9.	Riboflavin	Riboflavin is necessary to release the energy from food.
10.	Niacin	Niacin is necessary to release the energy from food.
11.	Pyridoxine	Pyridoxine is necessary to release the energy from food.

SCHEDULE – V
[See regulation 9 (2)]
Use of certain words or phrases

The following words or phrases used as specified in column 1 shall be used according to the conditions listed in column 2:

Sl. No.	Column 1	Column 2
1.	Natural	<p>The word may be used to describe:</p> <p>(a) A single food, derived from a recognised source viz., plant, animal, microorganism or mineral and to which nothing has been added and which have been subjected only to such processing which would only render it suitable for human consumption like:</p> <p>(i)smoking without chemicals, cooking processes such as roasting, blanching and dehydration and physical refining;</p> <p>(ii)freezing, concentration, pasteurization, sterilisation and fermentation; and</p> <p>(Iii)packaging done without chemicals and preservatives.</p> <p>(b) Permitted food additives that are obtained from natural sources by appropriate physical processing.</p> <p>(c) Composite foods shall not themselves be described directly or by implication as “natural” but such foods may be described as “made from natural ingredients” if all the ingredients or food additives meet the criteria in (a) and (b) above:</p> <p>Provided that, the above principles shall also apply to use of other words or</p>

Sl. No.	Column 1	Column 2
		<p>expressions such as “real”, “genuine”, when used in place of “natural “in such a way as to imply similar benefits.</p> <p>Provided further that the, claims such as “natural goodness”, “naturally better”, “nature’s way” shall not be used.</p>
2.	Fresh	<p>(a) The term “fresh” shall only be used on products which have not been processed in any manner except, washed, peeled, chilled, trimmed or cut, irradiated by ionizing radiation not exceeding 1kGy or other processing necessary for making the product safe for consumption without altering its basic characteristics in any manner. If such processing also leads to extension in the shelf-life of the product the term “fresh” shall not be used.</p> <p>(b) The term “fresh” or “freshly” shall have no other connotation than the immediacy of the action being described. A food containing additives or subjected to packaging, storing or any other supply chain processes that control freshness shall not be termed as “freshly stored”, “freshly packed”, etc.:</p> <p>Provided that “Fresh” may be permitted to be used along with “frozen” if it is clear from the context. - “Frozen from fresh” “fresh frozen” “Freshly frozen”– which would indicate that the food was quickly frozen while still fresh.</p>
3.	Pure	<p>(a) The term “pure” shall only be used to describe a single ingredient food to which nothing has been added and which is free from avoidable contamination and the levels of unavoidable contaminants shall need to be below the levels prescribed in the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 or in any other standard given under Food Safety and Standards Act, Rules and Regulations thereof.</p> <p>(b) Compound foods shall not generally be described, directly or by implication, as “pure” but such foods may be described as “made with pure ingredients” if all the ingredients meet the criteria in (a) above.</p> <p>(c) “Pure” shall not be included in any brand or fancy names, nor in coined or meaningless phrases, in such a way as to imply that a food that does not meet the criteria above is pure or made from pure ingredients.</p>
4.	Authentic, Genuine, Real	<p>These terms may be used only if the label or advertisement also clarify in what way the overall quality is tangibly justified and why the particular term has been used.</p>
5.	Traditional	<p>The term “traditional” shall demonstrably be used to describe a recipe, fundamental formulation or processing method for a product that has existed for a generation (thirty years), should have been available substantially unchanged, for that same period.</p>
6.	Original	<p>(a)The term “original” shall only be used to describe a food that is made to a formulation, the origin of which can be traced, and that has remained essentially unchanged over time. It should not contain replacements for major ingredients. It may similarly be used to describe a process, provided it is the process first used in the making of the food, and which has remained essentially unchanged over time, although it may be mass-produced.</p> <p>(b) To be termed “original”, a product shall not have changed to any material</p>

Sl. No.	Column 1	Column 2
		degree and shall remain available as the 'standard' product when new variants are introduced. A product re-introduced onto the market after a period of absence shall only be described as "original" if it can be shown to meet these criteria.

Note:The principal regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number F.No. 1-94/FSSAI/SP(Claims and Advertisements)/2017, dated the 19th November, 2018 and subsequently amended vide notification no.:

1. F. No. Stds/SP(L&C/A)/Oil Claims/FSSAI-2018, dated 9th October, 2020.