

File No.1-94/FSSAI/SP/(Labelling)/2009
Food Safety and Standards Authority of India
(Ministry of Health and Family Welfare)

FDA Bhavan, Kotla Road
New Delhi-110002
Date: 27th Dec, 2012

Subject: Draft “Regulation on Labelling (Claims)”

FSSAI has prepared the Draft “Regulation on Labelling (Claims)”. These are being placed on website for wider consultation/ and soliciting suggestions.

The Suggestions, if any may be addressed to Dr. A. Madhavan, Assistant Director, Food Safety and Standards Authority of India, FDA Bhawan, Kotla Road, New Delhi-110002 or sent by E-mail at madhavan.fssai@gmail.com on or before 31 /01/2013.

Yours faithfully,

Sd/-
(Dr. A. Madhavan)
Assistant Director (Enf-I)

Draft Regulation on [Labelling (Claims)]

PART 4.1: DEFINITIONS

1. “Act” means the Food Safety and Standards Act, 2006 (Act 34 of 2006);
2. “Best before” means the date which signifies the end of the period under any stated storage conditions during which the product shall remain fully marketable and shall retain any specific qualities for which tacit or express claims have been made. Beyond that date, the food may still be perfectly safe to consume, however, its quality may have diminished..
3. “Bulk Pack” means a commodity of food packed in bulk for storage, transportation or selling to an intermediary to enable such intermediary for further processing or selling, distributing or delivering such commodity of food in smaller quantities, for sale to the consumer.
4. “Assorted pack” means a package containing two or more individual packages of different/dissimilar foods.
5. “Confectionery “ means sugar boiled confectionery, lozenges and chewing gum and bubble gum
6. “Date of manufacture” means the date on which the food becomes the product as described
7. “Date of packaging” means the date on which the food product is placed in the immediate container in which it will be ultimately sold;
8. “Dietary Fibre” means carbohydrate polymers with a degree of polymerisation (DP) not lower than 3 which are not hydrolysed by the endogenous enzymes in the small intestine of humans. Dietary fibre consists of one or more of:
 - Edible carbohydrate polymers naturally occurring in the food as consumed,
 - carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means,.
 - synthetic carbohydrate polymers.
9. ‘**Industrial Pack**’ means a packaged commodity purchased from the manufacturer / packer for further processing by the business operator / industrial consumer in order to make a finished product to be used by the end consumer
10. "Infant" means a child not more than twelve months of age;
11. “Institutional pack” means a packaged commodity purchased from the manufacturer / packed for an institutional consumer for its own use or redistribution, but not for retail sale.
12. "Label” means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed graphic, perforated, stamped or impressed or securely affixed to the container, cover, lid or crown of any food package.
13. “Labeling” includes any written, printed or graphic matter that is present on the

- label accompanying the food.
- 14.** “Lot number” or “code number” or “batch number” means the number either in numericals or alphabets or in combination thereof, representing the lot number or code number or batch number, being preceded by the words “Lot No” or “Lot” or “code number” or “Code” or Batch No” or “Batch” or any other distinguishing prefix by which the food can be traced in manufacture and identified in distribution
- 15.** "Multipiece package" means a package containing two or more individually packaged or labelled pieces of the same commodity of identical quantity, intended for retail either in individual pieces or packages as a whole.
- 16.** "Non- Vegetarian Food” means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but does not include milk, milk products or honey as an ingredient;
- 17.** “Nutrient” means any substance normally consumed as a constituent of food
- a) which provides energy; or
 - b) which is needed for growth and development and maintenance of healthy life; or
 - c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur. These include Vitamins, minerals & trace elements, protein, carbohydrate, fat, fibre, amino acids.
- 18.** “Prepackaged” or “Pre-packed food” means food, which is placed in a package of any nature, in such a manner that the contents cannot be changed without tampering it and which is ready for sale to the consumer.
- Note: The expression “package” wherever it occurs in these Regulations, shall be construed as package containing prepacked food articles.
- 19.** “Principal display panel” in relation to a package means that part of total surface area of a label, which is intended or is likely to be displayed, and presented or shown to a customer under normal and customary conditions of display, sale or purchase of the commodity contained in the package.
- 20.** “Retail pack or Retail unit” The smallest unit of food packaged individually that can be sold to the ultimate consumer
- 21.** “Use – by date” or “Recommended last consumption date” or “Expiry date” means the date which signifies the end of the estimated period under any stated storage conditions, after which product may not remain safe and the food shall not be consumed.
- 22.** “Vegetarian Food” means any article of Food other than Non- Vegetarian Food as defined in these regulations.
- 23.** “Wholesale package” means a package containing -
- a. a number of retail packages, where such first mentioned package is intended for

sale, distribution or delivery to an intermediary and is not intended for sale direct to a single consumer; or

- b. Packages containing two or more retail packs which is not intended to be sold as such to consumer but only after opening and individually as retail packs.
- c. a commodity of food sold to an intermediary in bulk to enable such intermediary to sell, distribute or deliver such commodity of food to the consumer in smaller quantities.

Other expressions used in these Regulations but have not been defined herein shall have the meaning ascribed to them in the Act or as provided in the Regulations, various Chapters and Appendices.

DRAFT

PART 4.2: MANDATORY LABELLING

REQUIREMENTS Regulation 4.2.1: General

Requirements

- A. Every prepackaged food shall carry a label containing information as required under these regulations unless otherwise provided;
- B. When a food product is sold through websites, using mobile phones or any other direct selling means, the statutory requirements of the label as given in these regulations shall be provided to the consumer through appropriate means before a purchase to enable the consumers to make an informed decision of purchase.
- C. A label shall not contain any statement, claim, design, device, fancy name or abbreviation which is false or misleading in any way particularly concerning the food contained in the package, or concerning the quantity, quality or the nutritive value of the food or in relation to the place of origin of the said food or is likely to create an erroneous impression regarding its character of the food.

Any information or pictorial device written, printed, or graphic matter may be displayed on the label provided that it is not in conflict with the requirements of these Regulations. **Provided** that established trade or fancy names of confectionery, biscuits and sweets, such as, barley sugar or in respect of aerated waters, such as, Ginger Beer or Gold-Spot or any other name in existence in international trade practice may be used.

- D. The particulars of declaration required under these Regulations printed on the label shall be in English or Hindi in Devnagri script.

Provided that nothing herein contained shall prevent the use of any other Indian language in addition to the language required under this regulation.

Also provided that the information provided in such other language must not contradict the information on the label in the English or Hindi.

- E. Label on pre-packaged foods shall be applied in such a manner that they will not become separated from the container under normal conditions of handling and distribution.
- F. Contents on the label shall be clear, unambiguous, prominent, conspicuous, indelible and readily legible by the consumer under normal conditions of purchase and use. The declarations should be printed or inscribed on the package in such style or type of lettering so as to be boldly, clearly and conspicuously present in distinct contrast to the background of the label.

Provided that where any label information is blown, formed or moulded on a glass or plastic surface or where such information is embossed or perforated on a package, that information is not be required to be presented in contrasting colours but shall be prominent and clearly legible.

- G. Where any declaration on a package is printed either in the form of a handwriting or hand script, such declaration shall be clear, unambiguous and legible. No declaration shall be made so as to require it to be read through any liquid commodity contained in the package
- H. Where a package or combination of product packages is provided with an outside container or wrapper, such container or wrapper shall also contain all the declarations which are required to appear on the package except where such container or wrapper itself is transparent and the declarations on the package(s) are easily readable through such outside container or wrapper.
- I. Any specific non mandatory indication on labels related to quality certification etc. shall be supported by proper substantiation and label shall carry reference to the source or agency providing such certificate.

Regulation 4.2.2: Labelling of Pre-packaged Foods: Every package of food shall carry the following information on the label.

- 1) **The Name of Food:** The name of the food shall be the common or generic names which may additionally include trade name or description of food contained in the package. For products standardized or mentioned under the Food Safety & Standards (Food Product Standards and Food Additives) Regulation 2011 n , the name of the food should be the name of the product or category used therein.. In absence of a common or generic name, based on the nature of the food the category shall be mentioned which will not mislead or confuse the consumer in regard to the true nature and physical condition of the food. If the food falls under the category of any type of analogues as given in the food code, then the exact category name as given in the said code shall be given.

This should be provided in the same field of vision as that of the Brand name/trade name and Veg./ Non-Veg. symbol.on the front of Panel

- 2) **List of Ingredients:** Except for single ingredient foods, a list of ingredients shall be declared on the label in the following manner:-

- (a) The list of ingredients shall contain an appropriate title, such as the term **“Ingredients”**;
- (b) The name of Ingredients used in the product shall be listed in descending order of their composition by weight or volume, at the time of its manufacture, as the case may be.
- (c) A specific name shall be used for ingredients in the list of Ingredients;

For Ingredients falling in the respective classes, the following class titles may be used, namely:–

Name of the classes	Class names
Edible vegetable oils/Edible vegetable fat	Edible vegetable oil/ Edible vegetable fat or both hydrogenated or Partially hydrogenated oil
Animal fat / oil other than milk fat	Give name of the source of fat. Pork fat, lard and beef fat or extracts thereof shall be declared by specific names
Starches, other than chemically modified starches	Starch
All species of fish where the fish constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to	Fish
All types of poultry meat where such meat constitutes an ingredient of another food and provided that the labelling and presentation of such a food does not	Poultry meat
All types of cheese where cheese or mixture of cheeses constitute an ingredient of another food and provided that labelling and presentation of such	Cheese
All spices and condiments and their extracts	Spices and condiments or mixed spices/ condiments as
All types of gum or preparations used in the manufacture	Gum Base
Anhydrous dextrose and dextrose monohydrate	Dextrose or Glucose
All types of sucrose	Sugar
All types of Caseinates	Caseinates
Press, expeller or refined cocoa butter	Cocoa butter
All crystallized fruit	Crystallized fruit
All milk and milk products derived solely from milk	Milk solids

Cocoa bean, Coco nib, Cocoa mass, Cocoa press cakes,	Cocoa solids
All Vitamins	Vitamins
All minerals & Trace elements	Minerals

- (a) Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (which has been standardized in these regulations) constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

Provided that the following ingredients which are known to cause hypersensitivity shall be listed even if the ingoing quantity is less than 5%.

- i. Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these
 - ii. Crustacean and their products
 - iii. Milk & Milk products
 - iv. Eggs and egg products
 - v. Fish and fish products
 - vi. Peanuts, Tree nuts, nut products,
 - vii. Blackgram and soybeans and products of these;
- (b) Added water shall be declared in the list of ingredients except in cases where water forms part of an ingredient, such as, brine, syrup or broth, used in the compound food and so declared in the list of ingredients. However, water or other volatile ingredients evaporated in the course of manufacture need not be declared;
- (c) In case of dehydrated or condensed food, which are intended to be reconstituted by addition of water, the ingredients in such reconstituted food may be declared in descending order of weight or volume as the case may be. Provided that a statement such as “Ingredients after reconstitution” shall be given on the label.
- (d) Every package of food sold as a mixture or combination shall disclose the percentage of the ingredient (including compound ingredients or categories of ingredients) used at the time of the manufacture of the food, if such ingredient—
- a. is emphasized as present on the label through words or pictures or graphics; or
 - b. is not within the name of the food but, is essential to characterize the food and is expected to be present in the food by consumers, if the omission of the

quantitative ingredient declaration will mislead or deceive the consumer.

In sub-section (b) above, a reference in the name of the food to an ingredient or category of ingredients shall not require quantitative ingredient declaration if that reference would not mislead or deceive or would not be likely to create an erroneous impression to the consumer regarding the character of the food because of its accepted common usage as a category or product or trade name or if the named ingredient is not commonly known to be present or to characterize the food.

Further, if a name of an ingredient or product is within the name of the food or is expected to be present in the food by consumers because it generally characterizes the food by the name used, but is not present at all, like analogues or substitutes etc., then the label shall clearly mention alongside the product name “.....analogue or substitute”. Blank to be filled in by the ingredient or product of which it is a substitute.

Explanation –the absence or variation in quantity of the referred ingredient(s) between products is not necessary to characterise the food or distinguish it from similar foods.

- i. This information shall be declared on the product label as a numerical percentage.
- ii. For foodstuffs which have lost moisture following heat or other treatment, the percentage (by weight or volume) shall correspond to the quantity of the ingredient(s) used, related to the finished product.
- iii. When the quantity of an ingredient or the total quantity of all ingredients expressed on the labelling exceeds 100%, the percentage may be replaced by the declaration of the weight of the ingredient(s) used to prepare 100g of finished product”.
- iv. Such disclosure shall not be required:
 - (a) where the ingredient is used in small quantities for the purpose of flavouring; or
 - (b) where commodity specific standards under FSS Regulations are in conflict with the requirements described here.

3. Declaration of Food Additives:

- a. For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific names or recognized international numerical identifications:
 - i. Acidity regulator,
 - ii. Anticaking agent
 - iii. Antifoaming agent
 - iv. Antioxidant
 - v. Bulking agent
 - vi. Carbonating agent
 - vii. Colour
 - viii. Colour retention agent
 - ix. Emulsifier

- x. Emulsifying salt
- xi. Firming agent
- xii. Flavour enhancer
- xiii. Flour treatment agent
- xiv. Foaming agent
- xv. Gelling agent
- xvi. Glazing agent
- xvii. Humectant
- xviii. Packaging gas
- xix. Preservative
- xx. Propellant
- xxi. Raising agent
- xxii. Sequestrant
- xxiii. Stabilizer
- xxiv. Sweetener
- xxv. Thickener

The following class titles may be used for food additives falling in the respective classes and appearing in lists of food additives permitted generally for use in foods: Flavor(s) and Flavoring(s)

The expression “flavors” may be qualified by “natural”, “nature identical”, “artificial” or a combination of these words as appropriate.

4. Net Quantity or Net Weight

- (i) Net Quantity or Net Weight by weight or volume or number, as the case may be, shall be declared on every package of food in metric system (“Système International” units)
- (ii) In addition to the declaration of net contents, a food packed in a liquid medium shall carry a declaration of the drained weight of the food.

Explanation 1. - For the purposes of this requirement the expression “liquid medium” include water, aqueous solutions of sugar and salt, fruit and vegetable juices or vinegar, either singly or in combination.

Explanation 2. - In declaring the net quantity of the commodity contained in the package, the weight of the wrappers and packaging materials shall be excluded:

- (iii) For foodstuffs which have lost moisture following heat or other treatment, the percentage (by weight or by volume) shall correspond to the quantity of the ingredient(s) used, related to the finished product.
- (iv) When the quantity of an ingredient or the total quantity of all ingredients expressed

on the labelling exceeds 100%, the percentage may be replaced by the declaration of the weight of the ingredient(s) used to prepare 100g of finished product.

- (v) In case of Multipiece Packages, the number of retail units should be mentioned while giving the net quantity. eg. Net quantity: 30 x 10g = 300g
- (vi) In case of alcoholic beverages the alcoholic strength (ethyl alcohol content at 20°C) V/V shall be declared in close proximity to the brand name of alcoholic beverages.

S. Lot/Code/Batch identification

A distinctive batch number or Lot number or Code number, either numeral(s) or alphabet(s) or in any combination, representing the batch number or Lot number or Code number being preceded by the words “Batch No., or Batch, or Lot No., or Lot, or Code No., or Code shall be given on the label for the purpose of traceability as per the specification of FSSAI.

6. Name and address of the manufacturer

- (i) The name and complete address of the manufacturer and in case the manufacturer is not the packer or bottler, the name and complete address of the manufacturer and the packing or bottling unit as the case may be including the PIN Code shall be declared on every package of food .The address should be preceded by the qualifying words like “Manufactured by” or “Mfg by” or “Mfd by” or “Pkd by”. When the manufacturer has multiple manufacturing units, Registered office address of the Manufacturer may be declared.
- (ii) Where an article of food is manufactured or packed or bottled by a person or a company under the written authority of some other manufacturer or company, under his or its brand name, the label shall carry the name and complete address of the manufacturing or packing or bottling unit as the case may be, and also the name and complete address of the manufacturer to the company, for and on whose behalf it is manufactured or packed or bottled;
- (iii) Complete address would mean including a telephone number and /or an email address of a person or a designation in charge of consumer care.

7. Date Marking

a. Best Before

The “Best before” shall be declared on every package, unless otherwise provided in these Regulations. No food shall be sold or distributed to a consumer after the best before period.

b. **Date of manufacture and/or packing** - is the date or month on which the food becomes the product as described and this date, month and year, in which the commodity is manufactured, packed or pre-packed, may be additionally given on the label.

c. **Use by date/expiry date** —

- (i) On packages of Aspartame, instead of Best Before date, **Use by Date** shall be given, which shall be not more than three years from the date of packing;
- (ii) In case of infant milk substitute and infant foods instead of Best Before date, Use by date/recommended last consumption date/expiry date shall be given
- (iii) In case of fat spreads both milk and vegetable fat based, Use by date shall be given instead of Best Before

d. The labelling of best before, Date of manufacturing and Use by/expiry shall provide:

- (i) the day, month and year using the date/ month/ year format for products with a minimum durability of not more than three months;
- (ii) the month and the year for products with a minimum durability of more than three months.

e. The day or date or month or year as provided may be declared in either of the following manners:

“BEST BEFORE/USE BY / EXPIRY ...” where the days or date and month is indicated; “BEST BEFORE/ USE BY/ EXPIRY end ...”
BEST BEFORE/ USE BY/ Expiry MONTHS FROM MANUFACTURING or PACKAGING

The day, month and year shall be declared in uncoded numerical sequence except that the month shall be indicated by letters and abbreviations (at least first three letters) may be used.

f. **In addition to the best before or Use by Date, any special conditions for the storage** of the food shall be declared on the label if the validity of the date depends thereon. If required, storage conditions after opening the pack may also be specified. These conditions may be provided next to the Date marking.

g. Instructions for use including reconstitution where applicable shall be included on the label, if necessary to ensure correct utilization of the food.

PROVIDED FURTHER that in the case of returnable new glass bottle manufactured and used for packing of such beverages **on or after 19th March 2009** shall carry these declarations on its body”.

h. **Notwithstanding anything contained in this regulation, an indication of the Best Before** shall not be required for:

- (1) Beverages containing 10% or more by volume of alcohol
- (2) Vinegar
- (3) Food grade salt
- (4) Solid sugars

Provided further that all the above provisions except net weight/net content, manufacturer's name and address, date of manufacture and “best before” shall not apply in respect of carbonated water (plain soda and potable water impregnated with carbon dioxide under pressure) packed in returnable glass bottles

8. Veg/ Non veg declaration —

(i) Every package of "Non Vegetarian" food shall bear a declaration to this effect made by a symbol and colour code as stipulated below to indicate that the product is Non-Vegetarian Food. The symbol shall consist of a brown colour filled circle having a diameter not less than the minimum size specified in the Table mentioned in **the Regulation 4.2.2 (5) (iv), at the centre of a brown triangle** and the sides of the triangle should not touch the circle.



Brown
colour

(ii) Where any article of food contains egg only as Non-Vegetarian ingredient, the manufacturer, or packer or seller may give declaration to this effect in addition to the said symbol.

(iii) Every package of Vegetarian Food shall bear a declaration to this effect by a symbol and colour code as stipulated below for this purpose to indicate that the product is Vegetarian Food. The symbol shall consist of a green colour filled circle, having a diameter not less than the minimum size specified in the Table below, inside the square with green outline having size double the diameter of the circle, as indicated below :

Green colour



(iv) **Size of the Vegetarian/Nonvegetarian logo**

SI No.	Area of principal display panel	Minimum size of diameters in mm
1.	Upto 100 cms. Square	3

DRAFT

2.	Above 100 cms. Square upto 500 cms square	4
3.	Above 500 cms square upto 2500 cms square	6
4.	Above 2500 cms. Square	8

- (a) the symbol shall be prominently displayed
- (i) on the package having contrast background on principal display panel
- (ii) just close in proximity to the name or brand name of the product
- (iii) on the labels, containers, pamphlets, leaflets, advertisements in any media

Provided also that the provisions of this clause shall not apply in respect of mineral water or packaged drinking water or carbonated water or liquid and powdered milk.

Regulation 4.2.3: Manner of Declaration

- 1) All information required under this regulation:
 - i. Shall be clear, prominent, and of such conspicuousness (as compared with other words, statements, designs, or devices, in the labelling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
 - ii. Shall be indelible;
 - iii. shall use a single easy-to-read type style (upper & lower case letters); and
 - iv. Letters should never touch each other.
 - v. The colour contrast used for making labeling declarations shall always be dark fonts against light background, so that the declarations are clearly legible.
- 2) The information required under these Regulations shall be given on the principal display panel of the package or container and such information may be given in the following manner:
 - i. Product name / Category name & Veg/Non Veg symbol should all appear at the same field of vision.
 - ii. 'Date of Manufacture', 'Best before' / Date of Expiry if preprinted shall be in the same field of vision as that of Net Weight/Net content

- iii. The 'Date of Manufacture', Best Before / Use before / Expiry date shall always be in Black colour against white background.
- iv. All online information i.e. information which are not preprinted on the label but get printed at the day or time of packing shall be grouped together and given in one place in contrast background.

3) The area of principal Display panel shall not be less than:

- a) In the case of a rectangular container, forty percent of the product of height and width of the panel of such container having the largest area;
- b) In case of cylindrical or nearly cylindrical, round or nearly round, oval or nearly oval container, twenty percent of the product of the height and average circumference of such container; or
- c) In the case of container of any other shape, twenty percent of the total surface area of the container except where there is label, securely affixed to the container, such label shall give a surface area of not less than ten percent of the total surface area of the container.

In computing the area of the Principal Display Panel, the tops, bottoms, flanges at top and bottoms of cans, and shoulders and necks of bottles or jars shall be excluded.

Provided that in the case of package having a capacity of five cubic centimeters or less, the principal display panel may be card or tape affixed firmly to the package or container and bearing the required information under these Regulations.

4). The height of numeral in the declaration

- 1. The height of all letters and numerals for declarations other than net quantity and date marking required under these regulations, shall not be less than 1.5 mm based on the numeral "1".
- 2 The height of all the letters and numerals for mandatory labeling shall not be less than 1mm, based on the numeral "1" in case of packages with Principal Display Panel not more than 50 cm square.
- 3 The size of letters in declaring Product name / Category name etc. shall be at least ½ of the biggest font size used on the label subject to a maximum of 5mm

- 4 However, for the purpose of declaration of **net quantity and date marking**, the height of any letter or numeral on the label shall not be less than as shown in the Table below

S. No	Net quantity	Minimum height in mm Normal case
1	Up to 200g/ml	2
2	Above 200g/ml up to	4
3	Above 500g/ml	6

The width of the letter or numeral shall not be less than one-third of its height, but this proviso shall not apply in the case of numeral “1” and letters “m”, “l” and “i”.

Provided further that in case of label declarations required under **Part 4.6** except in case of declaration specifying instructions for use or preparation of the product, the size of letters shall not be less than 3mm.

Regulation 4.2.4: Product Specific Labelling Requirements.

1. Labelling of Milk and Milk products

- a. All Milk powders, skimmed milk powders and condensed milk or similar products, which can be reconstituted into liquid milk, shall carry the following declaration on label:

“Not to be used as infant milk substitute”

- b. In the case of milk powder:

“MILK POWDER”

This tin contains the equivalent of
(x)..... litres of toned milk”

- c. In the case of skimmed milk powder:

“SKIMMED MILK POWDER”

This tin contains the equivalent of (x) ... litres of skimmed milk”

- d. All packages of standardized milk if reconstituted, shall declare on label

“Reconstituted from milk powder / skimmed milk powder”.

- e. In case of milk powder the following instruction should be given on the label: “To make a fluid not below the composition of toned milk or skimmed milk (as the case may be) with the contents of this package, add (here insert the number of parts) of water by volume to one part by volume of this condensed milk or desiccated (dried) milk”

- f. Ice cream -- Every dealer in ice-cream or mixed ice-cream who in the street or other place of public resort, sells or offers or exposes for sale, ice-cream or ice-candy, from a stall or from a cart, barrow or other vehicle or from a basket, phial, tray or other container used without a staff or a vehicle shall have his name and address along with the name and address of the manufacturer, if any, legibly and conspicuously 'displayed' on the stall, vehicle or container as the case may be.

- g. Every package of **Cheese(s)**, if packed in polyfilm/wrapping of cloth, shall bear the following: label, namely:-

“Remove the outer packing before consumption”

- h. Every package of **Frozen Dessert / Frozen Confection** shall bear the following label, namely:-

“Frozen Desserts / Frozen Confection Contain Milk Fat / Edible Vegetable Oil* /

and Vegetable Fat**

*fill in the quantity and strike out whatever is not applicable

- i. If the product contains only vegetable fat then the following shall separately appear **“Contains no milk fat”**

2. Labelling of Edible oils and fats

- 1) The package, label or the advertisement of edible oils and fats may use the expression “Refined Oil” but not any other exaggerated expressions like “Super-Refined”, “Extra-Refined”, “Micro-

Refined”, “Double-Refined”, Ultra-Refined”, “Anti-Cholesterol”, Cholesterol Fighter”, “Soothing to Heart”, “Cholesterol Friendly”, “Saturated Fat Free” or such other expressions which are an exaggeration of the quality of the Product.

2) Every container in which solvent-extracted oil or de-oiled meal or edible flour is packed for sale shall, at the time of sale by the producer, bear the following particulars in English or Hindi (Devnagri script):-

(i) the name, trade name, if any, or description of the solvent-extracted oil or de-oiled meal or edible flour, as the case may be:

(ii) in the case of oil not conforming to the standards of quality for “refined” grade solvent extracted oils specified in **Regulation 2.2.6 (1) of the Food Standards Regulation** for Edible vegetable oil/Vanaspati, a declaration in a type-size of not less than 5 mm, as follows shall appear on the label:

(a) “NOT FOR DIRECT EDIBLE CONSUMPTION”, in the case of oils complying with the requirements for the “semi-refined” or “raw-grade 1” grades of oil specified in **Regulation 2.2.6 (1)**

(b) “FOR INDUSTRIAL NON-EDIBLE USES ONLY”, in the case of oils not complying with the requirements under item (a) above;

(i) the name and business particulars of the producer;

(ii) the net weight of the contents in the container;

(iii) the batch number, month and year of manufacture:

Provided that where solvent extracted oils are transported in bulk in rail tank-wagons or road tankers, or where de-oiled meal or edible flour is transported in bulk either for storage in silos or transferred to ship for bulk shipment, it shall be sufficient if the aforesaid particulars are furnished in the accompanying documents.

3) Every container in which vanaspati, margarine, bakery shortening, blended edible vegetable oils, mixed fat spread and refined vegetable oil is packed shall bear the following particulars in English or Hindi in Devnagri script:

(i) the name/description of the contents,

(ii) “free from Argemone Oil”;

(iii) the net mass/volume of the contents.

4) Every container of refined vegetable oil shall bear the following label, namely:-

Refined (name of the Oil) Oil

Provided that the container of imported edible oil shall also bear the word, “Imported”, as prefix.

5) Every package containing Fat Spread shall also carry the following information on labels as follows:

Milk Fat Spread

Total Milk Fat Content..

o r

Mixed Fat Spread

Milk Fat Content

or

Vegetable Fat Spread Total Fat Content

In case of vegetable fat spread, the word 'butter' shall not be associated while labeling the product.

- 6) Every package containing an admixture of edible oils shall carry the following label, namely:- **"BLENDED EDIBLE OIL"**

Or

"BLENDED EDIBLE VEGETABLE OIL"

There shall also be the following declaration along with the name of product on front/central panel,–

"NOT TO BE SOLD LOOSE"

8. Every container of refined salseed fat shall bear the following label, namely: **"Refined salseed fat for use in bakery and confectionery only"**

3. Labelling of Fruits, Vegetables & their Products

- 1) Every package of fresh fruit if coated with wax shall carry the following label, namely **"Coated with wax (name of the wax)"**

All types of Fruit and /or vegetable juices shall be labeled as per the amount of Fruit / vegetable juices present in the product according to the specified standard and the label shall mention the Product / category name in Bold.

- 2) Only undiluted 100% fruit and / or vegetable juices as defined in the standard shall be labeled as 'Juice' and where the juice is not consumable as such and needs dilution with water to produce a consumable product then the label shall mention 'Diluted juice (blank shall be filled up by the name of the fruit and / or vegetable) and the percentage of the juice shall be mentioned along with, otherwise depending on the content of the juice present in the product, the name of the category shall be declared on the label
- 3) Reconstituted Fruit and / or vegetable juices shall clearly be labeled as following **"Reconstituted from concentrate/powder" (as the case may be)**

- 4) Any fruit syrup, fruit juice, fruit squash, fruit beverages, cordial, crush or any other fruit products standardised under **Chapter 2 of FSS Food Standards Regulations, 2010** which does not contain the prescribed amount of fruit juice or fruit pulp or fruit content shall not be described as a fruit syrup, fruit juice, fruit squash, fruit beverages, cordial, crush or any other fruit product as the case may be.
- 5) Any food product which contains less than the specified amount of fruit and/or vegetable juice as per respective standards laid down in these regulations or contains only fruit/vegetable flavours and is likely to deceive or mislead or give a false impression to the consumer that the product contains fruit/vegetable, whether by use of words or pictorial representation, shall be clearly and conspicuously marked on the label as “(NAME OF THE FRUIT/Vegetable) FLAVOURED” as the case may be.

4. Others

1. Every package containing maida treated with improver or bleaching agents shall carry the following label:

“Wheat flour treated with improver/bleaching agents, to be used by bakeries only”

2. Every container or package of iron fortified iodized common salt shall bear the following label, namely

“Iron fortified iodized common salt”

Regulation 4.2.5: Specific Labeling Requirements for certain Additives used in foods

1. Artificial Sweeteners - Every package of table top sweeteners and foods permitted to contain artificial sweetener under these Regulations and any advertisement for such foods shall carry the following label, namely:—

(i) Contains Artificial sweetener(s): _____ (Name(s) of the artificial sweeteners(s)).

(ii) Not recommended for children.

(iii) Not for Phenylketoneurics (only applicable if Aspartame is added)

2 Every package of food containing more than 5% Polyols shall bear the following label “Polyols may have laxative effects”

3. Every package of food containing more than 10% Polydextrose shall bear the following label “Polydextrose may have laxative effects”

4 Every package of Dried Glucose Syrup containing sulphur dioxide exceeding 40 ppm shall bear the following label namely

“Dried glucose syrup for industrial use in sugar confectionery only”

5. Every container or package of flavour emulsion and flavour paste meant for use in carbonated or non-carbonated beverages shall carry the following declaration, in addition to the instructions for dilution, namely:—

“Flavour emulsion and flavour paste for use in carbonated or non carbonated beverages only”

6. Gelatin meant for human consumption should be labeled as **“Gelatin Food Grade”**

7 Every container or package of table iodised salt or iron fortified common salt containing permitted anticaking agent shall bear the following label:

“Iodized salt and or iron fortified common salt* (as the case may be)

* Strike out whichever is not applicable

8. Labeling for Packages of Synthetic Food Colours for sale - No person shall sell permitted synthetic food colours or their mixtures or colour preparations for use in or upon food unless the container carries a label stating the following particulars:

a. T

he words “ Food Colours” or “Food Colour Mixture” as the case may be

b. The chemical and the common or commercial name and colour index of the dye(s)

c. Names of ingredients used in the preparation

Regulation 4.2.6: Labelling of irradiated Food

- 1) The label of a food, which has been treated with ionizing radiation, shall carry a written statement indicating the treatment in close proximity to the name of the food.

The labeling of prepacked irradiated food shall also be in accordance with the provisions of the Atomic Energy (Control of Irradiation of Food) Rules, 1991, under the Atomic Energy Act, 1962 (Act 33 of 1962).

- 2) In addition all packages of irradiated food shall bear the following declaration and logo, namely :-

**PROCESSED BY
IRRADIATION METHOD
DATE OF IRRADIATION**



LICENCE NO

PURPOSE OF IRRADIATION

Regulation 4.2.7: Mandatory Warnings to be given on label

1. One time usable plastic bottles of packaged drinking water shall carry the following

declaration. **“CRUSH THE BOTTLE AFTER USE”**

2. Every package of food having added caffeine shall carry the following label, namely:— **“CONTAINS ADDED CAFFEINE”**

Provided if caffeine is added in the products, it shall be declared on the body of the Container/bottle.

Provided also that in case of returnable glass bottles, which are recycled for refilling the Declaration of caffeine, may be given on the crown.

3. Every package of Pan Masala and/or other similar products containing supari (betel nut) as one of the ingredients and advertisements relating thereto, shall carry the following warning, namely :-
“ THIS PRODUCT CONTAINS SUPARI, CHEWING OF WHICH IS INJURIOUS TO HEALTH”

5. Every package of chewing tobacco shall bear the following label, namely

CHEWING TOBACCO IS INJURIOUS TO HEALTH

Regulation 4.2.8 Exemptions from labelling requirements-

- 1) Where the surface area of the package is not more than 100 square centimeters, the label of such package shall be exempted from the requirements of list of ingredients, Lot Number or Batch Number or Code Number, nutritional information and instructions for use, but these information shall be given on Wholesale Packages or Multipiece Packages, as the case may be.
- 2) the ‘date of manufacture’ or ‘best before date’ or ‘expiry date’ may not be required to be mentioned on the package having a surface area of not more than 50 square centimeters but these information shall be given on the Wholesale Packages or Multipiece Packages, as the case may be;
- 3) Marking Net Weight may not be required for packages weighing less than 10 grams
- 4) in case of liquid products marketed in bottles, if such bottle is intended to be reused for refilling, the requirement of list of ingredients shall be exempted, but the nutritional information specified in **Regulation 4.3** of this Regulation shall be given on the label.

PROVIDED that in case of such glass bottles manufactured **after March 19, 2009**, the list of ingredients and nutritional information shall be given on the bottle.

- 5) in case of food with shelf-life of not more than seven days, the ‘date of manufacture’ may not be required to be mentioned on the label of packaged food articles, but the ‘use by date’ shall be mentioned on the label by the manufacturer or packer. In case of Wholesale Packages and bulk packages, the particulars regarding List of ingredients, Nutritional information, Date Marking and consumer care details need not be specified as

long as the same is given on individual retail packs.

- 6) In case of Institutional packs, consumer care details may not be required. However, a clear indication should be given on the label that the product is “Not for retail sale – For Institutional consumer only.”
- 7) , In case of Industrial packs, list of ingredients, nutritional information and consumer care details may not be required. However, a clear indication should be given on the label that the product is “Not for retail sale – For Industrial use only.”

Part 4.2.9: Restrictions on Product

labels (1) General Prohibitions

a. Labels not to contain reference to Act or rules or regulations contradictory to required particulars — The label shall not contain any reference to the Act or any of these regulations or any comment on, or reference to, or explanation of any particulars or declaration required by the Act or any of these regulations to be included in the label which directly or by implication, contradicts, qualifies or modifies such particulars or declaration.

b. Labels not to use words implying recommendations by medical profession — There shall not appear in the label of any package, containing food for sale the words “recommended by the medical profession” or any words which imply or suggest that the food is recommended, prescribed, or approved by medical practitioners or approved for medical purpose.

c. Unauthorized use of word imitation prohibited: There shall not be written in the statement or label attached to any package containing any article of food the word “imitation” for any food, unless the use of the said word or words is specifically permitted under these regulations.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it is not nutritionally inferior to the food for which it substitutes and which it resembles.

(2) Labeling prohibitions on Packaged Drinking Water and Packaged Mineral Water

1. The name of the locality, hamlet or specified place may not form part of the trade name unless it refers to packaged water collected at the place designated by that trade name.
2. The use of any statement or of any pictorial device which may create confusion in the mind of the public or in any way mislead the public about the nature, origin, composition, and properties of such waters put on sale is prohibited.

(3) Restriction on advertisement

There shall be no advertisement of any food which is misleading or contravening the

provisions of Food Safety and Standards Act, 2006 (34 of 2006) or the rules/regulations made thereunder.

PART 4.3: NUTRITIONAL INFORMATION —

1 For the purposes of this standard, nutritional information labeling is a description intended to inform the consumer of nutritional properties of the food and the following definitions shall be applicable.

- a. Sugar** means only sucrose present in the food.
- b. Sugars** means all mono-saccharides (glucose, fructose, , etc.) and di-saccharides (maltose, sucrose, lactose, etc.) present in food but excludes polyols.
- c. Fat** means total lipids including trans fat, saturates, MUFA, PUFA.
- d. Saturated fats or saturates** means fatty acids without double bonds.
- e. Monounsaturated fat means fatty acids** with one cis double bond.
- f. Polyunsaturated fat means fatty acids** with cis-cis methylene interrupted double bonds.
- g. 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 and double bonds in the trans configuration, excluding the conjugated linoleic acid from milk fat.
- h. Dietary fibre:** Dietary fibre means edible plant material not hydrolyzed by the endogenous enzymes of the human digestive tract as determined by agreed upon method and includes polysaccharides, oligosaccharides (degree of polymerization > 2) and lignins

2 Nutritional Information or nutritional facts per 100 gm or 100ml or per serving* of the product shall be given on the label containing the following:-

- i. energy value in kcal;
the amounts of protein,
- ii. Total carbohydrate of which
 - i) total sugars
 - ii) added sugar
- iii. Total fat in gram (g);
Of which

- i) total saturated fat (only if fat content is more than 0.5%)
 - ii) trans fat (if more than 0.2g per serving)
- iv. Cholesterol expressed in mg. In products where product contains less than 2 milligrams cholesterol in a serving and makes no claim about fat, fatty acids, or cholesterol content such products may state the cholesterol content as zero and/or may also give a statement "Not a significant source of cholesterol" at the bottom of the table of nutrient values in the same type size. Provided that Cholesterol level need not be mentioned on products which do not contain any fat or those which contain only vegetable oil.
- v. Sodium in g/ml
- vi. Any other nutrient including vitamins and minerals if they form basis of a claim alongwith the percentage of Indian RDA and wherever Indian RDA is not available then in reference of other internationally accepted values like codex/WHO etc.

3 **“serving or serve size”** means an amount of food customarily consumed per eating occasion by the target consumers or as defined on the label which is expressed in metric unit. Additionally it may also be given in common household measures like tea spoon, table spoon, cup etc. that is appropriate to the food.

4 The amount and/or type of fatty acids (including amount of saturated fatty acids(g) or SFA, polyunsaturated fatty acids(g) or PUFA, monounsaturated fatty acids(g) or MUFA, trans fatty acids(g) or TFA and cholesterol (mg) per serving shall be given, where a claim is made regarding the type or amount of fatty acids.

5 All products containing partially hydrogenated oils or fats and having Trans fatty acids (TFA) in excess of 0.2g per serving (or when serving size is not known, then 1%) shall declare the value of Trans Fatty Acids (TFA) per 100g or per 100ml or per serving just below the total fat in the nutritional information.

- 6 The nutritional information shall not be necessary, in case of the following categories.
- a. Foods served in hospitals, restaurants, food service vendors etc or delivered to consumers ready for immediate consumption
 - b. Bakery products, snacks and confections that are sold directly to consumers from a location where prepared or displayed for direct sale (not in prepackaged condition) like halwais, bakeries, confectionery & pastry shops etc.
 - c. Foods which are either single ingredient products like sugar, jaggery, salt, spices, water etc., or are known to provide no significant nutrition like coffee, coffee chicory mixture, tea, condiments etc.,

- d. Bulk foods shipped for further processing or packaging before retail sale
- e. Packaged fresh produce like fresh fruits and vegetables, fresh seafood, egg cartons and fresh meat
- f. Alcoholic beverages

However, nutritional information will be required in these products if a nutrition claim is made or any nutrition information about the food is provided on the label.

- 7 The compliance to quantity of declared nutrients on the label shall be according to the established practices.

Explanation – For the purpose of this provision, at the time of analysis, due consideration, based on shelf-life, storage, and inherent nature of the food shall be kept in view in case of quantity declared nutrients;

- 8 The values used in nutrient declaration should either be the weighted average values or typical statistical values derived from data specifically obtained from analysis of products, which are representative of the product being labeled or these can be calculated based on data for ingredients from recognized sources/scientific literature e.g. “Nutritive Value of Indian Foods”.

9. Nutrient content of a food shall be at least 80 percent of the value for that nutrient content declared on the label at any point in time within the expected shelf life or minimum durability of the product. However for Trans fatty acids, Saturated fatty acids and Cholesterol, the actual values should not exceed 120 percent value of the declared values. Similarly, products claiming low in fat, low in sugar, low in sodium etc. the actual nutrient value should not exceed 120 percent of the value declared.

- 10 Sugar in liquid food is known to be reduced with time (shelf life). Therefore, such values should be checked a fresh for compliance purpose.

Regulation 4.4: Calculation of Nutritional output:

- a. Calculation of energy - The amount of energy to be listed should be calculated by using the following conversion factors:

Carbohydrates	4 kcal/g
Polyols except erythritol	2 kcal/g
Protein	4 kcal/g
Fat	9 kcal/g
Alcohol (Ethanol)	7 kcal/g
Organic acid	3 kcal/g

- b. Calculation of Protein - The amount of protein to be listed should be calculated using the formula:

Protein = Total Kjeldahl Nitrogen x 6.25 (Unless a different factor is used, which is scientifically justified as in the case of milk protein)

Regulation 4.5: Imported foods

All food products imported into India shall comply with the labeling requirements as specified in these regulations including those related to font size and shall have at least 60% of shelf life remaining on the date of landing at the Port of import.

In addition imported foods shall also bear the following on the label:

- (i) Name and complete address of the importer in India.
- (ii) Where any food article manufactured outside India is packed or bottled in India, the name and complete address of the importer and the premises of packing or bottling in India along-with the country of origin of the food article.

When a food undergoes processing in a second country which changes its nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

Use of Stickers

Stickers may only be permitted for making declarations (if not preprinted) regarding name and address of the importer, date of manufacturing and / or packing and veg / non veg logo.

Part 4.5: CLAIMS

Regulation 4.5.1 - General Principles for making claims on pre-packaged foods

1. Nutrition and health claims should be based on scientific documentation about nutritional requirements of the target groups/individuals in the country or the national nutrition policy.
2. Claims must be truthful, unambiguous, meaningful and not misleading
3. The person marketing the food should be able to justify the claims made. Claims that cannot be scientifically substantiated should not be made.
4. The claims should not encourage or condone excess consumption of a particular food.
5. The claims should be clear and meaningful and shall help consumers to comprehend the information provided, to understand the relative significance of such information and choose-wholesome diets. The nutrient or ingredient or substance which will be used to make the claims on a food should be nutrients, ingredients or substances or using technologies or processes or combinations thereof whose safety has been established through the Act and the rules and regulations there under or which have a history of safe use.
6. If the claimed effect is attributed to a constituent of the food, there must be a validated method as accepted by FSSAI to quantify the food constituent that forms the basis of the claim.
7. All nutritional and health claims on products intended for children shall be accompanied by a declaration in bold "Regular balanced diet is important for children in their growing up years".
8. Claims shall not state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients as required by the body.
9. Claims containing adjectives such as 'natural', 'fresh', 'pure', 'organic', 'original', 'traditional', 'premium', 'Finest', 'Best', 'Authentic', 'Genuine', 'Real' etc. when used, shall be in accordance with conditions laid down in Annexure I. or any other Regulations in force in India . However, 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. Claims related to religious or ritual practices like Halal, Jhatka can be made provided that the food conforms to the requirements of the appropriate religious or ritual authorities and is certified by concerned authorized agencies.
11. The conditions above are also applicable where a claim is made on the finally prepared form of a food, that is, food prepared in some manner, either by cooking or mixing with another food etc. In such a case, the label of such a food must also contain appropriate instructions on the preparation required in order to ensure that the finally prepared product meets the claim made on it.
12. The Food Authority may at any time ask a manufacturer and/or brand owner of any food on which claims are being made to substantiate the claim scientifically and /or furnish details regarding the nutrients added or modified for their safety & efficacy.
13. All disclaimers related to a claim should appear in the same field of vision as that of the claim.

Regulation 4.5.2: Nutritional and Health Claims

1) General Conditions for Nutritional and Health Claims

- a. This part relates to use of nutritional and /or health claims made on any food, as defined under Food Safety & Standards Act 2006, and rules and regulations therein, on label irrespective of whether or not the particular food is covered by any individual standard under these Regulations. The foods intended for special nutritional purposes like Health Supplements or Foods for Special Dietary uses will have to comply additionally with specific labelling and claim conditions laid down under the specific standards/regulations.
- b. This Regulation shall also apply to nutrition and health claims made on commercial communications including internet, whether in labelling, presentation or advertising (both print & electronic format) of foods to be delivered as such to the final consumer.
- c. If the meaning of a trade mark, brand name or fancy name appearing in the labelling, presentation or advertising of a food is such that it may be construed as a nutrition or health claim then it shall follow all the general & specific conditions, prohibitions and restrictions as laid down in this part of the Regulation.
- d. This regulation shall also apply to claims on specialized packaged foods marketed through direct distribution channels or manufactured specifically for distribution or supply to hotels, restaurants, hospitals, health-fitness or wellness clinics, gymnasiums, schools, canteens and similar establishments.

2. Definitions

For the purpose of these regulations, Nutritional & Health claims are defined as follows:

1. **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 can be of two types:
 - a. **Nutrient content claim** is a nutrition claim that directly or indirectly describes the level of a nutrient contained in a food.
(Examples: “contains/source of.....”; “high in”, “rich in.....”, “low in, etc.)
 - b. **Nutrient comparative claim** is a claim that compares the nutrient levels and/or energy value of two or more foods.
(Examples: “reduced”; “less than”; “fewer”; “increased”; “more than”.)

The following do not constitute nutrition claims:

- (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 national legislation.

2. **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.

Health Claims can be of three types

- a. Nutrient Function claims
- b. Other function claims
- c. Disease Risk Reduction claim

i) **A 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 & development). Food X is a rich source of / high in nutrient 'A'. Example: "Nutrient A is good for health"(particular function) etc.

ii) **Other Function claims** - that describe the specific beneficial effects of the consumption of food(s) or their constituents, in the context of the total diet or normal functions or biological activities of the body. Such claims 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 claim** - Claims that state, suggest or imply that consumption of such food(s) or food constituents in the context of the total diet, reduce the risk factor of developing disease or health related conditions.

Disease Risk-reduction means significantly altering a major risk factor(s) for a disease or health related condition. Diseases have multiple risk factors and altering one of these risk factors may or may not have beneficial effects. The presentation of risk reduction claim must ensure, for example, by use of appropriate language and relevance to risk factors, that consumers do not interpret them as prevention claims.

3 - Principles for making Nutritional and Health claims on prepackaged foods

1. Claims shall be based on science and supported by sound and sufficient scientific evidence.

2. When a function claim is made about the benefit of a nutrient, the food carrying the claim must at least be a source of the nutrient.
3. All Health claims should be accompanied by instructions on maximum per day serving of the product.
4. Words signifying that the food will provide complete nutrition like “complete” “planned”, “exhaustive”, “total”, “absolute” or other synonymous words shall not be generally used in foods which are not proposed as complete diet replacement for weight management or those which are intended to be sold as foods for special medical purposes.
5. The use of nutrition and health claims shall be permitted if the nutrient for which the claim is being made:
 - (i) is contained in the final product in a quantity as defined under the conditions given in Annexure I, II & III
 - (ii) the nutrient for which the claim is made shall be in a form that is available to be used by the body.

4. Specific conditions for making Nutrition Claims including Nutrient Content and Comparative claims

- a. Nutrition Claims shall be permitted in relation to energy, protein, carbohydrate, fat and their components thereof, fibre, sodium, vitamins and minerals.
- b. Nutrient content or Nutrient comparative claim as listed in Annexure II or any synonymous claims in Annexure III shall be made provided the conditions specified in the list of claims in the Annexures and in this Regulation are fulfilled.
- c. Flexibility in the wordings of a nutrition claim may be allowed as per Annexure III, provided the claims comply with the conditions outlined in Annexure II and the meaning of the claim is not altered.
- d. Where a food is by its nature high, low or free of nutrient and that is the subject of the claim, the term describing the level of nutrients shall be preceded by ‘natural / naturally’ and immediately preceded by the name of the food and shall be in the form of, for example: “a low (naming a nutrient or substance) food” or “a (naming the nutrient or the substance) free food”.
- e. For making a nutrient comparative claim, the compared foods shall be different versions of the same food or similar foods having similar nutrient level. The foods being compared shall be easily identifiable.
- f. Where a Comparative claim is being made, a statement on the amount of difference in energy value or nutrient content shall be given and following information shall appear in close proximity to the comparative claim:
 - i) the identity of the food(s) to which the food is being compared for ready identification by consumers
 - ii) the amount of difference related to the nutrient quantity, expressed as a percentage, fraction or an absolute amount, details shall be given

- g. A Comparison shall be based on a relative difference of at least 25% in the energy value or nutrient content, except for micronutrients where at least a 10% difference in the NRV shall be required between the compared foods and the minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as 'low' or 'reduced' as provided in the list of claims in Annexure II.

5. Specific Conditions for making Health Claims

Health claims shall comply with all the general and nutritional conditions outlined above and the specific requirements laid down hereunder:

- a. Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data.
- b. The health claim must consist of two parts:
 - i. Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by
 - ii. Information on the composition of the product relevant to the physiological role of the nutrient 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.
- c. While adding nutrients in foods, the manufacturer shall ensure that amount of such nutrients in per day serve remain below 50% of the scientifically established upper safe levels for each nutrient.
- d. The following information should appear on the label or labelling of the food bearing health claims:
 - a. quantity of any nutrient or other constituent of the food that is the subject of the claim in the nutritional label
 - b. The target group, if appropriate.
 - c. How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.
 - d. Any contraindications if applicable and advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.
 - e. Maximum safe intake of the food or constituent, if necessary.
 - f. A statement indicating the importance of a varied and balanced diet and a healthy lifestyle in close proximity to the claim and
 - g. how the food constituent or the food fits within the context of the total diet, where necessary.
- e. Any nutrient function or other function claim for promotion of normal growth & development or for maintaining good health or towards positive contribution to health or to the improvement of a function may be used, can be made only if substantiated by scientific data as per Annexure – VI.

- f. Specific health claims indicating maintenance of normal health condition by use of specific nutrient shall be accompanied by the following indication-“For maintenance of optimum functions and not for therapeutic use.” Claims on Foods which are high in salt or sugar or fat, shall alongside the claim also mention the fact that the food is high in one or more of the these ingredients in the manner - “This food is high in”(to be filled in by sugars and/or salt and/or fat) as the case may be. However, no DRR claims shall be made on products which are high in fat, salt or sugar.

For the purpose of this regulation high shall be defined as being present in quantity in excess of the figures given against each ingredient for the target age group.

Nutrients	Units	Pre-schoolers (4-6 yrs)	Schoolage Children (7-17 yrs)	Adults (18-50 yrs)
Total fat	g/serve	6.8	11.0	11.6
Sat fat	g/serve	2.3	3.4	3.9
Trans fat^	g/serve	0.23	0.37	0.39
Total Sugars	g/serve	17.7	28.7	30.5
Sodium	mg/serve	300	300	300

Footnote: the figures have been arrived at basedon WHO 2004, USIOM and ICMR RDA 2010

If the product has levels of any one of the two fat constituents like sat fat or trans fat in excess of the amount mentioned in the above table then a declaration “this food is high in saturated fat and/or trans fat” shall also be given.

Moreover, if the claim is based on reduction of any one of these ingredients i.e. salt or sugar or fat but is high in any or both of the other two, then a declaration “this food is low in but high in” as applicable shall be given additionally.

- a. When a claimed benefit is attributed directly to the product or used on labels, advertisements or any other means as a mode of communication to the consumer, it shall be based on statistically significant results from appropriate scientific research studies or a well designed, randomised double blind (unless technically not feasible) clinical study, conducted by or under guidance of established research institutions, in line with the principles of GCP and peer reviewed or published in a peer reviewed reputed scientific journal with a impact factor of not less than 1.0 at the time of submission. FBO shall submit all the relevant substantiating documents alongwith the report of the peer review mentioning in detail the composition of the peer review group alongwith their designations or the copy of the published article as the case may be to the Authority before launch of the product for scrutiny. Following the scrutiny,

if the claim is found unsubstantiated, Authority may order amendment or withdrawal of the claim and may file a compliant with the concerned Designated Officer.

- b. Scientific research on a particular nutrient shall cover its efficacy over the age group, geographical situation, social & economic criteria which the concerned product intends to target.
- c. Claims related to disease risk reduction shall be made from the list of approved claims (Annexure IV) and in accordance with the conditions laid down in the list and in this Regulation.

Any new claim on disease risk reduction shall be made only after taking prior approval from Authority. An application in the format given in Annexure VB of this Regulation shall be made for inclusion of the claim in the approved list of claims (Annexure IV). Once approved the claim can be made by other manufacturers provided all the other specific conditions laid down in this regulation are fulfilled.

Regulation: 4.5.3: CLAIMS RELATED TO DIETARY GUIDELINES OR HEALTHY DIETS

1. Claims can be made related to a “healthy diet” or any synonymous term referring to the pattern of eating or dietary guidelines as in official records or determined by study or survey conducted with the approval of Government and the label shall carry a statement relating the food to the pattern of eating described in the official records or study /survey. . .
2. Foods which are described as part of a healthy diet, balanced diet, etc., should not be based on selective consideration of one or more aspects of the food. They should also satisfy the criteria for other major nutrients related to the dietary guidelines, based on scientific evidence.
3. Foods should not be described as “healthy” or be represented in a manner that implies that a food in and of itself will impart health.

Regulation: 4.5.4: Prohibitions

1. No Claims shall be made which refer to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition.
2. No product shall claim “added nutrient” if such nutrients have been added merely to compensate the nutrients lost while processing of the food.
3. Foods for Infants shall not carry any claim unless specifically permitted under product standard or specific labelling requirement.
4. Claims which could give rise to doubt or suspicion about the safety of similar food or which could arouse fear in consumer shall not be made.

8. The health claims which suggest that health could be affected by not consuming the food shall not be allowed

Regulation: 4.5.5: Other Conditions

1. If at any given point of time any of the nutrients come under question on the basis of prime facie scientific evidence regarding its safety and a fresh risk analysis is ascertained by FSSAI, the nutrient in question shall not be used till further notification

2. Amendments to **Annex I, Annex II, Annex III & Annex IV** (list of approved claims) shall be adopted in accordance with the regulatory procedures laid down for general as well as special types of foods and Authority, where appropriate, shall involve interested parties, in particular food business operators and consumer groups, in order to evaluate the perception and understanding of the claims in question.

3. Health Claims based on novel nutrient or emerging science shall require prior approval from authority and follow the procedure as laid down under Novel Food Regulation and apply in the prescribed format as provided in the Novel food regulation to the concern authority along with required scientific documents and information as proof on the nutrient or the procedure on which the claim is based. Authority after evaluating the application if see value in the substance may approve the same for use and subsequent claim.

4. Proprietary data (claim) for new DRRs requesting for privacy shall be applied in accordance with the procedure laid down giving all the required information. The Scientific Panel upon scrutiny of the documents may grant approval with a time line till which the confidentiality would be maintained or reject the request by providing sufficient reason for such refusal.

5. All types of approved DRR claims shall remain open for re-evaluation. Food authority either periodically or following an emergent situation or arise of new evidence may either withdraw or alter the wordings of the claim along with its conditions.

6. The applicant/user of a claim from one of the lists may also apply for a modification of the relevant list or a particular claim.

7. At any point of time all the enlisted claims and those are in practice will remain open for further evaluation on the basis of new information or new research received.

Regulation 4.5.6: Transitional measures

1. If the label of a product placed on the market or labelled prior to the date of of this Regulation is deficient in any manner and to any extent with respect to the provisions of this Regulation, the manufacturer of such products shall ensure compliance with this Regulation within six months from the date of notification of the Regulation.
2. The manufacturer and /or brand owner of such products making Health Claims, shall submit to the authority forthwith and not later than one month all such labels along with scientific substantiation and other relevant documents including clinical data for product specific claims. Manufacturing / Marketing of such products may be carried on till further communication from FSSAI.
3. The manufacturers of products making Disease risk reduction (DRR) claims which are not included in the approved list in Annexure III that have been placed in the market or labelled prior to the date of this Regulation shall forthwith and not later than one month of the date of notification of this Regulation apply for approval from the Authority in compliance with the procedure set out in [Annexure IV A and B] this Regulation. The manufacturing, distribution and marketing of such products may be resumed only after grant of approval by the Authority.

Regulation: 4.5.7- Procedure for Enforcement

The enforcement for this Regulation shall be in accordance with the provisions of the Act & the Rules, limited to the Labeling & claim provisions only, except to the extent provided for here. [Note to Draft: To include the definition of 'Rules' in the definitions section]

1 A complaint regarding non-compliance with the provisions of these Regulations may be initiated by any person, including without limitation, a consumer, purchaser, any food audit and inspection agency, and shall be made in writing to the relevant Food Safety Officer.

2 On receiving a written complaint under 4.5.7.1 above or if any article of food appears to him to be in evident non-compliance, the Food Safety Officer shall:

i Follow the procedure for taking a sample as prescribed in section 47(a) of the Act and Rules 2.4.1.1 to 2.4.1.8 with only exception of 2 samples instead of 4 samples.

ii The Food Safety Officer shall then pack and seal the two samples of the article of food in the manner prescribed in Rule 2.4.1.9 and dispatch such samples to the Designated Officer together with two copies of the memorandum prescribed in Form VI of the Rules for further deliberations.

3 If, after considering the sample, the Designated Officer is of the opinion for reason(s) to be recorded in writing, that the article of food is not evidently contravening the Labeling provisions of this Regulation, he shall immediately inform the Food Business Operator from whom the sample was taken.

4 If, after considering the sample, the Designated Officer is of the opinion for reason(s) to be recorded in writing, that the article of food is evidently contravening the Labeling or claim provisions of this Regulation, based on an examination of the relevant sections, he shall follow the procedures prescribed in Chapter 3 of the Rules, regarding Adjudication and Appeal to the Tribunal except for the procedure in Rule 3.1.1.1 (Holding of Inquiry).

- Any advertisement of Food and Beverages whether in print or electronic media must comply with the F& B code of the ASCI. No advertising which violates ASCI code can be released in print or TV, in India. The decision of FSSAI is final in the matter.

Annex I: Conditions for using specific words or phrases as part of claims/Brand or Fancy name/ Trademark

Annex II: Conditions for use of Nutrient content & Nutrient Comparative Claims & their Conditions

Annex III : Conditions for use of Synonymous claims

Annex IV: Approved list of Disease Risk Claims

Annexure V Procedure for new DRR Claim Approval

Annexure VI : Criteria for substantiation

DRAFT

Conditions for using specific words or phrases as part of claims/Brand or Fancy name/ Trademark

Serial no.	Claim	Conditions
1.	Natural	<p>1 The word “Natural” can be used to:</p> <p>a describe a single food of a traditional nature, to which nothing has been added and which have been subjected only to such processing which would only render them suitable for human consumption like :</p> <ul style="list-style-type: none"> i. smoking without chemicals, traditional cooking processes such as roasting, blanching & traditional methods of dehydration, etc. ii. freezing, concentration, pasteurization, sterilization only to describe the process to which a natural product has been subjected to(example: pasteurized natural orange juice) iii. packaging to be done without chemicals and preservatives. <p>b describe permitted food additives that are obtained from natural sources (For eg. Food and plant by appropriate physical processing.</p> <p>2Compound foods shall not themselves be described directly or by implication as “natural” but such foods may be described as “made from natural ingredients” if <u>all</u> the ingredients meet the criteria in para a & b above.</p> <p>Provided however, the above principles shall also apply to use of other words or expressions such as “real”, “genuine”, “original” etc. when used in place of “natural” in such a way as to imply similar benefits.</p> <p>Provided however, claims such as “natural goodness”,</p>

		“naturally better”, “nature’s way” etc. shall not be used.
2	Pure	<p>1. 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 significantly below the levels given in the FSS Regulations on Contaminants and Toxins or Food Standards. eg milk from single source i.e. only milk or ghee obtained from single variety of milch animal like cow or buffalo or any other milch animal can be called pure and not their mixtures.</p> <p>Compound foods shall not be directly or by implication defined as “pure”, however, a compound food may be claimed to be “made with pure ingredients” if all the ingredients meet the above criteria, eg – combination of cow’s and buffalo’s milk/ghee shall not be claimed as “pure ghee” or “pure milk”.</p> <p>2. No further adjectives shall be prefixed to the word “pure”, like “ultra pure”, “super pure” etc.</p>
3	Fresh	<p>1. The term “fresh” can only be used on products which have not been processed in any manner except, washed, peeled, chilled, trimmed or cut. The term “fresh” or “freshly” shall have no other connotation than the immediacy of the action being described. A food 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>2. The term “freshly squeezed” or any other synonymous terms shall only be used to describe juice obtained direct from the fruits / vegetables and not prepared from their concentrates, where there has been a short time between extraction and packaging and such foods shall carry a “use by date” which shall be within two weeks of juice extraction.</p> <p>3. The term “freshly baked” or any other synonymous terms can be used only if the offered products have been made freshly on site from basic raw materials which also satisfy the</p>

		<p>conditions of fresh as given above.</p> <p>Products which are made from pre baked ingredients which are frozen or preserved in any other manner shall not claim to be freshly baked.</p> <p>“High temperature pasteurised” milk has a recognised meaning and should not carry the term “fresh”.</p>
4	Premium, Finest, Best, Authentic, Genuine, Realetc.	<p>These terms can be used only if the label and/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” should demonstrably be used to describe a recipe, fundamental formulation or processing method for a product that has existed for a significant period running over generations should have been available, substantially unchanged, for that same period.</p> <p><i>[To be discussed for inclusion]</i></p>
6	Original	<p>The term “original” should 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 can 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>To be termed “original”, a product should not have changed to any material degree and should remain available as the 'standard' product when new variants are introduced. A product re-introduced onto the market after a period of absence should only be described as “original” if it can be shown to meet these criteria.</p>

DRAFT

**Annexure II: LIST OF NUTRITIONAL CLAIMS INCLUDING NUTRIENT
COMPARATIVE CLAIMS**

Serial no.	Claim	Conditions
1.	LOW OR REDUCED ENERGY	A claim that a food is low in energy, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain energy more than 40 kcal (170 kJ)/100 g for solids or not more than 20 kcal (80 kJ)/100 ml for liquids. For table-top sweeteners the limit of 4 kcal (17 kJ)/portion, with equivalent sweetening properties to 6 g of sucrose (approximately one teaspoon of sucrose), applies.
	ENERGY FREE	A claim that a food is energy free and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain energy more than 4 kcal per 100 g (liquids)
2.	LOW-FAT	A claim that a food is low in fat, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 3 g of fat per 100 g for solids or 1.5 g of fat per 100ml for liquids (1.8 g of fat per 100 ml for semi-skimmed milk).
3.	FAT-FREE	A claim that a food is fat-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.5 g of fat per 100 g or 100 ml. Claims expressed as 'X % fat-free' shall be prohibited.
4	LOW CHOLESTEROL	A claim that a food is low in Cholesterol and any claim likely to have the same meaning for the consumer, may only be made where the product contains not more than 20 mg cholesterol / 100g (solids) or 10mg per 100 ml (liquids) of food. Additionally the food shall not contain more than

		1.5 g saturated fat per 100 gm (solids) or 0.75 gm of saturated fat per 100 ml (liquids) or 10% of energy of saturated fat and shall be trans fat free.
5.	CHOLESTEROL free	<p>A claim that a food is Cholesterol free and any claim likely to have the same meaning for the consumer, may only be made where the product contains not more than 5 mg cholesterol / 100g /ml of food</p> <p>Additionally the food shall not contain more than 1.5 g saturated fat per 100 gm (solids) or 0.75 gm of saturated fat per 100 ml (liquids) or 10% of energy of saturated fat and shall be trans fat free. and not less than 40% of cis – polyunsaturated or cis – monounsaturated fatty acids</p>
6	LOW SATURATED FAT	A claim that a food is low in saturated fat, and any claim likely to have the same meaning for the consumer, shall only be made where the saturated fat does not exceed 1.5 gm per 100 gm (solids) or 0.75 gm per 100 ml (liquids) and shall be trans fat free. .
7.	SATURATED FAT FREE	A claim that a food does not contain saturated fat, and any claim likely to have the same meaning for the consumer, may only be made where the saturated fat does not exceed 0.1 gm per 100 g or 100 ml. of food and shall be trans fat free.
8.	TRANS FAT FREE	If less than 0.2gm trans fat is present per serving of the product, then the product can be claimed to be Trans Fat free
9.	RICH IN MUFA (mono unsaturated fatty acid) AND/ OR PUFA(poly unsaturated fatty acid)	A claim that a food is high in monounsaturated fat, and any claim likely to have the same meaning for the consumer, may only be made where at least 45% of the fatty acids present in the product derive from monounsaturated fat under the condition that saturated fat must not provide more than 10% of energy.

10	Contains Omega3 fatty acids	<p>(1)Total saturated fatty acids and trans fatty acids is no more than 28% of total fatty acid content of the food, or</p> <p>food contains no more than 5 g of saturated fatty acids and trans fatty acids per 100 g of the food.</p> <p>(2)No less than 200 mg alpha linolenic acid (ALA) per serving , or</p> <p>30 g of total EPA and DHA per serving</p> <p>(3)Specify the source of omega fatty acid present</p> <p>(4) Indicate the source of omega -3 fatty ALA, DHA and /or EPA.</p>
11.	SOURCE OF OMEGA 3 FATTY ACIDS	<p>(1)Total saturated fatty acids and trans fatty acids is no more than 28% of total fatty acid content of the food, or</p> <p>food contains no more than 5 g of saturated fatty acids and trans fatty acids per 100 g of the food.</p> <p>(2)No less than 60 mg total EPA and DHA per serving.</p> <p>(3)Indicate the source of omega -3 fatty acid namely alpha linolenic acid, DHA and /or EPA.</p>
12.	Omega 6 Source	Total saturated fatty acids and trans fatty acids is no more than 28% of total fatty acid content of the food and fatty acid in respect of which the nutrition claim is made comprises no less than 40 % of total fatty acid content of the food.
13.	LOW SUGAR	A claim that a food is low in sugar, and any claim likely to have the same meaning for the consumer, may only be made where the product contains not more than 5g of sugar per 100 g for solids or 2.5 g of sugar per 100 ml for liquids.
14.	SUGAR-FREE	A claim that a food is sugar-free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains not more than 0.5 g of sugar per 100 g or 100 ml.

		<p>(For a food that meets the definition of a meal or main dish, the food must contain less than 0.5 g of sugars per labelled serving. In addition, such foods may not contain any ingredient that is a sugar or that is generally understood by consumers to contain sugars, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement that appears below the list of ingredients, and that provides:</p> <p>‘adds a trivial amount of sugar, adds a negligible amount of sugar, or adds a dietarily insignificant amount of sugar’</p>
15.	WITH NO ADDED SUGAR / WITHOUT ADDED SUGAR	<p>A claim stating that sugars have not been added to a food, and any claim likely to have the same meaning for the consumer, may only be made where the product does not contain any added mono- or disaccharides or any other food used for its sweetening properties like sucrose, fructose, lactose, honey etc. If sugars are naturally present in the food, the following indication should also appear on the label: ‘CONTAINS NATURALLY OCCURRING SUGARS’.</p> <p>It should also comply with the following conditions:-</p> <ul style="list-style-type: none"> d. a.No sugars of any type have been added to the food (examples: sucrose, glucose, honey, molasses, corn syrup, etc); (b) The food contains no ingredients that contain sugars as an ingredient (examples: jams, jellies, sweetened chocolate, sweetened fruit pieces, etc); (c) The food contains no ingredients containing sugars that functionally substitute for added sugars (examples: concentrated fruit juice not reconstituted, dried fruit paste, etc); (d) The sugars content of the food itself has not been increased above the amount contributed by the ingredients by some other means (examples: by enzymes); (e) The food that it resembles and for which it

		substitutes normally contains added sugars
16.	LOW SODIUM/SALT	A claim that a food is low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.12 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml.
17	Very low sodium/salt	A claim that a food is very low in sodium/salt, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.04 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml
18	Sodium free	A claim that a food is sodium/salt free, and any claim likely to have the same meaning for the consumer, may only be made where the product contains no more than 0.005 g of sodium, or the equivalent value for salt, per 100 g or per 100 ml
19	No added salt	<p>(a) The food contains no added sodium salts</p> <p>(b) The food contains no ingredients that contain added sodium salts (examples: Worcestershire sauce, condiments, pickles, pepperoni, soya sauce, etc);</p> <p>(c) The food contains no ingredients that contain</p>

		<p>sodium salts that functionally substitute for added salt (like seaweed);</p> <p>(d) The food that it resembles and for which it substitutes normally contains added sodium salts</p>
19.	SOURCE OF DIETARY FIBRE	A claim that a food is a source of fibre and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 3 g of fibre per 100 g
21.	HIGH IN DIETARY FIBRE OR RICH IN DIETARY FIBRE	A claim that a food is high in fibre and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 6 g of fibre per 100 g or 100 ml or 20% of RDA per serving.
22	Low Protein	<p>A claim that a food is low in protein, and any claim likely to have the same meaning for the consumer, may only be made when the food contains not more than 1gm of protein per 100 gm or 100 ml.</p> <p>Also energy from protein should not be more than 5% of total energy</p>
23.	SOURCE OF PROTEIN	<p>A claim that a food is a source of protein, and any claim likely to have the same meaning for the consumer, may only be made when at least 12 % of the energy value of the food is provided by protein or the food contains at least</p> <p>10% of RDA per 100 g (solids) or</p> <p>5% of RDA per 100 ml (liquids) or</p> <p>5% of RDA per 100 kcal or</p> <p>10% of RDA per serving</p>
24.	RICH IN PROTEIN / HIGH PROTEIN	A claim that a food is high or rich in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20 %

		<p>of the energy value of the food is provided by protein or has 2 at least or the food contains at least</p> <p>20% of RDA per 100 g (solids) or</p> <p>10% of RDA per 100 ml (liquids) or</p> <p>10% of RDA per 100 kcal or</p> <p>20% of RDA per serving</p>
25.	SOURCE OF (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)	<p>A claim that a food is a source of vitamins and/or minerals and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least</p> <p>15% of RDA per 100 g (solids) or</p> <p>7.5% of RDA per 100 ml (liquids) or</p> <p>5% of RDA per 100 kcal or</p> <p>15% of RDA per serving</p>
19.	HIGH (NAME OF VITAMIN/S) AND/OR (NAME OF MINERAL/S)	<p>A claim that a food is high in vitamins and/or minerals and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least</p> <p>30% of RDA per 100 g (solids) or</p> <p>15% of RDA per 100 ml (liquids) or</p> <p>10% of RDA per 100 kcal or</p> <p>30% of RDA per serving</p>
20.	CONTAINS (NAME OF THE NUTRIENT OR OTHER SUBSTANCE)	<p>A claim that a food contains a nutrient or other nutritive substance, for which specific conditions are not laid down in this Regulation, or any claim likely to have the same meaning for the consumer, may only be made where the product complies with all the applicable provisions of this Regulation, and in particular, for vitamins and minerals the conditions of the claim 'source of' shall apply</p>

21.	INCREASED (NAME OF THE NUTRIENT)	A claim stating that the content of one or more nutrients, other than vitamins and minerals, has been increased and any claim likely to have the same meaning for the consumer like “added” may only be made where the product meets the conditions for the claim ‘source of’ and the increase in content is at least 30 % compared to a same or a similar category product, provided the increased nutrient / s content have positive beneficial effect on the target consumer.
22.	REDUCED (NAME OF THE NUTRIENT)	A claim stating that the content in one or more nutrients has been reduced, and any claim likely to have the same meaning for the consumer, may only be made where the reduction in content is at least 30 % compared to a same or a similar category product, except for micronutrients where a 10 % difference in the reference values shall be acceptable and for sodium, or the equivalent value for salt, a 25 % difference shall be acceptable, provided that the reduction in the nutrient / nutrients content is having positive beneficial effect on the target consumer.
23.	NATURALLY/NATURAL	Where a food naturally meets the condition(s) like pure, fresh, real or without addition or deletion of any nutrient substances and additives excluding natural additives for the use of a nutritional claim, the term ‘naturally/ natural’ may be used as a prefix to the claim.
24.	LIGHT/ LITE	A claim stating that a product is ‘light’ or ‘lite’, and any claim likely to have the same meaning for the consumer, shall follow the same conditions as those set for the term ‘reduced’; the claim shall also be accompanied by an indication of the characteristic(s) which make(s) the food ‘light’ or ‘lite’.
25.	DIET	The term refers to products having energy content significantly lower than its reference counterpart. When a food is described as 'diet' in this context, it must comply with the following conditions: (a) the energy content of the food must not be more than 60 per cent of the energy content of the same

		quantity of the reference food; and (b) there must be a reduction in energy content of at least 170 kj per 100 g of food, or 80 kj per 100 g of liquid food, compared with the same quantity of the reference food and (c) there must be a statement of comparison with the reference food.
26	Emphasis on ingredient(s) in the name of product	Claimed ingredient(s) to be present in min 3% of total solids of the finished product.
27	If more than one ingredients are emphasized in the product (such as multigrain etc)	Multiple ingredient – min 2% of each ingredient by weight;

28	Prebiotic Fiber	Source	Min 8gm recommended dosage (daily serve)
29	Probiotics	Source	Probiotic organisms should be at least 10^6 cfu per serve of the product

SYNONYMS WHICH MAY BE USED FOR THE CLAIMS DEFINED IN ABOVE TABLES

Free	Low	Reduced/Less	Increased/More
<p>Synonyms for "Free":</p> <p>"Zero", "No", "Without", "Trivial Source of", "Negligible Source of", "Dietary Insignificant Source of"</p> <p>"Definitions for "Free" for meals and main dishes are the stated values per labeled serving</p>	<p>Synonyms for "Low":</p> <p>"Little", ("Few" for Calories), "Contains a Small Amount of", "Low Source of"</p>	<p>Synonyms for "Reduced/Less":</p> <p>"Lower" ("Fewer" for Calories)</p> <p>For this claim: The food is processed, formulated, reformulated or otherwise modified so that it contains at least 25% fewer calories or nutrient per referred amount of food compared to the amount of an appropriate reference food.</p> <p>For meals and main dishes, at least 25% fewer calories per 100g</p>	<p>Synonyms for More /Increased:</p> <p>Increased /More</p> <p>For this claim: The food is processed, formulated, reformulated or otherwise modified so that it contains min 25% higher calories or nutrient per referred amount of food compared to the amount of an appropriate reference food.</p> <p>For meals and main dishes, at least 25% higher calories per 100g</p>

DRAFT

Annexure IV

CONDITIONS FOR DISEASE RISK REDUCTION CLAIMS

(the words contain/source/high/low/rich etc used here will have the same meaning as those defined under Annexure 1)

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Calcium vitamin D and Osteoporosis--	<ul style="list-style-type: none">- High in calcium, Vit D,- Phosphorus content cannot exceed calcium content (w/w basis)	<p>Indicates disease depends on many factors by listing risk factors or the disease:</p> <p>Gender--Female.</p> <p>Age—Growing older.</p> <p>Primary target population: Females, Caucasian and Asian races, and teens and young adults in their bone-forming years.</p> <p>Additional factors necessary to reduce risk: Eating healthful meals, regular exercise.</p> <p>Mechanism relating calcium to osteoporosis: Optimizes peak bone mass.</p> <p>Foods or supplements containing more than 400 mg calcium must state that total intakes of greater than 2,000 mg calcium provide no</p>	Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

		added benefit to bone health.	
--	--	-------------------------------	--

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Sodium and Hypertension--	- Low sodium	<p><i>Required terms:</i></p> <p>- "Sodium", "High blood pressure"</p> <p>Includes labeling advisory statement:” Individuals with high blood pressure should consult their physicians” if claim defines high or normal blood pressure .</p>	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Dietary Fat and Cancer	<p>- Low fat</p> <p>(Fish & game meats: "Extra lean" means less than 5g total fat, less than 2g saturated fat and less than 95mg cholesterol per serve and/or</p>	<p><i>Required terms:</i></p> <p>- "Total fat" or "Fat"</p> <p>- "Some types of cancers" or "Some cancers"</p> <p>Does not specify types of fats or fatty acids that may be related to risk of cancer.</p>	Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

	per 100g.)		
--	------------	--	--

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Dietary Saturated Fat & Cholesterol and Risk of Coronary Heart Disease	<ul style="list-style-type: none"> - Low saturated fat, - Low cholesterol, and - Low fat (Fish & game meats: "Extra lean")	<p><i>Required terms:</i></p> <ul style="list-style-type: none"> - "Saturated fat and cholesterol", - "Coronary heart disease" or "Heart disease" <p>Includes physician statement (individuals with elevated blood total--or LDL--cholesterol should consult their physicians) if claim defines high or normal blood total--and LDL--cholesterol.</p>	While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer-	<ul style="list-style-type: none"> - A grain product, fruit, or vegetable that contains dietary fiber; - Low fat, and - Good source of dietary fiber (without fortification) 	<p><i>Required terms:</i></p> <ul style="list-style-type: none"> - "Fiber", "Dietary fiber", or "Total dietary fiber" - "Some types of cancer" or "Some cancers" <p>Does not specify types of dietary fiber that may be related to risk of cancer.</p>	Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease- -	<ul style="list-style-type: none"> - A fruit, vegetable, or grain product that contains fiber; - Low saturated fat, - Low cholesterol, - Low fat, - At least 0.6 grams of soluble fiber per RA (without fortification), and, - Soluble fiber content provided on label 	<p><i>Required terms:</i></p> <ul style="list-style-type: none"> - "Fiber", "Dietary fiber", "Some types of dietary fiber", "Some dietary fibers", or "Some fibers" - "Saturated fat" and "Cholesterol" - "Heart disease" or "Coronary heart disease" <p>Includes physician statement ("Individuals with elevated blood total--or LDL--cholesterol should consult their physicians") if claim defines high or normal blood total--and LDL--cholesterol.</p>	Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Fruits and	- A fruit or	<i>Required terms:</i>	Low fat diets rich in fruits

Vegetables and Cancer--	<p>vegetable,</p> <ul style="list-style-type: none"> - Low fat, and - Good source (without fortification) of at least one of the following: <ul style="list-style-type: none"> • Vitamin A, • Vitamin C, or • Dietary fiber 	<ul style="list-style-type: none"> - "Fiber", "Dietary fiber", or "Total dietary fiber"; - "Total fat" or "Fat", - "Some types of cancer" or "Some cancers" <p>Characterizes fruits and vegetables as "Foods that are low in fat and may contain Vitamin A, Vitamin C, and dietary fiber."</p> <p>Characterizes specific food as a "Good source" of one or more of the following: Dietary fiber, Vitamin A, or Vitamin C.</p> <p>Does not specify types of fats or fatty acids or types of dietary fiber that may be related to risk of cancer.</p>	<p>and vegetables (foods that are low in fat and may contain dietary fiber, Vitamin A, or Vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamin A and C, and it is a good source of dietary fiber.</p>
-------------------------	---	---	--

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
-----------------	-------------------	--------------------	-------------------------

Folate and Neural Tube Defects--	<p>"Good source" of folate (at least 40 mcg folate per serving)</p> <p>- Dietary supplements, or conventional food forms that are naturally good sources of folate (i.e., only non-fortified food in conventional food form)</p> <p>- The claim shall not be made on products that contain more than 100% of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D</p> <p>- Dietary supplements shall meet USP standards for disintegration and dissolution or otherwise bioavailable</p> <p>-Amount of folate required in N.L.</p>	<p><i>Required terms:</i></p> <p>- Terms that specify the relationship (e.g., women who are capable of becoming pregnant and who consume adequate amounts of folate) "Folate", "folic acid", "folacin","folate a B vitamin", "folic acid, a B vitamin," "folacin, a B vitamin," "neural tube defects", "birth defects, spinal bifida, or anencephaly", "birth defects of the brain or spinal cord -- anencephaly or spinal bifida", "spinal bifida or anencephaly, birth defects of the brain or spinal cord".</p> <p>Must also include information on the multifactorial nature of neural tube defects, and the safe upper limit of daily intake.</p>	<p>Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.</p>
----------------------------------	--	--	---

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
-----------------	-------------------	--------------------	-------------------------

Dietary non cariogenic carbohydrate sweeteners and Dental Caries--	<p>-Sugar free</p> <p>-The sugar alcohol must be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of these</p> <p>-When a fermentable carbohydrate is present, the food must not be lower plaque pH below 5.7.</p>	<p><i>Required terms:</i></p> <p>- "does not promote," "may reduce the risk of," "useful [or is useful] in not promoting" or "expressly [or is expressly] for not promoting" dental caries;</p> <p>- "sugar alcohol" or "sugar alcohols" or the name or names of the sugar alcohols, e.g., sorbitol;</p> <p>- "dental caries" or "tooth decay."</p> <p>Includes statement that frequent between meal consumption of foods high in sugars and starches can promote tooth decay. Packages with less than 15 square inches of surface area available for labeling may use a shortened claim.</p>	<p>Full claim: Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.</p> <p>Shortened claim (on small packages only): Does not promote tooth decay.</p>
--	---	---	---

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Soluble Fiber from Certain Foods and	<p>-Low saturated fat</p> <p>-Low cholesterol</p>	<p><i>Required terms:</i></p> <p>- "Heart disease" or "coronary heart</p>	Soluble fiber from foods such as [name of soluble fiber source, and, if

<p>Risk of Coronary Heart Disease -</p>	<p>-Low fat</p> <p>-Include either (1) one or more eligible sources of whole oats, containing at least 0.75 g whole oat soluble fiber per RA; or (2) psyllium seed husk containing at least 1.7 g of psyllium husk soluble fiber per RA</p> <p>-Amount of soluble fiber per RA declared in nutrition label.</p> <p>Eligible Source of Soluble Fiber (See <u>updated information</u>)</p> <p>Beta (β) glucan soluble fiber from oat bran, rolled oats (or oatmeal), and whole oat flour. Oat bran must provide at least 5.5% β-glucan soluble fiber, rolled oats must provide at least 4% β-glucan soluble fiber, and whole oat flour must provide at least 4% β-glucan soluble fiber or Psyllium husk with purity of no less than 95%</p>	<p>disease."</p> <p>- "Soluble fiber" qualified by either "psyllium seed husk" or the name of the eligible source of whole oat soluble fiber.</p> <p>- "Saturated fat" and "cholesterol."</p> <p>- "Daily dietary intake of the soluble fiber source necessary to reduce the risk of CHD and the contribution one serving of the product makes to this level of intake."</p> <p>Additional Required Label Statement</p> <p>Foods bearing a psyllium seed husk health claim must also bear a label statement concerning the need to consume them with adequate amounts of</p>	<p><i>desired, name of food product</i>], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [<i>name of food product</i>] supplies ___ grams of the [necessary daily dietary intake for the benefit] soluble fiber from [<i>name of soluble fiber source</i>] necessary per day to have this effect.</p>
---	--	---	---

		fluids; e.g., "NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty in swallowing." (21 CFR 101.17(f))	
--	--	---	--

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Soy Protein and Risk of Coronary Heart Disease	<ul style="list-style-type: none"> - At least 6.25 g soy protein per RA - Low saturated fat, - Low cholesterol, and - Low fat (except that foods made from whole soybeans that contain no fat in addition to that inherent in the whole soybean are exempt from 	<p><i>Required terms:</i></p> <ul style="list-style-type: none"> - "Heart disease" or "coronary heart disease" - "Soy protein" - "Saturated fat" and "cholesterol" <p>Claim specifies daily dietary intake levels of soy protein associated with reduced risk</p> <p>Claim specifies amount of soy protein in a serving of food</p>	<p>(1) 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of <i>[name of food]</i> supplies __ grams of soy protein.</p> <p>(2) Diets low in saturated fat and cholesterol that includes 25 grams of soy protein a day may reduce the risk of heart disease. One serving of <i>[name of food]</i> provides __ grams of soy protein.</p>

	the "low fat" requirement)		
--	----------------------------	--	--

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Plant Sterol/stanol esters and Risk of Coronary Heart Disease	<ul style="list-style-type: none"> - At least 0.65 g plant sterol esters per RA of spreads and salad dressings, or - At least 1.7 g plant stanol esters per RA of spreads, salad dressings, snack bars, and dietary supplements. - Low saturated fat, - Low cholesterol, and - Spreads and salad dressings that exceed 13 g fat per 50 g must bear the statement "<i>see nutrition information for fat content</i>" <p>Salad dressings</p>	<p><i>Required terms:</i></p> <ul style="list-style-type: none"> - " May" or " might" reduce the risk of CHD - " Heart disease" or " coronary heart disease" - " Plant sterol esters" or " plant stanol esters" ; except " vegetable oil" may replace the term " plant" if vegetable oil is the sole source of the sterol/stanol ester <p>Claim specifies plant stero/stanol esters are part of a diet low in saturated fat and cholesterol.</p> <p>Claim does not attribute any degree of CHD risk reduction.</p> <p>Claim specifies the daily dietary intake of plant sterol or stanol esters necessary to reduce CHD risk, and the amount provided</p>	<p>(1) Foods containing at least 0.65 gram per serving of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of vegetable oil sterol esters.</p> <p>(2) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of plant stanol esters.</p>

	are exempted from the[minimum 10% DV nutrient requirement (see General Criteria below)	per serving. Claim specifies that plant sterol or stanol esters should be consumed with two different meals each a day.	
--	---	--	--

APPROVED CLAIMS	FOOD REQUIREMENTS	CLAIM REQUIREMENTS	MODEL CLAIM STATEMENTS
Whole Grain Foods and Risk of Heart Disease and Certain Cancers	<ul style="list-style-type: none"> - Contains 51 percent or more whole grain ingredients by weight per RA, and - Dietary fiber content at least: <ul style="list-style-type: none"> 3.0 g per RA of 55 g 2.8 g per RA of 50 g 2.5 g per RA of 45 g 1.7 g per RA of 35 g - Low fat 	<p><i>Required wording of the claim:</i></p> <p>"Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers."</p>	NA

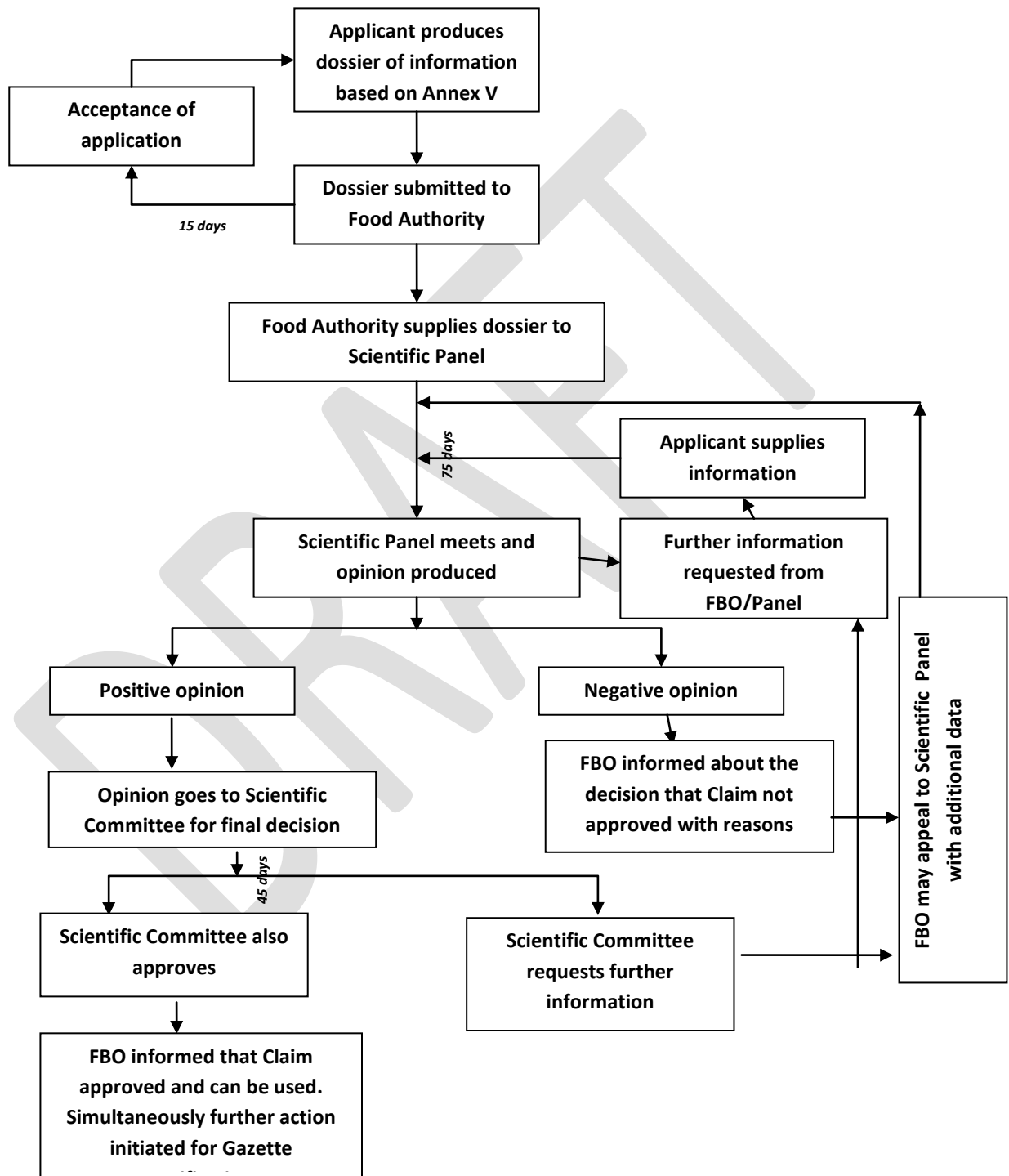
APPROVED CLAIMS	FOOD REQUIREMENTS	CLAIM REQUIREMENTS	MODEL CLAIM STATEMENTS
Potassium and the Risk of High Blood Pressure and Stroke	<ul style="list-style-type: none"> - Good source of potassium - Low sodium - Low total fat - Low saturated fat - Low cholesterol 	<p><i>Required wording for the claim:</i></p> <p>"Diets containing foods that are a good source of potassium and that</p>	

		are low in sodium may reduce the risk of high blood pressure and stroke."	
--	--	---	--

DRAFT

[Note to Draft: To confirm]

Annexure V A: FLOW CHART SHOWING PROCESS OF AUTHORIZATION OF CLAIMS



Annexure V B: Approval process for new Disease Risk Reduction Claims

- 1 Claim substantiation document is submitted by FBO to the Authority with the data on claim and criteria as per Annexure V required for establishing the food/food constituent health relationship that is disease risk reduction along with the product profile, clinical data or generic data supporting the same.
- 2 Within a period of 15 days of submitting the application, the Authority secretariat shall review the data and shall ask for any further information which may be required by the scientific panel or forwards the data to the members of the Scientific Panel on labeling and claims and shall call for a meeting of the Panel at the earliest but not later than 45 days from the receipt of an application.
- 3 At the Scientific Panel meeting, during the initial deliberations, the representatives of the claim submitting FBO, shall be called for explaining the case.
- 4 Scientific Panel evaluates the data and gives their decision on the claim. The decision may not require the Panel to meet again physically.
- 5 The Scientific Panel on claims may either
 - Find the data adequate to establish a food and its disease risk reduction relationship and approve the claim
 - Find the data inadequate to establish a food and its disease risk reduction relationship and ask the claim submitting company for further data required to re-evaluate the claim
 - Do not find any relationship between the food and its disease risk reduction relationship and reject the claim giving detailed reasoning for the same
- 6 Communication on the decision at Step 5, shall be conveyed to the FBO, through a letter, email or fax, with the stated reason of approval or rejection or resubmission within a period of 10 days from the scientific panel meeting by the food authority secretariat.
- 7 After approval from the Panel, if it deems necessary, Authority may refer the case to the Scientific Committee for final approval and in such case shall forthwith forward the application along-with the decision of the Panel to the members of Scientific Committee who shall forward their written comments or queries.
- 8 Any queries from the members of the scientific committee shall be forwarded to the Panel or the claim submitting FBO (if required). The response from panel members(s) or FBO shall be forthwith forwarded to scientific Committee members and decision sought.
- 9 If required a meeting of the scientific committee may be called and any member of the Panel or the FBO may be called for a hearing at this meeting.
- 10 Authority shall on basis of the decision of Scientific committee, inform the FBO through a letter, email or fax, with the stated reason of approval or rejection or resubmission within a period of one week from the scientific committee meeting and the FBO will henceforth be able to launch the product with the said claim on receiving this letter.
- 11 Authority shall simultaneously initiate action towards notifying the claim in the Gazette for inclusion in the list of approved claims in the Regulations.
- 12 Till the Gazette notification is out, the approval letter from food authority to the company will serve as a legal note

ANNEXURE VI: SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS FOR CLAIMANTS & REVIEWERS

1. SCIENTIFIC SUBSTANTIATION OF HEALTH CLAIMS

1. This criteria is intended to assist Authority in evaluation of health claims in order to determine their acceptability for use by the industry. The recommendations focus on the criteria for substantiating a health claim and the general principles for the systematic review of the scientific evidence. The criteria and principles apply to the three types of health claims as defined in this regulation.
2. These recommendations include consideration of safety in the evaluation of proposed health claims, but are not intended for the complete evaluation of the safety and the quality of a food, for which relevant provisions are laid out by other Standards in the FSS Regulations.

2. PROCESS FOR THE SUBSTANTIATION OF HEALTH CLAIMS

The systematic review of the scientific evidence for health claims shall take into account the general principles for substantiation. Such a process typically includes the following steps:

- (a) Identify the proposed relationship between the food or food constituent and the health effect;
- (b) Identify appropriate valid measurements for the food or food constituent and for the health effect;
- (c) Identify and categorize the relevant scientific data;
- (d) Assess the quality of and interpret relevant scientific study;
- (e) Evaluate the totality of the available relevant scientific data, weigh the evidence across studies and determine if, and under what circumstances, a claimed relationship is substantiated.

3. CRITERIA FOR THE SUBSTANTIATION OF HEALTH CLAIMS

The following criteria are applicable to the three types of health claims as defined in the regulations:

- a. Health claims should primarily be based on evidence provided by well-designed human intervention studies. Human observational studies may contribute to the totality of evidence. Animal model studies, ex vivo or in vitro data may be provided as supporting knowledge base for the relationship between the food or food constituent and the health effect but cannot be considered as sufficient per se to substantiate any type of health claim.
- b. The totality of the evidence, including unpublished data where appropriate, should be identified and reviewed, including: evidence to support the claimed effect; evidence that contradicts the claimed effect; and evidence that is ambiguous or unclear.

- c. Evidence based on human studies should demonstrate association between the food or food constituent and the health effect, with little or no evidence to the contrary.

Although a high quality of scientific evidence should always be maintained, substantiation may take into account specific situations and alternate processes, such as:

(a) 'Nutrient function' claims may be substantiated based on generally accepted authoritative statements by recognized expert scientific bodies, peer-reviewed scientific literature. This includes text book references that been established over long time periods.

(b) Some Health claims, such as those involving a relationship between a food category and a health effect, may be substantiated based on observational evidence such as epidemiological studies. Such studies should provide a consistent body of evidence from a number of well-designed studies. Evidence-based dietary guidelines and authoritative statements prepared or endorsed by a competent authoritative body and meeting the same high scientific standards may also be used.

4. CONSIDERATION OF THE EVIDENCE

- a. The scientific studies considered relevant for the substantiation of health claim are those addressing the relationship between the food or food constituent and the health effect. In case of a claimed health effect that cannot be measured directly, relevant validated biomarkers may be used (e.g. plasma cholesterol concentrations for cardiovascular disease risk).
- b. The scientific data should provide adequate characterization of the food or food constituent considered as responsible for the health effect. Where applicable, the characterization includes a summary of the studies undertaken on production conditions, batch-to-batch variability, analytical procedures, results and conclusions of the stability studies, and the conclusions with respect to storage conditions and shelf-life.
- c. The relevant data and rationale that the constituent for which the health claim is made is in a form that is available to be used by the human body should be provided where applicable. If absorption is not necessary to produce the claimed effect (e.g. plant sterols, fibres, lactic acid bacteria), the relevant data and rationale that the constituent reaches the target site or mediates the effect are provided. All available data on factors (e.g. forms of the constituents) that could affect the absorption or utilisation in the body of the constituent for which the health claim is made should also be provided.
- d. The methodological quality of each type of study should be assessed, including study design and statistical analysis.
- e. The design of human intervention studies should notably include an appropriate control group, characterize the study groups' background diet and other relevant aspects of lifestyle, be of an adequate duration, take account of the level of consumption of the food or food constituent that can be reasonably achieved in a balanced diet, and assess the influence of the food matrix and total dietary context on the health effect.
- f. Statistical analysis of the data should be conducted with methods recognized as appropriate for such studies by the scientific community and with proper interpretation of statistical significance.

- g. Studies should be excluded from further review and not included in the relevant scientific data if they do not use appropriate measurements for the food or food constituent and health effect, have major design flaws, or are not applicable to the targeted population for a health claim.
- h. By taking into account the totality of the available relevant scientific data and by weighing the evidence, the systematic review should demonstrate the extent to which:
 - i. the claimed effect of the food or food constituent is beneficial for human health;
 - ii. a cause and effect relationship is established between consumption of the food or food constituent and the claimed effect in humans such as the strength, consistency, specificity, dose-response, where appropriate, and biological plausibility of the relationship;
 - iii. the quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet as relevant for the target population for which the claim is intended;
 - iv. the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

5. SPECIFIC SAFETY CONCERNS

- a. The expected level of consumption should not exceed relevant upper levels of intake for food constituents.
- b. The exposure assessment should be based on an evaluation of the distribution of usual total daily intakes for the general population and, where relevant, those for vulnerable population groups.

6. RE-EVALUATION

Health claims shall be re-evaluated either periodically or following the emergence of significant new evidence that has the potential to alter previous conclusions about the relationship between the food or food constituent and the health effect.