

Product Development

A Regulatory Journey

Turning Point for Food Industry- Year 2006



Parliament of India promulgates Food Safety and Standards Act, 2006

Establishes independent body – Food Safety & Standards Authority of India (FSSAI)

Raises punishment bar for offences

Repeals previous multiple laws

Introduces Food Recall procedure

Shifts focus to safe, wholesome food

Food Safety and Standards Authority of India (FSSAI)

FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.



Food Product Classification

Standardized Food
Product

Proprietary Food

Food Product Standards

“Standard”, in relation to any article of food, means the standards notified by the Food Authority

FSSAI Standards - Examples

2.1.4: DAHI OR CURD

1. Dahi or curd means the product obtained from pasteurised or boiled milk by souring, natural or otherwise, by a harmless lactic acid culture or other harmless bacterial culture may also be used in conjunction with lactic acid bacteria cultures for souring. Dahi may contain added cane sugar. Dahi shall have the same minimum percentage of milk fat and milk solids-not-fat as the milk from which it is prepared.

Where dahi or curd is sold or offered for sale without any indication of class of milk, the standards prescribed for dahi prepared from buffalo milk shall apply.

Milk solids may also be used in preparation of this product.

Obtained by
souring

May contain
harmless lactic acid
bacteria

May contain added
cane sugar

Must have same %
of milk fat & MSNF
as the milk from
which it is prepared

Milk solids may be
used in preparation

FSSAI Standards - Examples

2.1.12: FERMENTED MILK PRODUCTS

1. **Yoghurt** means a coagulated product obtained from pasteurised or boiled milk or concentrated milk, pasteurised skimmed milk and /or pasteurised cream or a mixture of two or more of these products by lactic acid fermentation through the action of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. It may also contain cultures of *Bifidobacterium bifidus* and *Lactobacillus acidophilus* and other cultures of suitable lactic acid producing harmless bacteria and if added a declaration to this effect shall be made on the label. The microorganisms in the final product must be viable and abundant. It may contain milk powder, skimmed milk powder, unfermented buttermilk, concentrated whey, whey powder, whey protein, whey protein concentrate, water soluble milk proteins, edible casein, and caseinates manufactured from pasteurised products. It may also contain sugar, corn syrup or glucose syrup in sweetened, flavoured and fruit yoghurt or fruits in fruits yoghurt. It shall have smooth surface and thick consistency without separation of whey. It shall be free from vegetable oil/ fat, animal body fat, mineral oil and any other substance foreign to milk. The product may contain food additives permitted in these regulation including Appendix A. It shall conform to the microbiological requirements prescribed in Appendix B. It shall conform to the following requirements:—

FSSAI Standards - Examples

Fermented Milk Products

Product	Milk Fat	Milk solids not fat	Milk Protein	Sugar
Yoghurt	Not < 3%	Not < 8.5%	Not < 3.2%	-
Partly skimmed Yoghurt	Not < 0.5% & not > 3%	Not < 8.5%	Not < 3.2%	-
Skimmed Yoghurt	Not > 0.5%	Not < 8.5%	Not < 3.2%	-
Sweetened Flavoured Yoghurt	Not < 3%	Not < 8.5%	Not < 3.2%	Not < 6%
Fruit Yoghurt	Not < 1.5%	Not < 8.5%	Not < 2.6%	Not < 6%

- Provided that titrable acidity as lactic acid shall not be < 0.85% and not > 1.2%
- The specific lactic acid producing bacterial count per gram shall not be < 10,00,000.
- Minimum requirement of specific lactic acid producing bacteria not applicable to heat treated yoghurt.

Dahi and Yogurt in India



Food Product Standard

Proprietary Food

Article of food not standardized under FSSAI regulation

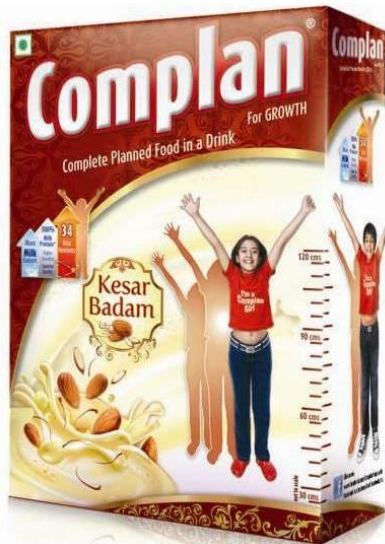
Does not include

- Novel foods
- Foods for special dietary uses
- Foods for special medical purposes
- Functional Foods
- Nutraceuticals
- Health Supplements

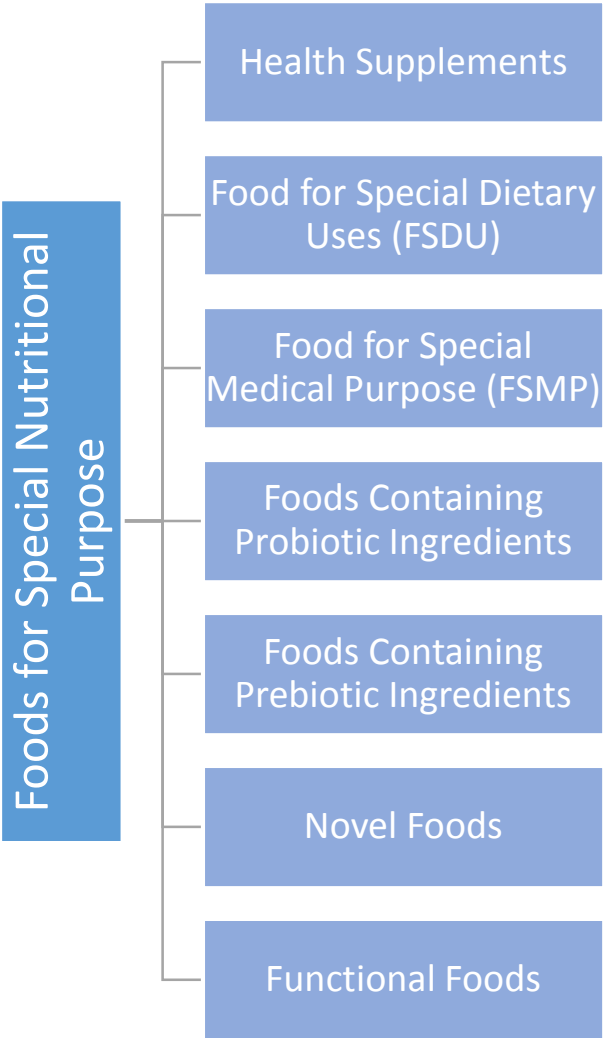
Contain only those ingredients other than additives which are either standardized or permitted in other standardized food

Comply with all other regulatory provisions specified in these regulations and in Appendices A and B.

Proprietary Foods



Draft Regulation on Foods for Special Nutritional Purpose



Food Product Standards

Appendix A

- List of additives and amount for various food categories and sub-categories

Appendix B

- Microbiological requirements for various food categories and sub-categories

Shelf Life Study

Why

- Determine the period for which the food remains safe and acceptable in terms of
 - Microbial count
 - Taste
 - Appearance
 - Vitamin levels
 - Odour

How

- Establish a protocol based on product & packaging
- Real Time Study – entire proposed shelf life duration at ambient temperature and RH
- Accelerated Study – typically done at 37°C & 90% RH
- Typical analysis – vitamin levels, microbial load, moisture, water activity

No FSSAI Guideline exists as yet for shelf life studies
Validated shelf life study report should be available before product launch

Lab analysis – NABL accredited & FSSAI recognized

Heavy Metals (Pb,
As, Hg, Sn)

Pesticide Residues

Contaminants
(Melamine,
Aflatoxin)

Nutritional
Parameters (Initial &
end of shelf life)

Microbiology
(pathogens)

Packaging



FSSAI Regulations

- General
- Product Specific
 - Milk and Milk Products
 - Edible oil/fat
 - Fruits & Vegetable Products
 - Canned Meat Products
 - Drinking Water

Product Label - Mandatory Items

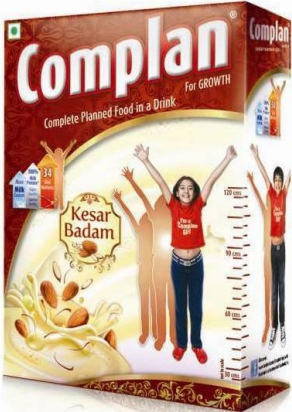
Ingredient List

Nutrition Facts

Veg or Non-Veg

Name of Food

List of Food Additives



Name and Address of Manufacturer

Lot Code Batch Identification

Net Quantity

Date of manufacture or Packaging

Best before and Use by date

Additional Guidelines for Labelling of Specific Foods

Product Claims

Nutrition Claim

- Nutrient Content Claim
- Nutrient Comparative Claim
- Non-addition Claim

Health Claim

- Nutrient Function Claim
- Other Function Claim
- Reduction of Disease Risk Claim

Regulations for Nutrition and Health Claims



Nutrient Content Claim



Describes the level of a nutrient contained in a food

Source of Calcium	High in Fibre
Low in Saturated Fat	Fat Free
Low Sodium	

Table of conditions for nutrient content claims

COMPONENT	CLAIM	CONDITIONS (not more than)
Energy	Low	40 kcal (170 kJ) per 100 g (solids) or 20 kcal (80 kJ) per 100 ml (liquids)
	Free	4 kcal per 100 ml (liquids)
Fat	Low	3 g per 100 g (solids) 1.5 g per 100 ml (liquids)
	Free	0.5 g per 100 g (solids) or 100 ml (liquids)
Saturated Fat ²	Low	1.5 g per 100 g (solids) 0.75 g per 100 ml (liquids) and 10% of energy from saturated fat
	Free	0.1 g per 100 g (solids) 0.1 g per 100 ml (liquids)
Cholesterol ²	Low	0.02 g per 100 g (solids) 0.01 g per 100 ml (liquids)
	Free	0.005 g per 100 g (solids) 0.005 g per 100 ml (liquids) and, for both claims, less than: 1.5 g saturated fat per 100 g (solids) 0.75 g saturated fat per 100 ml (liquids) and 10% of energy from saturated fat
Sugars	Free	0.5 g per 100 g (solids) 0.5 g per 100 ml (liquids)
Sodium	Low	0.12 g per 100 g
	Very Low	0.04 g per 100 g
	Free	0.005 g per 100 g
COMPONENT	CLAIM	CONDITIONS (not less than)
Protein	Source	10% of NRV per 100 g (solids) 5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 10% of NRV per serving
	High	2 times the values for "source"
Vitamins and Minerals	Source	15% of NRV per 100 g (solids) 7.5% of NRV per 100 ml (liquids) or 5% of NRV per 100 kcal (12% of NRV per 1 MJ) or 15% of NRV per serving
	High	2 times the value for "source"
Dietary Fibre	Source	3 g per 100 g ³ or 1.5 g per 100 kcal or 10 % of daily reference value per serving ⁴
	High	6 g per 100 g ³ or 3 g per 100 kcal or 20 % of daily reference value per serving ⁴

Nutrient Comparative Claim



Compares the nutrient levels and/or energy value of two or more foods

Product A contains 25% less fat than Product B

Product A contains less sugar than Product B

6. COMPARATIVE CLAIMS

Comparative claims should be permitted subject to the following conditions and based on the food as sold, taking into account further preparation required for consumption according to the instructions for use on the label:

- 6.1 The foods being compared should be different versions of the same food or similar foods. The foods being compared should be clearly identified.
- 6.2 A statement of the amount of difference in the energy value or nutrient content should be given. The following information should appear in close proximity to the comparative claim:
 - 6.2.1 The amount of difference related to the same quantity, expressed as a percentage, fraction, or an absolute amount. Full details of the comparison should be given.
 - 6.2.2 The identity of the food(s) to which the food is being compared. The food(s) should be described in such a manner that it (they) can be readily identified by consumers.
- 6.3.1 For comparative claims about energy or macronutrients and sodium, the comparison should be based on a relative difference of at least 25% in the energy value or the nutrient content respectively between the compared foods and a minimum absolute difference in the energy value or nutrient content equivalent to the figure defined as "low" or as a "source" in the Table to these Guidelines.
- 6.3.2 For comparative claims about micronutrients other than sodium the comparison should be based on a difference of at least 10% of the NRV between the compared foods.
- 6.4 In addition to the conditions set out in Section 6.3, the content of trans fatty acids should not increase for foods carrying a comparison claim for decreased saturated fatty acids content.
- 6.5 The use of the word "light" or a synonymous claim should follow the criteria listed in Section 6.3 of these Guidelines and include an indication of the characteristics which make the food "light".

Non-Addition Claim

Ingredient has not been added to a food, either directly or indirectly. The ingredient is one whose presence or addition is permitted in the food and which consumers would normally expect to find in the food

7. NON-ADDITION CLAIMS

7.1 Non-Addition of Sugars

Claims regarding the non-addition of sugars to a food may be made provided the following conditions are met.

- (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 substitute for added sugars (Examples: non-reconstituted concentrated fruit juice, dried fruit paste, etc.); and
- (d) The sugars content of the food itself has not been increased above the amount contributed by the ingredients by some other means (Example: the use of enzymes to hydrolyse starches to release sugars).

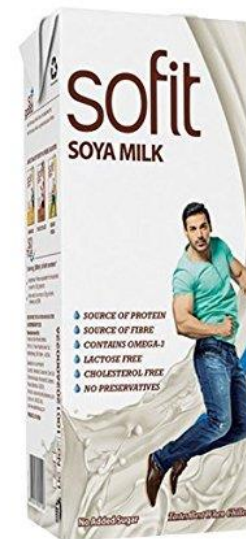
7.2 Non-Addition of Sodium Salts

Claims regarding the non-addition of sodium salts to a food, including “no added salt”, may be made provided the following conditions are met⁶.

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



No added sugar



7.3 Additional Conditions

Additional conditions and/or disclaimer statements may be used with non-addition claims to assist consumer understanding of the claims within countries. Disclaimer statements should appear in close proximity to, on the same side and in the same prominence as the claim. These may be developed based on evidence of consumer use and understanding.

Health Claim

Any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health

Nutrient Function Claim

Describes the physiological role of the nutrient in growth, development and normal functions of the body

Calcium is necessary for normal bone and teeth structure. Product A is high in Calcium

Iron contributes to normal cognitive function. Product A is a good source of Iron



8. HEALTH CLAIMS

- 8.1 Health claims should be permitted provided that all of the following conditions are met:
- 8.1.1 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 and the scientific substantiation should be reviewed as new knowledge becomes available.⁶ The health claim must consist of two parts:
- 1) Information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by
 - 2) 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.
- 8.1.2 Any health claim must be accepted by or be acceptable to the competent authorities of the country where the product is sold.
- 8.1.3 The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituent in the context of a healthy diet.
- 8.1.4 If the claimed benefit is attributed to a constituent in the food, for which a Nutrient Reference value is established, the food in question should be:
- (i) a source of or high in the constituent in the case where increased consumption is recommended; or,
 - (ii) low in, reduced in, or free of the constituent in the case where reduced consumption is recommended.
- Where applicable, the conditions for nutrient content claims and comparative claims will be used to determine the levels for "high", "low", "reduced", and "free".
- 8.1.5 Only those essential nutrients for which a Nutrient Reference Value (NRV) has been established in the Codex *Guidelines on Nutrition Labelling* or those nutrients which are mentioned in officially recognized dietary guidelines of the national authority having jurisdiction, should be the subject of a nutrient function claim.
- 8.2 Health claims should have a clear regulatory framework for qualifying and/or disqualifying conditions for eligibility to use the specific claim, including the ability of competent national authorities to prohibit claims made for foods that contain nutrients or constituents in amounts that increase the risk of disease or an adverse health-related condition. The health claim should not be made if it encourages or condones excessive consumption of any food or disparages good dietary practice.
- 8.3 If the claimed effect is attributed to a constituent of the food, there must be a validated method to quantify the food constituent that forms the basis of the claim.
- 8.4 The following information should appear on the label or labelling of the food bearing health claims:
- 8.4.1 A statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim.
- 8.4.2 The target group, if appropriate.
- 8.4.3 How to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate.
- 8.4.4 If appropriate, advice to vulnerable groups on how to use the food and to groups, if any, who need to avoid the food.
- 8.4.5 Maximum safe intake of the food or constituent where necessary.
- 8.4.6 How the food or food constituent fits within the context of the total diet.
- 8.4.7 A statement on the importance of maintaining a healthy diet.

Other Function Claim

Concern specific beneficial effects of the consumption of foods or constituents, **in the context of the total diet** on 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

A diet rich in Dietary Fibre contributes to regular laxation. Product A is high in fibre

A diet containing 500 mg of EPA and DHA per day contributes to heart health. Product A contains 500 mg of EPA and DHA per serving



SCHEDULE 3 (continued)

**Conditions for permitted general level health claims
Part 3 – Other (continued)**

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	Specific health effect	Relevant population	Dietary Context	Conditions
Dietary fibre	Contributes to regular laxation			The food must meet the general conditions for making a nutrition content claim about dietary fibre
Eicosapentaenoic acid (EPA) and Docosa-hexaenoic acid (DHA) (but not Omega-3)	Contributes to heart health		Diet containing 500 mg of EPA and DHA per day	<ul style="list-style-type: none"> (a) the food must contain a minimum of 50 mg EPA and DHA combined in a serving of food; b) other than for fish or fish products with no added saturated fatty acids, the food contains – <ul style="list-style-type: none"> (i) as a proportion of the total fatty acid content, no more than 28% saturated fatty acids and trans fatty acids; or (ii) no more than 5 g per 100 g saturated fatty acids and trans fatty acids.

Reduction of Disease Risk Claims

Relating the consumption of a food or food constituent, **in the context of a total diet** to the reduced risk of developing a disease or a health-related condition

A healthy diet low in saturated fat reduces LDL cholesterol. Product A is low in saturated fat

A healthy diet low in salt or sodium reduces blood pressure. Product A is low in sodium/salt

Column 1	Column 2	Column 3	Column 4	Column 5
Food or property of food	Specific health effect	Relevant population	Context claim statements	Conditions
Increased intake of fruit and vegetables	Reduces risk of coronary heart disease		Diet containing an increased amount of both fruit and vegetables	(a) claims are not permitted on – (i) fruit juice or vegetable juice as standardised in Standard 2.6.1; or (ii) a food standardised in Standard 2.6.2; and (b) the food must contain no less than 90% fruit or vegetable by weight
Phytosterols, phytosterols and their esters	Reduces blood cholesterol		Diet low in saturated fatty acids Diet containing 2 g of phytosterols, phytosterols and their esters per day	The food must – (a) meet the relevant conditions specified in Columns 1 and 2 of the Table to clause 2 in Standard 1.5.1; and (b) contain a minimum of 0.8 g total plant sterol equivalents content per serving
Saturated fatty acids	Reduces total blood cholesterol or blood LDL cholesterol		Diet low in saturated fatty acids	The food must meet the conditions for making a nutrition content claim about low saturated fatty acids
Saturated and trans fatty acids	Reduces total blood cholesterol or blood LDL cholesterol		Diet low in saturated and trans fatty acids	The food must meet the conditions for making a nutrition content claim about low saturated and trans fatty acids
Sodium or salt	Reduces blood pressure		Diet low in salt or sodium	The food must meet the conditions for making a nutrition content claim about low sodium or salt

Thank You