

SCIENTIFIC BASIS FOR LABELING, CLAIMS & REGULATIONS FOR PROBIOTICS: A GUIDANCE DOCUMENT

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on
Functional Foods,
Immunity and Gut Health
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Appendix I

Overview on Current Research in India

Key Research Work	
National Dairy Research Institute (NDRI) Indian Council of Agricultural Research (ICAR)	<p>In 2006, they commenced work in the field of probiotics of Indian gut origin. The key highlights of the work are given below:</p> <ul style="list-style-type: none"> • Characterization of approximately 100 indigenous probiotics strains and maintaining them as a repository of indigenous probiotics at Molecular Biology Unit (MBU), Dairy Microbiology Division, ICAR, NDRI, Karnal. • Development of method named as MLST (Multi Locus Sequence Typing) which help to resolve the intra-species diversity among <i>L. plantarum</i> species. • Research on indigenous probiotic strains and their role as a bio-therapeutics in the management of chronic inflammatory metabolic disorders like diabetes and other life style diseases. • Metagenomic study on healthy human subjects from North India and North East (NE) India in order to determine the difference in the metagenome and their respective commensal gut microbiota, dominance of specific phylotypes under different dietary conditions and any shift in the structure of microbiota on ageing. This study is yet to be published. • A comparative study on link between the autism spectrum disorder with dysbiotic gut. In this study the gut enterotypes in healthy and autistic children was studied. • Study on link between Type 2 Diabetes and key metabolic bacteria named <i>Faecalibacterium prausnitzii</i>. • Study determining the comparative abundance of major gut enterotypes in healthy, Moderate Acute Malnourished (MAM) and Severe Acute Malnourished (SAM) children using absolute qPCR technique.
Indian Council of Medical Research (ICMR)	<p>Several studies have been conducted by ICMR that provides scientific substantiation regarding role of probiotics in health. The key work are as follows:</p> <ul style="list-style-type: none"> • Field trial named as ADBRC (Deep Binary Reconstruction) among children in the age group between 1-5 years, to determine the role of probiotics in managing diarrhoea. • Study on the role of Probiotics in preventing necrotizing enterocolitis (NE) in preterm Neonates: A Meta -Analysis. • Effect of probiotics as a daily supplementation in the risk reduction of neonatal sepsis among LBW infants.
National Institute of Nutrition (NIN) Indian Council of Medical Research (ICMR)	<p>They have conducted the following studies:</p> <ul style="list-style-type: none"> • Study on role of probiotics in treating bacterial vaginitis (BV) among pregnant women. • Study on the effect of probiotics on vaginal health and pro-inflammatory cytokines showing nearly 80% cure rate (Hemalatha et al, 2012). • Study showing that oral supplementation of probiotics strains- <i>Lactobacillus rhamnosus</i> GR-1 and <i>Lactobacillus reuteri</i> RC-14 with the concentration of 2×10^8 CFU /capsule in pregnant women helps in restoring the normal flora of vagina and reduce the relapse of BV infection: A randomized, double blind, placebo-controlled trial.
Translational Health Sciences and Technology Institute (THSTI) Department of Biotechnology	<ul style="list-style-type: none"> • Development of an improved DNA extraction method. This method enables extraction of DNA more easily from different environmental and human samples. • Studies showing that decreased nutritional status and increased abundance of pathogenic microbial groups has caused depletion of several commensal bacteria, such as <i>Roseburia</i>, <i>Faecalibacterium</i>, <i>Butyrivibrio</i>, <i>Eubacterium</i> and <i>Phascolarctobacterium</i>.

	<ul style="list-style-type: none"> • Studies highlighting that the gut microbiome of Indian communities living in high altitude areas and urban areas have a specific microflora signature. Moreover, the microbial diversity, abundance variation and interaction patterns of the gastric microbiota of Indian patients with <i>Helicobacter pylori</i> infection present region-specific profiles. Further, the genome sequence of several gut anaerobes helps in understanding the ecology in Indian population context. • Investigation on the prevalence of antimicrobial resistance (AMR) encoding genes among pathogenic enteric bacteria from diarrheal patients and commensal microbiota residing in the gut of healthy subjects.
Institute of Microbial Technology (IMTECH)	<ul style="list-style-type: none"> • IMTECH has a large collection of readily available microbial strain with potential GRAS status including <i>Lactobacillus</i> species which can be used as an application in food and pharmaceutical industry. • A culture independent study was carried out at IMTECH for characterization of the lung and gut microbiome. • Another area on which IMTECH is working is named “Probiogenomics”. This will help to understand the origin, evolution and adaption of culturable commensal bacteria from oral, gut and skin using high-throughput genomics and transcriptomic approaches. • The team of researchers at IMTECH has also published a large scale phylogeographic studies on a commensal bacterium. • IMTECH scientists are involved in developing consortia of microbes with synergistic probiotic properties for human health through large scale studies on culturomics, genomics, evolutionary and functional.
Tata Chemicals Ltd. (TCL)	Studies on FOS (fructooligosaccharides) which are well known prebiotics that promote the growth of selective beneficial bacteria in the intestine. The following are the details of the studies: a single centre, randomized double-blind, placebo-controlled, dose-response study to explore the efficacy of FOS (fructooligosaccharides) on human gut microflora; a study on modulation of the gut microbiota by short chain Fructo-oligosaccharides in human microbiota-associated gnotobiotic mice. Moreover, a Cohort study which shows that the consumption of FOS increased the relative abundance of bacterial species belonging to the genera <i>Bifidobacterium</i> and <i>Lactobacillus</i> .
Central Food Technology Research Institute (CFTRI) Council of Scientific and Industrial Research	Several studies have been conducted by CFTRI using the strains of the <i>Lactobacillus</i> bacteria. Now they are working on 2 strains named <i>Bifidobacterium breve</i> NCIM 5671 and <i>Bifidobacterium longum</i> NCIM5672. Researchers have also explored the effects of these strains on arthritis <i>in vivo</i> studies which are carried out on rat models. These two strains were also used in the preparation of curds, soy curd and bifidocurd.
National Centre for Cell Science (NCCS) Council of Scientific and Industrial Research	A study has been undertaken by National Centre for Cell Science (NCCS) on Indian gut microbiome with 20,000 individuals of the different ethnic groups, found in different geographical areas across the country and will correlate the data with microbiome. Study will provide baseline data on gut microbiome of healthy Indians, dietary habits and other parameters such as lifestyle disorders. Anthropometric measurements and basic parameters like Haemoglobin and sugar will be monitored. Urine metabolomics will be covered in the study where urine metabolome will be compared with gut microbiome

Source: ILSI India Monograph on Probiotics In Promoting Healthy Microbiome For Health And Immunity

Appendix II

Schedule VII

(As per FSSAI, Nutraceuticals Regulation)

List of Strains as Probiotics (live micro-organisms)

S. No.	Name of the Microorganism
1.	<i>Lactobacillus acidophilus</i>
2.	<i>Lactobacillus plantarum</i>
3.	<i>Lactobacillus reuteri</i>
4.	<i>Lactobacillus rhamnosus</i>
5.	<i>Lactobacillus salivarius</i>
6.	<i>Lactobacillus casei</i>
7.	<i>Lactobacillus brevis</i>
8.	<i>Lactobacillus johnsonii</i>
9.	<i>Lactobacillus delbrueckii sub- sp. bulgaricus</i>
10.	<i>Bacillus coagulans</i>
11.	<i>Lactobacillus fermentum</i>
12.	<i>Lactobacillus caucasicus</i>
13.	<i>Lactobacillus helveticus</i>
14.	<i>Lactobacillus lactis</i>
15.	<i>Lactobacillus amylovorus</i>
16.	<i>Lactobacillus gallinarum</i>
17.	<i>Lactobacillus delbrueckii</i>
18.	<i>Bifidobacterium bifidum</i>
19.	<i>Bifidobacterium lactis</i>
20.	<i>Bifidobacterium breve</i>
21.	<i>Bifidobacterium longum</i>
22.	<i>Bifidobacterium animalis</i>
23.	<i>Bifidobacterium infantis</i>
24.	<i>Streptococcus thermophilus</i>
25.	<i>Saccharomyces boulardii</i>
26.	<i>Saccharomyces cerevisiae</i>
27.	<i>Lactobacillus paracasei</i>
28.	<i>Lactobacillus gasseri</i>

Note: - 1) These organisms may be used either singly or in combination but shall be declared on the label with full information and has to be Non-GMO.

2) The Food Authority may add any new strain of microorganism, possessing probiotic properties, after proper scientific evaluation, and include them.

Source: Food Safety and Standards Nutraceutical Regulation, 2016

Appendix III

Schedule VA
(As per FSSAI, Nutraceuticals Regulation)

List of Food Additives for Health Supplements, Nutraceuticals and Food with Added Probiotics and Prebiotics

S. No.	INS No.	Food Additive or Group	Maximum permitted level
1.	950	Acesulfame potassium	2,000 mg/kg
2.	304, 305	Ascorbyl Esters	500 mg/kg
3.	951	Aspartame	5,500 mg/kg
4.	962	Aspartame-Acesulfame salt	2,000 mg/kg
5.	901	Beeswax	GMP
6.	210, 211, 212, 213	Benzoates	2,000 mg/kg
7.	133	Brilliant blue FCF	300 mg/kg
8.	320	Butylated hydroxyanisole (BHA)	400 mg/kg
9.	321	Butylated hydroxytoluene (BHT)	400 mg/kg
10.	902	Candelilla wax	GMP
11.	150c	Caramel III – Ammonia caramel	20,000 mg/kg
12.	150d	Caramel IV – Sulfite ammonia caramel	20,000 mg/kg
13.	903	Carnauba wax	5,000 mg/kg
14.	160a(ii)	beta-Carotenes (vegetable)	600 mg/kg
15.	160a(i), (iii), 160e, 160f	Carotenoids	300 mg/kg
16.	1503	Castor oil	1,000 mg/kg
17.	141(i), (ii)	Chlorophylls and Chlorophyllins, Copper Complexes	500 mg/kg
18.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
19.	385, 386	Ethylene diamine tetra acetates	150 mg/kg
20.	143	Fast green FCF	600 mg/kg
21.	163(ii)	Grape skin extract	500 mg/kg
22.	132	Indigotine (Indigo carmine)	300 mg/kg
23.	961	Neotame	90 mg/kg
24.	338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i),(ii), 343(i)-(iii), 450(i)-(iii),(v)-(vii), 451(i),(ii), 452(i)-(v), 542	Phosphates	2,200 mg/kg
25.	1203	Polyvinyl alcohol	45,000 mg/kg
26.	900a	Polydimethylsiloxane	50 mg/kg
27.	1521	Polyethylene Glycol	70,000 mg/kg
28.	432-436	Polysorbates	25,000 mg/kg
29.	1201	Polyvinylpyrrolidone	GMP
30.	124	Ponceau 4R (Cochineal red A)	300 mg/kg
31.	310	Propyl gallate	400 mg/kg
32.	101(i)-(iii)	Riboflavins	300 mg/kg
33.	954(i)-(iv)	Saccharins	1,200 mg/kg
34.	904	Shellac, Bleached	GMP
35.	200-203	Sorbates	2,000 mg
36.	960	Steviol Glycosides	2,500 mg/kg
37.	955	Sucralose (Trichlorogalactosucrose)	2,400 mg/kg
38.	474	Sucroglycerides	2,500 mg/kg
39.	110	Sunset yellow FCF	300 mg/kg

**List of Food Additives for Foods for Special Dietary Use and Food with
Added Probiotics and Prebiotics**

S. No.	INS No.	Food Additive or Group	Maximum permitted level
1.	950	Acesulfame potassium	450 mg/kg
2.	956	Alitame	300 mg/kg
3.	304, 305	Ascorbyl Esters	500 mg/kg
4.	951	Aspartame	1,000 mg/kg
5.	962	Aspartame-acesulfame salt	450 mg/kg
6.	210, 211, 212, 213	Benzoates	2,000 mg/kg
7.	133	Brilliant blue FCF	300 mg/kg
8.	150c	Caramel III – Ammonia caramel	20,000 mg/kg
9.	150d	Caramel IV - Sulfite ammonia caramel	20,000 mg/kg
10.	160a(ii)	Beta-Carotenes (vegetable)	600 mg/ kg
11.	160a(i), (iii), 160e, 160f	Carotenoids	3mg/kg
12.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
13.	163(ii)	Grape skin extract	250 mg/kg
14.	132	Indigotine (Indigo carmine)	300 mg/kg
15.	961	Neotame	65 mg/kg
16.	338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i),(ii), 343(i)-(iii), 450(i)-(iii),(v)-(vii), 451(i),(ii),452(i)-(v), 542	Phosphates	2,200 mg/kg
17.	900a	Polydimethylsiloxane	50 mg/kg
18.	124	Ponceau 4R (Cochineal red A)	300 mg/kg
19.	101(i)-(iii)	Riboflavins	300 mg/kg
20.	954(i)-(iv)	Saccharins 200 mg/kg	200 mg/kg
21.	200-203	Sorbates	1,500 mg/kg
22.	960	Steviol glycosides	660 mg/kg
23.	955	Sucralose (Trichlorogalactosucrose)	400 mg/kg
24.	110	Sunset yellow FCF	300 mg/kg

List of Food Additives for Foods for Special Medical Purpose (Other than those Products Intended for Foods for Infants) and Food with Added Probiotics and Prebiotics

S. No.	INS No.	Food Additive or Group	Maximum permitted level
1.	950	Acesulfame potassium	500 mg/kg
2.	951	Aspartame	1,000 mg/kg
3.	962	Aspartame-acesulfame salt	500 mg/kg
4.	210-213	Benzoates	1,500 mg/kg
5.	133	Brilliant blue FCF	500 mg/kg
6.	150c	Caramel III – Ammonia caramel	20,000 mg/kg
7.	150d	Caramel IV - Sulfite Ammonia caramel	20,000 mg/kg
8.	160a(ii)	beta-Carotenes (vegetable)	600 mg/kg
9.	160a(i), (iii), 160e, 160f	Carotenoids	50 mg/kg
10.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
11.	163(ii)	Grape skin extract	250 mg/kg
12.	132	Indigotine (Indigo carmine)	50 mg/kg
13.	961	Neotame	33 mg/kg
14.	338, 339(i)-(iii), 340 (i)-(iii), 341(i)-(iii), 342 (i),(ii), 343(i), (iii), 450 (i)-(iii), (v)-(vii), 451(i), (ii), 452(i)-(v), 542	Phosphates	2,200 mg/kg
15.	900a	Polydimethylsiloxane	50 mg/kg
16.	432-436	Polysorbates	1,000 mg/kg
17.	124	Ponceau 4R (Cochineal red A)	50 mg/kg
18.	477	Propylene glycol esters of fatty acids	5,000 mg/kg
19.	101(i)-iii)	Riboflavins	300 mg/kg
20.	954 (i)-(iv)	Saccharins	200 mg/kg
21.	200-203	Sorbates	1,500 mg/kg
22.	960	Steviol glycosides	350 mg/kg
23.	955	Sucralose (Trichlorogalactosucrose)	400 mg/kg
24.	474	Sucroglycerides	5,000 mg/kg
25.	110	Sunset yellow FCF	50 mg/kg

List of Food Additives for Foods for Special Medical Purpose(Other than those Intended for Infant Foods); Formula for Slimming Purpose and Weight Reduction and Food with Added Probiotics and Prebiotics

S. No.	INS No.	Food Additive or Group	Maximum permitted level
1.	950	Acesulfame potassium	450 mg/kg
2.	304,305	Ascorbyl Esters	500 mg/kg
3.	951	Aspartame	800 mg/kg
4.	962	Aspartame-acesulfame salt	450 mg/kg
5.	210-213	Benzoates	1,500 mg/kg
6.	133	Brilliant blue FCF	50 mg/kg
7.	150c	Caramel III – Ammonia caramel	20,000 mg/kg
8.	150d	Caramel IV - Sulfite Ammonia carame	20,000 mg/kg
9.	160a(ii)	Beta-Carotenes (vegetable)	600 mg/kg
10.	160a(i), (iii), 160e, 160f	Carotenoids	50 mg/kg
11.	472e	Diacetyltartaric and fatty acid esters of glycerol	5,000 mg/kg
12.	163(ii)	Grape skin extract	250 mg/kg
13.	132	Indigotine (Indigo carmine)	50 mg/kg
14.	961	Neotame	33 mg/kg
15.	338, 339(i)-(iii), 340(i)-(iii), 341(i)-(iii), 342(i), (ii), 343(i)-(iii), 450 (i)-(iii),(v)-(vii), 451(i),(ii), 452(i)-(v), 542	Phosphates	2,200 mg/kg
16.	900a	Polydimethylsiloxane	50 mg/kg
17.	432-436	Polysorbates	1,000 mg/kg
18.	124	Ponceau 4R (Cochineal red A)	50 mg/kg
19.	477	Propylene glycol esters of fatty acids	5,000 mg/kg
20.	101(i)-iii)	Riboflavins	300 mg/kg
21.	954 (i)-(iv)	Saccharins	300 mg/kg
22.	200-203	Sorbates	1,500 mg/kg
23.	960	Steviol Glycosides	270 mg/kg
24.	955	Sucralose (Trichlorogalactosucrose)	320 mg/kg
25.	474	Sucroglycerides	5,000 mg/kg
26.	110	Sunset yellow FCF	50 mg/kg

Schedule VE

(As per FSSAI, Nutraceuticals Regulation)

List of Food Additives to be Used (at GMP Levels) for-

- (I) Nutraceuticals,
 (II) Foods for special dietary use other than foods for infants,
 (III) Foods for special medical purpose,
 (IV) Foods with added probiotic ingredients and prebiotic ingredients,
 (V) Specialty foods containing plant or botanical ingredients, and
 (VI) Health supplements

S. No.	INS No.	Additive	Functional Class
1.	260	Acetic acid, glacial	Acidity regulator, Preservative
2.	472a	Acetic and fatty acid esters of glycerol	Emulsifier, Sequestrant, Stabilizer
3.	1422	Acetylated distarch adipate	Emulsifier, Stabilizer, Thickener
4.	1417	Acetylated distarch phosphate	Emulsifier, Stabilizer, Thickener
5.	1451	Acetylated oxidized starch	Emulsifier, Stabilizer, Thickener
6.	1401	Acid treated starch	Emulsifier, Stabilizer, Thickener
7.	406	Agar	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
8.	400	Alginic acid	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener
9.	1402	Alkaline treated starch	Emulsifier, Stabilizer, Thickener
10.	1100 (i)	alpha-Amylase from <i>Aspergillus oryzae</i>	Flour treatment agent
11.	1100 (vi)	Carbohydrase from <i>Bacillus licheniformis</i>	Flour treatment agent
12.	1100 (iv)	alpha-Amylase from <i>Bacillus megaterium</i> expressed in <i>Bacillus subtilis</i>	Flour treatment agent
13.	1100 (ii)	alpha-Amylase from <i>Bacillus stearothermophilus</i>	Flour treatment agent
14.	1100 (v)	alpha-Amylase from <i>Bacillus stearothermophilus</i> expressed in <i>Bacillus subtilis</i>	Flour treatment agent
15.	1100 (iii)	alpha-Amylase from <i>Bacillus subtilis</i>	Flour treatment agent
16.	264	Ammonium acetate	Acidity regulator
17.	403	Ammonium alginate	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener
18.	503(i)	Ammonium carbonate	Acidity regulator, Raising agent
19.	510	Ammonium chloride	Flour treatment agent
20.	503(ii)	Ammonium hydrogen carbonate	Acidity regulator, Raising agent
21.	527	Ammonium hydroxide	Acidity regulator
22.	328	Ammonium lactate	Acidity regulator, Flour treatment agent
23.	300	Ascorbic acid L.	Acidity regulator, Anti -oxidant, Flour treatment agent

24.	162	Beet red	Colour
25.	1403	Bleached starch	Emulsifier, Stabilizer, Thickener
26.	1101(iii)	Bromelain	Flavour enhancer, Flour treatment agent, Stabilizer
27.	629	Calcium 5'-guanylate Flavour	Flavour enhancer
28.	633	Calcium 5'-inosinate	Flavour enhancer
29.	634	Calcium 5'-ribonucleotides	Flavour enhancer
30.	263	Calcium acetate	Acidity regulator, Preservative, Stabilizer
31.	404	Calcium alginate	Anti-foaming agent, Bulking agent, Carrier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer
32.	302	Calcium ascorbate	Anti-oxidant
33.	170(i)	Calcium carbonate	Acidity regulator, Anti-caking agent, Carrier, Firming agent, Flour treatment agent, Stabilizer
34.	509	Calcium chloride	Firming agent, Stabilizer, Thickener
35.	623	Calcium di-L-glutamate	Flavour enhancer
36.	578	Calcium gluconate	Acidity regulator, Firming agent, Sequestrant
37.	526	Calcium hydroxide	Acidity regulator, Firming agent
38.	327	Calcium lactate	Acidity regulator, Flour treatment agent
39.	352(ii)	Calcium malate, DL-	Acidity regulator
40.	529	Calcium oxide	Acidity regulator, Flour treatment agent
41.	282	Calcium propionate	Preservative
42.	552	Calcium silicate	Stabilizer
43.	516	Calcium sulfate	Firming agent, Flour treatment agent, Sequestrant, Stabilizer
44.	150a	Caramel I – plain caramel	Colour
45.	290	Carbon dioxide	Carbonating agent, Packaging gas, Preservative, Propellant
46.	410	Carob bean gum	Emulsifier, Stabilizer, Thickener
47.	407	Carrageenan	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
48.	427	Cassia gum	Emulsifier, Gelling agent, Stabilizer, Thickener
49.	140	Chlorophylls	Colour
50.	1001	Choline salts and esters	Emulsifier
51.	330	Citric acid	Acidity regulator, Anti-oxidant, Sequestrant
52.	472c	Citric and fatty acid esters of glycerol	Anti-oxidant, Emulsifier, Flour treatment agent, Sequestrant, Stabilizer
53.	466	Cross carmellose sodium	Binder, Thickening agent, Disintegrant
54.	468	Cross-linked sodium carboxymethyl cellulose (Crosslinked- cellulose gum)	Stabilizer, Thickener
55.	424	Curdlan	Firming agent, Gelling agent, Stabilizer, Thickener
56.	457	Cyclodextrin, alpha-	Stabilizer, Thickener
57.	458	Cyclodextrin, gamma-	Stabilizer, Thickener
58.	1504 (i)	Cyclotetraglucose	Carrier, Glazing agent
59.	1504 (ii)	Cyclotetraglucose syrup	Carrier
60.	1400	Dextrins, roasted starch	Emulsifier, Stabilizer, Thickener
61.	628	Dipotassium 5'-guanylate	Flavour enhancer
62.	627	Disodium 5'-guanylate	Flavour enhancer

Continued

63.	631	Disodium 5'-inosinate	Flavour enhancer
64.	635	Disodium 5'-ribonucleotides	Flavour enhancer
65.	1412	Distarch phosphate	Emulsifier, Stabilizer, Thickener
66.	315	Erythorbic Acid (Isoascorbic acid)	Anti-oxidant
67.	968	Erythritol	Flavour enhancer, Humectant, Sweetener
68.	462	Ethyl cellulose	Bulking agent, Carrier, Glazing agent, Thickener
69.	467	Ethyl hydroxyethyl cellulose	Emulsifier, Stabilizer, Thickener
70.	297	Fumaric acid	Acidity regulator
71.	418	Gellan gum	Stabilizer, Thickener
72.	575	Glucono delta-lactone	Acidity regulator, Raising agent, Stabilizer
73.	1102	Glucose oxidase	Anti-oxidant
74.	620	Glutamic acid, L(+)-	Flavour enhancer
75.	422	Glycerol	Humectant, Thickener
76.	626	Guanylic acid, 5'-	Flavour enhancer
77.	412	Guar gum	Emulsifier, Stabilizer, Thickener
78.	414	Gum arabic (Acacia gum)	Bulking agent, Carrier, Emulsifier, Glazing agent, Stabilizer, Thickener
79.	507	Hydrochloric acid	Acidity regulator
80.	463	Hydroxypropyl cellulose	Bulking agent, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener
81.	1442	Hydroxypropyl di starch phosphate	Emulsifier, Stabilizer, Thickener
82.	464	Hydroxypropyl methyl cellulose	Emulsifier, Glazing agent, Stabilizer, Thickener
83.	1440	Hydroxypropyl starch	Emulsifier, Stabilizer, Thickener
84.	630	Inosinic acid, 5'	Flavour enhancer
85.	953	Isomalt (Hydrogenated isomaltulose)	Anti-caking agent, Bulking agent, Glazing agent, Sweetener
86.	416	Karaya gum	Emulsifier, Stabilizer, Thickener
87.	425	Konjac flour	Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
88.	270	Lactic acid, L-, D- and DL-	Acidity regulator
89.	472b	Lactic and fatty acid esters of glycerol	Emulsifier, Sequestrant, Stabilizer
90.	966	Lactitol	Emulsifier, Sequestrant, Stabilizer
91.	322(i)	Lecithin (and its salts and esters from soya or other sources)	Anti-oxidant, Emulsifier
92.	1104	Lipases	Stabilizer
93.	160d(iii)	Lycopene, Blakeslea trispora	Colour
94.	160d(i)	Lycopene, synthetic	Colour
95.	160d(ii)	Lycopene, tomato	Colour
96.	504(i)	Magnesium carbonate	Acidity regulator, Anti-caking agent, Colour retention agent
97.	511	Magnesium chloride	Colour retention agent, Firming agent, Preservative
98.	625	Magnesium di-L-glutamate	Flavour enhancer
99.	580	Magnesium gluconate	Acidity regulator, Firming agent, Flavour enhancer

Continued

100.	528	Magnesium hydroxide	Acidity regulator, Colour retention agent
101.	504(ii)	Magnesium hydroxide carbonate	Acidity regulator, Anti-caking agent, Carrier, Colour retention agent
102.	329	Magnesium lactate, DL-	Acidity regulator, Flour treatment agent
103.	530	Magnesium oxide	Anti-caking agent
104.	553(i)	Magnesium silicate, synthetic	Anti-caking agent
105.	518	Magnesium sulfate	Firming agent, Flavour enhancer
106.	296	Malic acid, DL-	Acidity regulator
107.	965(i)	Maltitol	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener
108.	965(ii)	Maltitol syrup	Bulking agent, Emulsifier, Humectant, Stabilizer, Sweetener
109.	421	Mannitol	Anti-caking agent, Bulking agent, Humectant, Stabilizer, Sweetener
110.	461	Methyl cellulose	Bulking agent, Glazing agent, Humectant, Stabilizer, Thickener
111.	465	Methyl ethyl cellulose	Emulsifier, Gelling agent, Stabilizer, Thickener
112.	460(i)	Microcrystalline cellulose (Cellulose gel)	Anti-caking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener
113.	471	Mono and di-glycerides of fatty acids	Anti-foaming agent, Emulsifier, Stabilizer
114.	624	Monoammonium L-glutamate	Flavour enhancer
115.	622	Monopotassium L-glutamate	Flavour enhancer
116.	621	Monosodium L-glutamate	Flavour enhancer
117.	1410	Monostarch phosphate	Emulsifier, Stabilizer, Thickener
118.	941	Nitrogen	Packaging gas, Propellant
119.	942	Nitrous oxide	Anti-oxidant, Foaming agent, Packaging gas, Propellant
120.	1404	Oxidized starch	Emulsifier, Stabilizer, Thickener
121.	1101(ii)	Papain	Flavour enhancer
122.	440	Pectins	Emulsifier, Gelling agent, Stabilizer, Thickener
123.	1413	Phosphated distarch phosphate	Emulsifier, Stabilizer, Thickener
124.	1200	Polydextroses	Bulking agent, Glazing agent, Humectant, Stabilizer, Thickener
125.	964	Polyglycitol syrup	Sweetener
126.	1202	Poly vinyl pyrrolidone, insoluble, including cross povidone	Colour retention agent, Stabilizer
127.	632	Potassium 5'-inosinate	Flavour enhancer
128.	261	Potassium acetates	Acidity regulator, Stabilizer
129.	402	Potassium alginate	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener
130.	303	Potassium ascorbate	Anti-oxidant

131.	501(i)	Potassium carbonate	Acidity regulator, Stabilizer
132.	508	Potassium chloride	Flavour enhancer, Gelling agent, Stabilizer, Thickener
133.	332(i)	Potassium dihydrogen citrate	Acidity regulator, Sequestrant, Stabilizer
134.	577	Potassium gluconate	Acidity regulator, Stabilizer
135.	501(ii)	Potassium hydrogen carbonate	Acidity regulator, Raising agent, Stabilizer
136.	351(i)	Potassium hydrogen malate	Acidity regulator
137.	515 (ii)	Potassium hydrogen sulfate	Acidity regulator
138.	525	Potassium hydroxide	Acidity regulator
139.	326	Potassium lactate	Acidity regulator, Anti -oxidant
140.	351(ii)	Potassium malate	Acidity regulator
141.	283	Potassium propionate	Preservative
142.	515(i)	Potassium sulfate	Acidity regulator
143.	460(ii)	Powdered cellulose	Anti-caking agent, Bulking agent, Carrier, Emulsifier, Foaming agent, Glazing agent, Stabilizer, Thickener
144.	407a	Processed eucheuma seaweed	Bulking agent, Carrier, Emulsifier, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
145.	944	Propane	Propellant
146.	280	Propionic acid	Preservative
147.	1101(i)	Protease	Flavour enhancer, Flour treatment agent, 1999 Glazing agent, Stabilizer
148.	1204	Pullulan	Glazing agent, Thickener
149.	470(i)	Salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium	Anti-caking agent, Emulsifier, Stabilizer
150.	470(ii)	Salts of oleic acid with calcium, potassium and sodium	Anti-caking agent, Emulsifier, Stabilizer
151.	551	Silicon dioxide, amorphous	Anti-caking agent, Anti-foaming agent, Carrier
152.	262(i)	Sodium acetate	Acidity regulator, Preservative, Sequestrant
153.	401	Sodium alginate	Bulking agent, Carrier, Emulsifier, Foaming agent, Gelling agent, Glazing agent, Humectant, Sequestrant, Stabilizer, Thickener
154.	301	Sodium ascorbate	Anti-oxidant
155.	500(i)	Sodium carbonate	Acidity regulator, Anticaking agent, Raising agent
156.	466	Sodium carboxymethyl cellulose (Cellulose gum)	Bulking agent, Emulsifier, Firming agent, Gelling agent, Glazing agent, Humectant, Stabilizer, Thickener
157.	469	Sodium carboxymethyl cellulose, enzymatically hydrolysed (Cellulose gum, enzymatically hydrolyzed)	Stabilizer, Thickener

Continued

158.	331(i)	Sodium dihydrogen citrate	Acidity regulator, Emulsifier, Sequestrant, Thickener
159.	350(ii)	Sodium DL-malate	Acidity regulator, Humectant
160.	316	Sodium erythorbate (Sodium isoascorbate)	Anti-oxidant
161.	365	Sodium fumarates	Acidity regulator
162.	576	Sodium gluconate	Sequestrant, Stabilizer, Thickener
163.	500(ii)	Sodium hydrogen carbonate	Acidity regulator, Anti-caking agent, Raising agent
164.	350(i)	Sodium hydrogen DL-malate	Acidity regulator, Humectant
165.	514(ii)	Sodium hydrogen sulfate	Acidity regulator
166.	524	Sodium hydroxide	Acidity regulator
167.	325	Sodium lactate	Acidity regulator, Anti-oxidant, Bulking agent, Humectant, Thickener
168.	281	Sodium propionate	Preservative
169.	500(iii)	Sodium sesquicarbonate	Acidity regulator, Anti-caking agent, Raising agent
170.	-	Sodium starch glycolate	Binder, Thickening agent, Disintegrant
171.	514(i)	Sodium sulfate	Acidity regulator
172.	420(i)	Sorbitol	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener
173.	420(ii)	Sorbitol syrup	Bulking agent, Humectant, Sequestrant, Stabilizer, Sweetener
174.	1420	Starch acetate	Emulsifier, Stabilizer, Thickener
175.	1450	Starch sodium octenyl succinate	Emulsifier, Stabilizer, Thickener
176.	1405	Starches, enzyme treated	Emulsifier, Stabilizer, Thickener
177.	473a	Sucrose Oligoesters, Type I and Type II	Emulsifier, Stabilizer
178.	553(iii)	Talc	Anti-caking agent, Glazing agent, Thickener
179.	417	Tara gum	Gelling agent, Stabilizer, Thickener
180.	957	Thaumatococcus	Flavour enhancer, Sweetener
181.	171	Titanium dioxide	Colour
182.	413	Tragacanth gum	Emulsifier, Stabilizer, Thickener
183.	1518	Triacetin	Carrier, Emulsifier, Humectant
184.	380	Triammonium citrate	Acidity regulator
185.	333(iii)	Tricalcium citrate	Acidity regulator, Firming agent, Sequestrant, Stabilizer
186.	332(ii)	Tripotassium citrate	Acidity regulator, Sequestrant, Stabilizer
187.	331(iii)	Trisodium citrate	Acidity regulator, Emulsifier, Sequestrant, Stabilizer
188.	415	Xanthan gum	Emulsifier, Gelling agent, Stabilizer, Thickener
189.	967	Xylitol	Emulsifier, Humectant, Stabilizer, Thickener

List of Food Additives to be Used in Formats such as Tablets, Capsules and Syrups

- (I) Nutraceuticals,
- (II) Foods for special dietary use other than foods for infants,
- (III) Foods for special medical purpose,
- (IV) Foods with added probiotic ingredients and prebiotic ingredients,
- (V) Specialty foods containing plant or botanical ingredients, and
- (VI) Health supplements

S. No.	Additive (Pharmaceutical Aid)	Functionality	Maximum permitted level
1.	Acacia gum	Binding agent	GMP
2.	Acetone	Solvent for coating	GMP (does not remain in the tablet and residual levels to be as per IP)
3.	Ascorbic acid and its esters and salts	Antioxidant	0.5%
4.	Benzoic acid and its salts	Preservative	0.5%
5.	BHA	Antioxidant	0.5%
6.	BHT	Antioxidant	0.5%
7.	Bronopol	Preservative	0.5%
8.	Calcium carbonate	Diluent, Dissintegrant	GMP
9.	Calcium stearate	Lubricant	1%
10.	Carboxymethylcellulose Calcium	Binding agent	5-15%
11.	Carrageenan gum	Binding agent	2%
12.	Cellulose acetate phthalate	Cellulose acetate phthalate	2%
13.	Citric acid	Disintegrant	2%
14.	Citric and fatty acid esters of glycerol	Stabilizer	2%
15.	Copovidone	Binding agent	2-5%
16.	Corn oil	Vehicle	GMP
17.	Corn starch	Diluent, Binding agent, Dissintegrant	GMP
18.	Cross carmellose sodium	Disintegrant	2%
19.	Cyclodextrin	Diluent	GMP
20.	Dextrose	Diluent	GMP
21.	Dicalcium phosphate	Diluent	GMP
22.	Ethyl acetate	Solvent for coating	GMP (does not remain in the tablet and residual levels to be as per IP)
23.	Ethyl alcohol	Solvent for coating	GMP (does not remain in the tablet and residual levels to be as per IP)
24.	Ethyl cellulose	Coating agent, Ingredient of capsule shells	GMP
25.	Fructose	Diluent	GMP
26.	Gelatin	Binding agent, Ingredient of capsule shells	GMP
27.	Glycerin	Vehicle, Humectant for capsule shells	GMP

Continued

28.	Guar gum	Binding agent	GMP
29.	Hydrogenated castor oil	Lubricant	2%
30.	Hydrogenated vegetable oil	Lubricant	1%
31.	Hydroxy propyl methylcellulose	Coating agent, Ingredient of capsule shells	GMP
32.	Isomalt	Soluble fiber	15%
33.	Kaolin	Diluent	GMP
34.	Lactitol	Diluent	200 mg per capsule
35.	Lactose	Diluent	GMP
36.	Lecithin and its salts / esters from soya or other sources	Emulsifier, Stabilizer	GMP
37.	Light magnesium carbonate	Anticaking agent	0.5%
38.	Light magnesium oxide	Anticaking agent	0.5%
39.	Liquid glucose	Binding agent	GMP
40.	Magnesium carbonate	Adsorbant	0.3%
41.	Magnesium stearate	Antisticking agent, Glidant	2%
42.	Maize Starch	Diluent, Binding agent, Dissintegrant	GMP
43.	Maltitol	Sweetener, Diluent	GMP
44.	Maltodextrin	Diluent	GMP
45.	Maltose	Diluent	GMP
46.	Manitol	Diluent, Sweetner	GMP
47.	Methyl paraben and its salts	Preservative	0.2%
48.	Microcrystalline cellulose	Diluent	GMP
49.	Natural and synthetic colors as per FSSR	Coloring agents	Limits as per FSSR
50.	Peanut oil	Vehicle	GMP
51.	Pectin	Binding agent	GMP
52.	PEG 4000	Diluent for direct compression tablets	GMP
53.	Colors permitted under Rule 127 of Drugs & Cosmetics Rules including lake colours	Coloring agents	GMP
54.	Poly ethylene glycol (PEG)	Vehicle, Humectant for capsule shells	GMP
55.	Povidone	Binding agent	5%
56.	Propyl paraben and its salts	Preservative	0.02%
57.	Propylene glycol	Vehicle, Humectant for capsule shells	GMP
58.	Purified Talc	Glidant, Dusting powder for coating	2%
59.	Saff flower oil	Vehicle	GMP
60.	Sodium alginate	Binding agent	5%
61.	Sodium starch glycolate	Disintegrant, Binder, Thickening agent	2%
62.	Sorbitan crystalline	Diluent	15%
63.	Sorbitan oleate esters (Tweens)	Solubalizers	0.5%

Continued

64.	Sorbitol liquid	Vehicle, Humectant for capsule shells	GMP
65.	Starch, pregelatinized	Disintegrant	1%
66.	Stearic acid	Antisticking agent, Glidant	2%
67.	Sucrose	Diluent, Coating agent	GMP
68.	Sunflower oil	Vehicle	GMP
69.	TBHQ	Antioxidant	0.5%
70.	Tocopherol and its esters	Antioxidant	0.5%
71.	Tragacanth gum	Binding agent	GMP
72.	Tribasic calcium phosphate	Diluent, anticaking agent	GMP
73.	Tricalcium phosphate	Diluent	GMP
74.	Vegetable oils	Vehicle	GMP
75.	Xanthan gum	Binding agent	GMP
76.	Xylitol	Diluent, Sweetner	GMP
77.	Zinc stearate	Lubricant	0.5-1.5%

Source: FSSAI, Nutraceutical Regulation, 2016

Appendix IV

Schedule VIII
(As per FSSAI, Nutraceuticals Regulation)

List of Prebiotic Compounds

S. No.	Prebiotic Compounds
1.	<i>Polydextrose</i>
2.	<i>Soybean oligosaccharides</i>
3.	<i>Isomalto-oligosaccharides</i>
4.	<i>Fructo-oligosaccharides</i>
5.	<i>Gluco-oligosaccharides</i>
6.	<i>Xylo-oligosaccharides</i>
7.	<i>Inulin</i>
8.	<i>Isomaltulose</i>
9.	<i>Gentio-oligosaccharides</i>
10.	<i>Lactulose</i>
11.	<i>Lactoferrin</i>
12.	<i>Sugar alcohols such as lactitol, sorbitol, maltitol, inositol, isomalt</i>
13.	<i>Galacto-oligosaccharides</i>

Source: FSSAI, Nutraceutical Regulation, 2016

Note: - The Food Authority may add any new specific prebiotic after proper scientific evaluation and include them.

Appendix V

Schedule I

(As per FSSAI, Claims and Advertisements Regulation)

Nutrition Claims

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

(1)	(2)	(3)	(4)
Sl. No.	Nutrient/ Component	Claim	Conditions
1.	Energy/ Calorie	Low	Not more than <ul style="list-style-type: none"> 40 kcal# per 100 g for solids 20 kcal per 100 ml for liquids
		Free	Not more than <ul style="list-style-type: none"> 4 kcal per 100 ml for liquids
2.	Fat	Low	Not more than <ul style="list-style-type: none"> 3 g of fat per 100 g for solids or 1.5 g of fat per 100ml for liquids
		Free	Not more than <ul style="list-style-type: none"> 0.5 g of fat per 100 g for solids or 100 ml for liquids
3.	Cholesterol	Low	Not more than <ul style="list-style-type: none"> 20 mg cholesterol per 100 g for solids and 1.5 g saturated fat per 100 g for solids or 10 mg per 100 ml for liquids and 0.75 g of saturated fat per 100 ml for liquids and In either case must provide not more than 10% of energy from saturated fat
		Free*	Not more than <ul style="list-style-type: none"> 5 mg cholesterol per 100g for solids or 100 ml for liquids Additionally the food shall contain no more than <ul style="list-style-type: none"> 1.5 g saturated fat per 100 g for solids or 0.75 g of saturated fat per 100 ml for liquids and In either case must provide not more than 10% of energy from saturated fat
4.	Saturated fat	Low*	Not more than <ul style="list-style-type: none"> 1.5 g per 100 g for solids or 0.75 g per 100 ml for liquids and In either case must provide not more than 10% of energy from saturated fat
		Free	Saturated fatty acids do not exceed <ul style="list-style-type: none"> 0.1 g per 100 g or 100 ml of food
5.	Unsaturated fat	High*	At least 70% of the fatty acids present in the product are derive from unsaturated fat under the condition that unsaturated fat provides more than 20% of energy of the product
6.	Trans fat	Free	The food contains less than 0.2g trans fat per 100 g or 100ml of Food
7.	MUFA	High in MUFA*	Shall only be made where at least <ul style="list-style-type: none"> 45% of the total fatty acids present in the product are derived from mono unsaturated fat and under the condition that monounsaturated fat provides more than 20% of energy of the product

8.	PUFA	High in PUFA*	Shall only be made where at least <ul style="list-style-type: none"> 45% of the total fatty acids present in the product are derived from poly unsaturated fat and under the condition that polyunsaturated fat provides more than 20% of energy of the product
9.	Omega 3 fatty acids	Source	The product contains: <ul style="list-style-type: none"> At least 0.3g alpha-linolenic acid per 100 g and per 100kcal, or At least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal
		High	The product contains: <ul style="list-style-type: none"> At least 0.6 g alpha-linolenic acid per 100g and per 100kcal, or At least 80mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100g and per 100kcal
10.	Sugars	Low	The product contains not more than <ul style="list-style-type: none"> 5 g of sugars per 100 g for solids or 2.5 g of sugars per 100 ml for liquids
		Free	The product contains not more than <ul style="list-style-type: none"> 0.5 g of sugars per 100 g for solids or 100 ml for liquids
11.	Protein	Source*	<ul style="list-style-type: none"> 10% of RDA per 100 g for solids 5% of RDA per 100 ml for liquids or 5% of RDA per 100 kcal
		Rich/ High*	<ul style="list-style-type: none"> 20% of RDA per 100 g for solids 10% of RDA per 100 ml for liquids or 10% of RDA per 100 kcal
12.	Vitamin(s) and/ or Mineral(s)	Source	The food provides at least <ul style="list-style-type: none"> 15% of RDA of the vitamin/mineral per 100g for solids or 7.5% of RDA of the vitamin/mineral per 100 ml for liquids
		High	The food provides at least <ul style="list-style-type: none"> 30% of RDA per 100 g for solids or 15% of RDA per 100 ml for liquids
13.	Sodium	Low	Product contains not more than <ul style="list-style-type: none"> 0.12 g of sodium per 100 g for solids or 100 ml for liquids
		Very Low	Product contains not more than <ul style="list-style-type: none"> 0.04 g of sodium per 100 g for solids or 100 ml for liquids
		Sodium Free	Product contains not more than <ul style="list-style-type: none"> 0.005g of sodium per 100 g for solids or 100 ml for liquids
14.	Dietary Fibre	Source	Product contains at least <ul style="list-style-type: none"> 3 g of fibre per 100 g or 1.5 g per 100kcal
		High or Rich	The product contains at least <ul style="list-style-type: none"> 6 g per 100 g or 3 g per 100 kcal
15.	Probiotics	Source	Product contains =10 ⁸ CFU in the recommended serving size per day
16.	Glycemic Index (GI)	Low GI	GI value below 55 <ul style="list-style-type: none"> A food's GI indicates the rate at which the carbohydrate in the food is broken down into glucose and absorbed from the gut into the blood and expressed as a per cent of the response to the same amount of carbohydrate from a standard food, white bread

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

1 kcal = 4.2 kJ

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

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

Source: FSSAI, Claims and Advertisements Regulation, 2018

Appendix VI

Schedule II

(As per FSSAI, Claims and Advertisements Regulation)

Synonyms which may be Used for Claims defined in these Regulations

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

Source: FSSAI, Claims and Advertisements Regulation, 2018

Appendix VII

Schedule III

(As per FSSAI, Claims and Advertisements Regulation)

Health Claims

SI. No.	Nutrient/ Food-Health Relationship	Conditions for Claim	Claim Statement
1.	Calcium or Calcium and Vitamin D and osteoporosis	<ul style="list-style-type: none"> The food is a source or high in calcium or in calcium and vitamin D and A statement that the beneficial effect is obtained with a daily recommended intake (RDA) 	Adequate Calcium (or Calcium and Vitamin D) intake throughout life, through a balanced diet are essential for bone health and to reduce the risk of osteoporosis
2.	Sodium and Hypertension	A food which <ul style="list-style-type: none"> Is low in sodium (0.12g sodium/100g or 100ml) A statement that the beneficial effect is obtained with a low sodium diet 	Diets low in sodium may help in reducing the risk of high blood pressure
3.	Dietary saturated fat and blood cholesterol level	<ul style="list-style-type: none"> Low saturated fat A statement that the beneficial effect is obtained with a diet low in fat, saturated fat and physical activity 	Diets low in saturated fat contributes to the maintenance of normal blood cholesterol levels
4.	Potassium and risk of high blood pressure	the food is a good source of potassium and is <ul style="list-style-type: none"> Low in sodium Low in total fat and saturated fat. 	Diets containing good sources of potassium and low in sodium, fat and saturated fat may help reduce the risk of high blood pressure
5.	Alpha – linolenic acid (ALA) and blood cholesterol level	<ul style="list-style-type: none"> The food contains at least 1g of omega-3 fatty acids per 100g or 100ml or 100kcal Statement that the beneficial effect is obtained with daily intake of 2g of ALA 	Alpha – linolenic acid (ALA) contributes to the maintenance of normal blood cholesterol levels
6.	Soluble Dietary Fibre and lipid profile	<ul style="list-style-type: none"> Soluble dietary fibre from food sources including but not limited to oats, barley, millets or mixtures thereof Contains at least 1g per serving Statement that the beneficial effect is obtained with daily intake of 3g of soluble dietary fibre 	Soluble Dietary Fibre taken as part of a diet may help in the maintenance of normal lipid profile
7.	Phytosterol or stanol and lipid profile	Food with phytosterol or stanol <ul style="list-style-type: none"> Contains at least 1g plant sterols or stanols per serving and A statement that the beneficial effect is obtained with a daily intake of up to 3g per day. 	Foods containing plant sterols or stanols (as applicable) containing at least 1g of plant sterols or stanols eaten twice a day with meals for a daily intake of up to 3g may help in improving the lipid profile
8.	Beta-glucans (oats, barley) and blood glucose	<ul style="list-style-type: none"> The food is oats and/or barley, Contains at least 4g beta –glucans for each 30g of available carbohydrates in the quantified portion Statement that it is taken as part of the meal. 	Beta- glucans from oats or barley when taken as part of a meal may help in reduction of rise in blood glucose after that meal

Source: FSSAI, Claims and Advertisements Regulation, 2018

Appendix VIII

Schedule IV
(As per FSSAI, Claims and Advertisements Regulation)

Health Claims for Fortified Food Articles

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

Source: FSSAI, Claims and Advertisements Regulation

Appendix IX

Schedule IV

(As per FSSAI, Claims and Advertisements Regulation)

Use of Certain Words or Phrases

SI. No.	Column 1	Column 2
1.	Natural	<p>The word may be used to describe:</p> <ol style="list-style-type: none"> A single food, derived from a recognised source viz., plant, animal, microorganism or mineral and to which nothing has been added and which have been subjected only to such processing which would only render it suitable for human consumption like <ol style="list-style-type: none"> Smoking without chemicals, cooking processes such as roasting, blanching and dehydration and physical refining Freezing, concentration, pasteurization, sterilisation and fermentation and Packaging done without chemicals and preservatives Permitted food additives that are obtained from natural sources by appropriate physical processing Composite foods shall not themselves be described directly or by implication as “natural” but such foods may be described as “made from natural ingredients” if all the ingredients or food additives meet the criteria in (a) and (b) above: <ul style="list-style-type: none"> Provided that, the above principles shall also apply to use of other words or expressions such as “real”, “genuine”, when used in place of “natural” in such a way as to imply similar benefits. Provided further that the, claims such as “natural goodness”, “naturally better”, “nature’s way” shall not be used
2.	Fresh	<ol style="list-style-type: none"> The term “fresh” shall only be used on products which have not been processed in any manner except, washed, peeled, chilled, trimmed or cut, irradiated by ionizing radiation not exceeding 1kGy or other processing necessary for making the product safe for consumption without altering its basic characteristics in any manner. If such processing also leads to extension in the shelf life of the product the term “fresh” shall not be used The term “fresh” or “freshly” shall have no other connotation than the immediacy of the action being described. A food containing additives or subjected to packaging, storing or any other supply chain processes that control freshness shall not be termed as “freshly stored”, “freshly packed”, etc.: <ul style="list-style-type: none"> Provided that “Fresh” may be permitted to be used along with “frozen” if it is clear from the context.- “Frozen from fresh” “fresh frozen” “Freshly frozen”- which would indicate that the food was quickly frozen while still fresh.
3.	Pure	<ol style="list-style-type: none"> The term “pure” shall only be used to describe a single ingredient food to which nothing has been added and which is free from avoidable contamination and the levels of unavoidable contaminants shall need to be below the levels prescribed in the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 or in any other standard given under Food Safety and Standards Act, Rules and Regulations thereof. Compound foods shall not generally be described, directly or by implication, as “pure” but such foods may be described as “made with pure ingredients” if all the ingredients meet the criteria in (a) above. “Pure” shall not be included in any brand or fancy names, nor in coined or meaningless phrases, in such a way as to imply that a food that does not meet the criteria above is pure or made from pure ingredients.
4.	Authentic, Genuine, Real	These terms may be used only if the label or advertisement also clarify in what way the overall quality is tangibly justified and why the particular term has been used.
5.	Traditional	The term “traditional” shall demonstrably be used to describe a recipe, fundamental formulation or processing method for a product that has existed for a generation (thirty years), should have been available substantially unchanged, for that same period.
6.	Original	<ol style="list-style-type: none"> The term “original” shall only be used to describe a food that is made to a formulation, the origin of which can be traced, and that has remained essentially unchanged over time. It should not contain replacements for major ingredients. It may similarly be used to describe a process, provided it is the process first used in the making of the food, and which has remained essentially unchanged over time, although it may be mass-produced. To be termed “original”, a product shall not have changed to any material degree and shall remain available as the ‘standard’ product when new variants are introduced. A product re-introduced onto the market after a period of absence shall only be described as “original” if it can be shown to meet these criteria.

Source: FSSAI, Claims and Advertisements Regulation, 2018

Appendix X

The Hierarchy of Evidence in Human Efficacy Studies

1. **Metanalysis Systematic Review:** a meta-analysis reviews all the publicly available studies on the substance/disease relationship.
2. **Randomized, Controlled Trial (RCTs) or Randomized Controlled Intervention Studies:** It provide the strongest evidence of whether or not there is a relationship between a substance and a disease.
3. **Observational Studies:**
 - a. In contrast to intervention studies, even the best designed observational studies cannot establish cause and effect between an intervention and an outcome.
 - b. **Cohort studies** are considered to be the most reliable observational study design.
 - c. **Case-control studies** are considered to be less reliable than cohort studies.
 - d. **Nestedcase control or casecohort studies** are considered less reliable than cohort studies but more reliable than **case control studies**.
4. **Cross sectional studies:**
 - a. Cross sectional studies are considered to be a "relatively weak method of studying diet disease associations".
 - b. Subject to significant potential measurement error regarding dietary intake due to inaccuracy of survey methods used and limited ability to control for dietary intake variations.
 - c. Cross sectional studies are considered to be less reliable than cohort and case-control studies.
5. **Animal and in vitro Studies:** The use of animal and in vitro studies as background information helps to determine the mechanisms that might be involved in any relationship between the substance and disease.

Appendix XI

Application Form

S. No.	Information required (All points are mandatorily required to be filled by the applicant except point No. 20)	Response
1.	Name and Address of the Applicant	
2.	Name, email and contact number of the authorized signatory (All communications relating to the application will only be made through the above email and phone number)	
3.	License Number	
4.	Central/ State License (Also attach a copy of your license along with the application form)	
5.	Nature of License/ License Category	
6.	Name of the food product	
7.	Product Composition	
8.	Product Category	
9.	Does your ingredient/product fall under Non- specified category? If yes, please attach copy of approval letter from FSSAI.	
10.	Types of claim(s) required (on product/ ingredient)	
11.	Name of the ingredient, nutrient or substance on the basis of which the claims has to be made;	
12.	Claim Statement	
13.	Justification for the claim statement (How is the claim clear and meaningful and helps consumers to comprehend the information provided?)	
14.	Is the ingredient/ product on which claim is intended to be made protected under Intellectual Property Rights (IPR)/ patented?	
15.	Are any of the claim functions protected by IPR?	
16.	Scientific Substantiation supporting documents/ materials***	
17.	Cause effect relationship studies in respect of "reduction of disease risk claims" (Well designed human intervention studies conducted by or under guidance of established research institutions)	
18.	Validated Method of analysis of ingredients or substance for which the claim is to be made	
19.	Interaction/Contradictions/ Possible Adverse Effects/Warnings/ Advisories on the food product	
20.	Any other useful information	
Date of Application:		Authorised Signatory:

Source: https://www.fssai.gov.in/upload/advisories/2019/09/5d7871bfd7ab9Notice_Fees_Claims_05_09_2019.pdf

- *** Adequate published scientific literature/ studies should form part of Claim Support Dossiers (CSD) to be submitted by the applicants.
- a. Such dossiers should provide a succinct summary of published scientific data comprising in-vitro, in-vivo and human studies data.
- b. Hard copies of important publications be also appended to the summary data in the CSD with a commitment to provide copies of any other publications listed in the summary statement, if demanded by the Authority.
- c. Such succinct summary shall be provided separately in respect of each claim statement for which application has been made.
- d. Unpublished or under communication studies, if any, either undertaken by the applicant or reported by other organisations may also be provided where available in full form.
- Disclaimer:** Information provided in the claim Support Dossiers shall not be guarantee for approval of claims

General Information

- ✓ The application is made manually. The application shall be addressed to the CEO, FSSAI, FDA Bhawan, Kotla road, New Delhi-110002 or Advisor (Science & Standards), FSSAI, FDA Bhawan, Kotla road, New Delhi-110002.
- ✓ A fee of Rs 50,000/-only (Fifty thousand only) per application (per product or per ingredient) needs to be submitted through demand draft, payable to Senior Accounts Officer, FSSAI.
- ✓ Maximum three claims statement (per application).
- ✓ The fees paid by the applicant for recognition shall not be refunded under any circumstances.
- ✓ In case of scrutiny in the application, the applicant will be informed within ninety days from the date of receipt of application and the applicant shall provide the information required by the food authority within thirty days of the receipt of the communication, failing which the application shall be rejected without any further reference.
- ✓ Moreover, after scrutiny the Food Authority may pass a speaking order either for approval or rejection of concerned claims and may also suggest an amendment for the concerned claim.
- ✓ The amended claim referred to in sub-regulations (5) may be submitted to the Food Authority within thirty days for reconsideration.
- ✓ In case of rejection, the food business operator or marketer shall not use that claim in their advertising and marketing communication in respect of articles of food offered for sale or for promotion of sale, supply, use or consumption.



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