

List of Nutraceutical Products

Sl. No.	Product Name / Scientific Name		Regulations administering the Product and concerned Ministry/Department administering Regulation	Tariff line HS Code Classification
	Nutraceuticals/ Ingredients	Official / Common name		
1.	American ginseng (<i>Panax quinquefolius</i> L.)	Ginseng extract (American).	Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Probiotic and Probiotic Food) Regulations, 2022 as notified by Notification dated 29 th March, 2022 bearing No. F. No. Std/SP-05/T(Nutraceutical-2022)[E-5184] by Food Safety and Standards Authority of India / Ministry of Consumer Affairs, Food & Public Distribution, Government of India.	ITC (HS) Code 1302 or ITC (HS) Code 2106.
2.	Astaxanthin (from <i>Haematococcus pluvialis</i>), powder or oleoresin	-	Do	Do
3.	Beta Alanine	-	Do	Do
4.	Betaine (N,N,N,trimethylglycine)	-	Do	Do
5.	Boswellia serrata - gum resin extract	Salai guggul / Kundru	Do	Do
6.	Caffeine	Caffeine	Do	Do
7.	Calcium hydroxyl methyl butyrate (CaHMB)	-	Do	Do

8.	<i>Chlorella vulgaris</i> – dried powder	Green algae / Shaiwal	Do	Do
9.	Chromium picolinate/ nicotinate	-	Do	Do
10.	<i>Cimicifuga racemosa</i> (or <i>Actaea racemosa</i>). Extracted from rhizomes and roots	Black cohosh	Do	Do
11.	Citrus bioflavonoids (<i>Citrus paradisi</i> , <i>C. reticulata</i> , <i>C. maxima</i> , <i>C. sinensis</i> and <i>Citrus limon</i>)	Citrus / Jambir	Do	Do
12.	CoQ10 from non GM source and Ubiquinol acetate	Co enzyme Q10	Do	Do
13.	Colostrum	-	Do	Do
14.	Creatine (source Creatine monohydrate, Creatine hydrochloride and Creatine nitrate)	-	Do	Do
15.	Cryptoxanthin / Mesoxanthin	-	Do	Do
16.	<i>Echinacea</i> (<i>E. angustifolia</i> , <i>E. purpurea</i> , and <i>E. pallida</i>) <i>Liquid/powder extract</i>	Echinacea	Do	Do
17.	Ginkgo biloba extract obtained from dried leaves of Ginkgo (<i>Ginkgo biloba</i> . L.).	Ginkgo biloba extract	Do	Do
18.	Glucosamine Hydrochloride	Glucosamine	Do	Do
19.	Glucosamine sulphate	Glucosamine	Do	Do
20.	Glutathione / S-acetyl glutathione	-	Do	Do

21.	<i>Gymnema sylvestre</i> extract powder	Madhunashin i, Gudmar (extract)	Do	Do
22.	Lactase (β galactosidase)	-	Do	Do
23.	L-carnosine	-	Do	Do
24.	L- theanine	Chai suksham satva	Do	Do
25.	Melatonin	-	Do	Do
26.	Methyl sulfonyl methane	-	Do	Do
27.	<i>Panax ginseng</i> (Syn;Korean Ginseng) extract - (obtained from 0.6 to 2.0 g of Ginseng root, (<i>Panax ginseng</i> .C A. Meyer, Araliaceae)	Ginseng extract	Do	Do
28.	Phycocyanin from <i>Spirulina plantesis</i> (<i>Aethrospira plantesis</i>) Dried powder	Spirulina	Do	Do
29.	<i>Piper nigrum</i> / <i>Piper longum</i> extract	Pippali/ Pepper	Do	Do
30.	Quercetin obtained from extracts of citrus fruits, vegetables and other plant sources.	-	Do	Do
31.	<i>Schizandra</i> berry extract	Five-flavor berry	Do	Do
32.	<i>Scutellaria bicalensis</i>	Patwar topi, Skullcap	Do	Do
33.	Selenium Yeast	-	Do	Do

34.	Siberian ginseng-obtained from 0.6 to 2.0 g of Ginseng root (<i>Acanthopanax senticosus</i> , belonging to panax type, C A. Meyer, Araliaceae)	Ginseng extract	Do	Do
35.	<i>Silybum marianum</i> extract (silymarin extract)	Milk Thistle	Do	Do
36.	Spirulina (algae) from (<i>Spirulina platensis</i> , <i>Arthrospira platensis</i>)	Shaiwal/ Spirulina	Do	Do
37.	Undenatured type II collagen	-	Do	Do
38.	<i>Vaccinium myrstillus</i> extract	<i>Bilberry extract</i>	Do	Do
39.	Zeaxanthin	-	Do	Do
40.	Camellia sinensis Black /green tea extract, standardized powder	Chai & tea extract	Do	Do
41.	Camellia sinensis-Tea catechins (epigallo catechin gallate, epicatechin, catechin gallates)	Chai satva	Do	Do
42.	(+) Hydroxycitric acid	-	Do	Do
43.	<i>Albizia lebbek</i> - extract	Shireesh	Do	Do
44.	<i>Allium sativum</i> – bulbs dried standardized powder / extract	Rason/ Lashun/Garlic	Do	Do
45.	<i>Aloe vera</i> – juice /concentrate /powder of sap /gel	Ghrit Kumari /Indian aloe	Do	Do
46.	Alpha amylase	-	Do	Do
47.	Alpha mangostin	-	Do	Do

48	Alpha-galactosidase	-	Do	Do
49	Alpha-lipoic acid	-	Do	Do
50	<i>Amaranthus tricolor</i> – leaf powder / extract	Marisha-Rakt Extract	Do	Do
51	Amylase	-	Do	Do
52	Amyloglucosidase	-	Do	Do
53	<i>Anethum graveolens</i> L. - seeds and oil	Shatahva/ Sowa /Soa /Dill	Do	Do
54	Anthocyanin	-	Do	Do
55	Arabinogalactan	-	Do	Do
56	Arachidonic acid	-	Do	Do
57	<i>Asparagus densiflorus</i> - extract	Asparagus / Shatavari	Do	Do
58	<i>Bacopa monnieri</i> - leaf extract	Brahmi	Do	Do
59	Barley seed powder	Yava /Barley	Do	Do
60	<i>Bauhinia variegata</i> - extract	Kachnar	Do	Do
61	<i>Berberis vulgaris</i> / <i>B. aristata</i> / <i>B.asiatica</i> – stem/root extract	Berberry / Daru haridra	Do	Do
62	Beta carotene – standardized soft concentrate / emulsified concentrate / powder	-	Do	Do
63	Beta ecdysterone	-	Do	Do
64	β -glucans	-	Do	Do
65	<i>Beta vulgaris</i> – root extract	Palanki/Beet	Do	Do
66	β -sitosterol	-	Do	Do
67	<i>Betula platyphylla</i> / <i>B.utilis</i> - bark extract	Bhojapatra/Birch	Do	Do
68	<i>Biota orientalis</i> - seed powder	Biota	Do	Do

69	<i>Borago officinalis</i> - oil	Borage	Do	Do
70	Campestanol	-	Do	Do
71	Campesterol	-	Do	Do
72	<i>Capsicum annum</i> - extract / standardized to capsin content	Lanka/Cayenne pepper / Lal mirchi	Do	Do
73	<i>Caricus papaya</i> – leaf extract	Papaya / Papeeta, Erand-karkati	Do	Do
74	Carotenoids (natural mixed, including from algal sources)	-	Do	Do
75	Casein and caseinates	-	Do	Do
76	<i>Caulophyllum thalictroides</i> - root extract	Blue cohosh	Do	Do
77	Cellulase	-	Do	Do
78	<i>Centella asiatica</i> – leaf/aerial parts standardized extract	Mandukparni / Gotu Kola	Do	Do
79	<i>Matricaria chamomilla</i> (<i>Matricaria recutita</i>) – aerial parts extract	-	Do	Do
80	<i>Malpighia emarginata</i> (Cherry acerola)	Acerola	Do	Do
81	Chlorogenic acids	-	Do	Do
82	Caffeic acid	-	Do	Do
83	Chondroitin sulphate	Chondroitin	Do	Do
84	<i>Cichorium intybus</i> – roasted root powder	Kasani/ Chicory	Do	Do
85	<i>Cinnamomum verum</i> – bark powder / extract	Tvak bhed/Cinnamon	Do	Do
86	Citrulline/ L-citrulline DL-malate (2:1)	-	Do	Do
87	<i>Citrus aurantium</i> – peel extract / bioflavonoids standardized	Bitter orange	Do	Do
88	Citrus naringenin	-	Do	Do

89	D-Mannose	-	Do	Do
90	<i>Syzygium aromaticum</i> - Clove powder & oil	Lavang tail	Do	Do
91	<i>Cnicus benedictus</i> – aerial parts extract / root extract	Blessed thistle	Do	Do
92	<i>Theobroma cacao</i> - Cocoa (chocolate) bean - extract	-	Do	Do
93	<i>Coccinia grandis</i> (L.) Voigt - extract	Bimbi/Kunduru/ Ivy gourd	Do	Do
94	Collagen and its hydrolysed peptides and chelates	-	Do	Do
95	Conjugated linoleic acid concentrate	-	Do	Do
96	<i>Crataeva nurvala</i> - extract	Varun	Do	Do
97	Crustacean shells	-	Do	Do
98	<i>Cuminum cyminum</i> L – oil / extract	Jeerak/Safed Jeera/Cumin	Do	Do
99	<i>Curcuma longa</i> – rhizome powder / extract standardized	Haridra/Haldi/Tur meric	Do	Do
100	Curcuminoids – soft extract / powder and curcumin complex	-	Do	Do
101	<i>Cyperus rotundus</i> - extract	Mustak/Nagar motha	Do	Do
102	Diastase	-	Do	Do
103	D-Pinitol	-	Do	Do
104	<i>Dioscorea bulbifera</i> - extract	Varahi kand	Do	Do
105	Protein isolates/concentrates/hyd rolysates	-	Do	Do
106	Ellagic acid	-	Do	Do
107	<i>Emblica officinalis</i> – dried fruit extract / spray dried pulp powder	Indian gooseberry/ amlaki	Do	Do

108	Eriocitrin (from citrus fruit)	-	Do	Do
109	<i>Oenothera biennis</i> - Evening primrose oil	-	Do	Do
110	<i>Fagopyrum esculentum</i> - seed	Buckwheat	Do	Do
111	Fish oil	-	Do	Do
112	<i>Foeniculum vulgare</i> - fruit - oil / extract	Fennel / Saunf	Do	Do
113	Freeze-dried banana powder	-	Do	Do
114	Galactomannan	-	Do	Do
115	Gallic acid	-	Do	Do
116	Gamma-linoleic acid (GLA)	-	Do	Do
117	Gamma-oryzanol	-	Do	Do
118	<i>Garcinia gummi-gutta</i> and <i>Garcinia cambogia</i> / <i>G.indica</i> – fruit rind extract standardized to hydroxyl citric acid, powder)	Kokum / Vrikshamalak / Malabar tamarind	Do	Do
119	<i>Garcinia mangostana</i> – seed extract standardized	Mangosteen	Do	Do
120	Glucoamylase	-	Do	Do
121	Glucomannan	-	Do	Do
122	<i>Glycyrrhiza glabra</i> - extract	Madhuyashti/Licorice / Mulethi	Do	Do
123	Grape seed extract	-	Do	Do
124	<i>Coffea arabica</i> , <i>C. robusta</i> - Green coffee seed extract standardized, including decaffeinated coffee bean powder/extract	Kaphi	Do	Do
125	<i>Grifola frondosa</i> – standardized extract	Maitake mushroom	Do	Do

126	Guar gum and gum arabic and its derivatives as a source of fibers; Maltodextrin/Resistant maltodextrin/ Limit Dextrin; chia seed fiberand fibers from other food sources	-	Do	Do
127	Hemicellulase	-	Do	Do
128	Hesperidin	-	Do	Do
129	High oleic sun flower oil and other vegetable oils with high oleic content	-	Do	Do
130	<i>Hippophae rhamnoides</i> – leaf/fruit dried powder/extract / juice	Amalvetas /Sea buckthorn	Do	Do
131	<i>Humulus lupulus</i> L – powder / extract	Phaph/Hops	Do	Do
132	Hyaluronic acid and its salts	-	Do	Do
133	Hydrolysed whey peptide	Whey	Do	Do
134	<i>Hypericum perforatum</i> – aerial parts standardized extract	Basant/St. Johns Wort	Do	Do
135	<i>Inula racemosa</i> - root extract	Pushkarmoola extract	Do	Do
136	Invertase	-	Do	Do
137	Isoflavones (genistein, daidzein)	-	Do	Do
138	Kelp (brown algae)	-	Do	Do
139	Krill oil - standardized for DHA / EPA	-	Do	Do
140	Lactalbumin	-	Do	Do
141	Lactoferrin	-	Do	Do
142	Lactoperoxidase	-	Do	Do
143	<i>Lagerstroemia speciosa</i> L (leaf extract)	Jarul/Banaba	Do	Do
144	Lecithins	-	Do	Do

145	Lignans	-	Do	Do
146	<i>Linum usitatissimum</i> - seed powder and oil	Atasi/Alasi/Flaxseed	Do	Do
147	Lipase	-	Do	Do
148	Lutein	-	Do	Do
149	Lutein/zeaxanthin complex	-	Do	Do
150	Lycopene	-	Do	Do
151	<i>Lycium barbarum</i> / <i>Lycium europaeum</i> / <i>Lycium ruthenicum</i> fruit - dried powder/concentrate standardized	Goji berry (wolfberry)	Do	Do
152	Maltase	-	Do	Do
153	<i>Mangifera indica</i> – mangiferine, leaf extract	-	Do	Do
154	<i>Medicago sativa</i> extract	Ashar-bala/Alfalfa	Do	Do
155	Medium chain triglycerides	-	Do	Do
156	<i>Menyanthes trifoliata</i> - Leaf powder	Buckbean / bogbean	Do	Do
157	Millets and their powder	-	Do	Do
158	<i>Momordica charantia</i> - fruit / seed extract	Karvalli/Kodon,/ bitter gourd/, Karela	Do	Do
159	<i>Monodora myristica</i> (Gaertn.) Dunal – oil / extract	Nutmeg	Do	Do
160	<i>Morinda citrifolia</i> extract	Akshiki/Noni	Do	Do
161	<i>Moringa oleifera</i> leaf / pods / seed extract powder	Shigru/Moringa / drum stick	Do	Do
162	<i>Morus alba</i> - Mulberry tea– leaf / fruit extract	Toot/Mulberry	Do	Do
163	<i>Myrica cerifera</i> / <i>M. nagi</i> – bark extract	Katphala/Bayberry	Do	Do
164	<i>Myristica fragrans</i>	Jatipatri/Mace/	Do	Do

	<i>Houtt.</i>	Javitri		
165	N-Acetyl d-glucosamine	-	Do	Do
166	<i>Nardostachys jatamansi</i> - extract	Jatamansi	Do	Do
167	<i>Nasturtium officinale</i> - extract	Chhu nail/Watercress	Do	Do
168	Nattokinase enzyme (as Soy bean Fibrinase)	-	Do	Do
169	<i>Ocimum tenuiflorum</i> / <i>Ocimum sanctum</i> – aerial parts / seed extract	Surasa/ Basil /Tulasi	Do	Do
170	Omega-3 fatty acids (docosahexaenoic acid - eicosapentaenoic acid - alpha - linolenic acid)	-	Do	Do
171	Omega-6-fatty acids (linoleic acid, arachidonic acid and conjugated linoleic acid)	-	Do	Do
172	Oyster shell powder	Shukti/Seep	Do	Do
173	Pancreatin	-	Do	Do
174	Pancrelipase	-	Do	Do
175	Papain	-	Do	Do
176	<i>Passiflora foetida</i> - extract	Passion flower	Do	Do
177	<i>Arachis hypogaea</i> - (roasted) powder	Mandapi/Pea nut/ Munghphali	Do	Do
178	Pectin	-	Do	Do
179	Pepsin	-	Do	Do
180	<i>Perna canaliculus</i> (Green lipped mussel / Mussel Oil)	-	Do	Do
181	<i>Phellodendron amurense</i> leaf oil	Phellodendron	Do	Do
182	Phosphatides /Phospholipids	-	Do	Do
183	<i>Phyllanthus amarus</i> - extract	Tamalaki/ Bhuiamalaki	Do	Do

184	Phytase	-	Do	Do
185	<i>Picrorhiza kurroa</i> - Picrorhiza - extract	Katuka/Kutaki	Do	Do
186	<i>Pimento officinalis</i> L. - extract/powder	Allspice	Do	Do
187	<i>Pinus gerardiana</i> - bark extract	Nikochak/Pine nut	Do	Do
188	<i>Piper longum</i> - extract	Pippali/ Magha/Long pepper	Do	Do
189	<i>Piper nigrum</i> - green extract	Green pepper, Krishan Marich	Do	Do
190	<i>Piper nigrum</i> - powder / standardized extract	Krishan Marich/ Marich/ Black pepper	Do	Do
191	Policosanol	-	Do	Do
192	Protease	-	Do	Do
193	<i>Prunus serotina</i> - extract	Black cherry	Do	Do
194	<i>Plantago ovata</i> (major) – Psyllium (Isaphula)- seed husk	Isaphgul-Ashabgol	Do	Do
195	<i>Cucurbita pepo</i> , <i>C.</i> <i>maxima</i> - Pumpkin seed oil /meal	Kaddu beej tail	Do	Do
196	<i>Punica granatum</i> – fruit /seed /skin extract /leaf /powder	Dadima/Pomegrana te	Do	Do
197	<i>Raphanus sativus</i> var. <i>niger</i> - root powder/ extract	Mulika/ Muli /Black radish	Do	Do
198	Red wine - extract /concentrate	-	Do	Do
199	Red yeast rice	-	Do	Do
200	Resveratrol	-	Do	Do
201	<i>Rhododendron</i> <i>arboreum</i> / <i>R.</i> <i>campanulata</i> - juice/extract	Buras/Rhododendro n	Do	Do
202	Rice bran	-	Do	Do

203	Rice bran arabinoxylan compound	-	Do	Do
204	Rose hips	-	Do	Do
205	<i>Rosmarinus officinalis</i> – leaves/ needles extract /oil	Rosemary	Do	Do
206	Royal Jelly	-	Do	Do
207	Rutin from fruit peels	-	Do	Do
208	<i>Salvia officinalis</i> – leaf extract	Renuka Leaf Extract/Sage	Do	Do
209	<i>Sambucus nigra</i> - extract	Khaman Kabir /Elderberry/ Black elderberry	Do	Do
210	Shark cartilage /squalene oil	-	Do	Do
211	Shiitake mushroom - extract	-	Do	Do
212	<i>Solanum lycopersicum/ S. esculentum</i> – fruit powder/ extract	Tamatar/Tomato	Do	Do
213	Soy sprouts – dried powder	-	Do	Do
214	Soya protein isolate/ edible legume seed protein isolate	-	Do	Do
215	Spearmint – leaf and distillate	-	Do	Do
216	Sterols/Stanols including their esters	-	Do	Do
217	<i>Tagetes sp.</i> – petals oleo resin / extract	Marigold	Do	Do
218	<i>Terminalia arjuna</i> - bark /leaf extract (standardized extract)	Arjuna extract	Do	Do
219	<i>Terminalia bellerica</i> - fruit extract	Bibhitak/Baheda/Myrobalan	Do	Do
220	<i>Terminalia chebulia</i> - fruit extract	Haritaki / Harad/Myrobalan	Do	Do
221	Theaflavin	Chai sukshara satva	Do	Do
222	Theobromine	-	Do	Do

223	Tocopherols	-	Do	Do
224	<i>Trigonella-foenum-graecum</i> – seeds extract	Methika/Methi/Fenugreek	Do	Do
225	<i>Triticum sativum</i> - bran	Godhum/Wheat/Gehu	Do	Do
226	Trypsin	-	Do	Do
227	<i>Vaccinium corymbosum</i> - fruit - dried powder / concentrate standardized	Blueberry	Do	Do
228	<i>Vaccinium oxycoccos/Vaccinium macrocarpon</i> - fruit - dried powder / concentrate standardized		Do	Do
229	<i>Valeriana wallichii</i> - extract	Tagar	Do	Do
230	<i>Vitis alba and Vitis vinifera</i> - fruit - dried powder / concentrate standardized	Draksha/Munakka/Blue grapes	Do	Do
231	Wheat germ	-	Do	Do
232	<i>Zingiber officinale</i> - rhizome standardized extracts	Shunti/Ginger	Do	Do
233	Mucopolysaccharides		Do	Do

Note – 1 : “Nutraceuticals”

The Food Safety and Standards Authority of India (FSSAI) by a Notification being F. No. Std/SP-05/T(Nutraceutical-2022)[E-5184] dated 29th March, 2022 has overhauled the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 and drafted a new framework to be called as FSS (Health Supplements, Nutraceuticals, Food for Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 (hereinafter referred to as “the said Regulations, 2022”). The said Notification dated 29th March, 2022 also states that the said Regulations, 2022 notified by the said Notification dated 29th March, 2022 are in the process of draft publication and its final notifications will likely take some more time. In view of this, the provisions of the said Regulations, 2022 as enumerated in Annexure – I of the said Notification dated 29th March, 2022 shall be operative with effect from 1st April, 2022. Schedules as applicable to different categories of the said Regulations, 2022 are enclosed at Annexure 2 to the said Regulations, 2022 and the list of additives and purity are provided in Annexure 3 to the said Regulations, 2022.

Nutraceutical as per Regulation 3(g) of the said Regulations, 2022 is a category of foods which consists of extracts, isolates and purified chemical compounds having a physiological benefit and help to maintain health. Regulation 5(2) of the said Regulations, 2022 deals with “Ingredients” The said Regulation 5(2), inter-alia, states that the products shall contain approved ingredients as applicable to different categories of foods to be specified separately by the FSSAI in the form of Schedules as listed below :–

- (i) Schedule I : Nutrients (vitamin, minerals, amino acids and other nutrients)
- (ii) Schedule II : Plant or botanicals
- (iii) Schedule III : Molecules/isolates/extracts other than Schedule II
- (iv) Schedule IV : Prebiotics and Probiotic

Regulation 6(2) of the said Regulations, 2022 deals with Nutraceutical. Regulation 6(2)(a) provides for the scope whereas Regulation 6(2)(b) refers to nutrients/ingredients which are allowed. The said Regulation 6(2) is set out below –

“6. Category specific requirements

(2) Nutraceutical	
(a) Scope	The nutraceuticals are meant to provide a physiological benefit and help maintain good health and not intended to treat or cure any medical condition, disease, or disorder
(b) Nutrients/Ingredients allowed	Molecules/ isolates/extract from the Schedule III as specified by Food Authority from time to time. In addition, it may also contain nutrients and ingredients from other schedules as approved and specified by Food Authority from time to time as an optional ingredient.
(c) Nutrients/Ingredients usage level	(i) Ingredients: Limits as specified in Schedule III with standardisation to marker compounds specified and at daily usage levels specified therein. In case daily minimum and maximum usage levels have not been specified, the FBO shall adopt the usage level based on relevant scientific data and retain the documentary evidence of such data. The ingredient for which the standardisation of the marker compound has not been specified shall comply with manufacturer specifications or quality requirements and purity criteria as specified in regulation. FBO shall submit such data to the Food Authority as and when called for. (ii) Nutrients: Usage levels shall not be more than the level specified by the Food Authority. In case, the levels are not specified by the food Authority, usage level shall be minimum 15 % of RDA as specified by ICMR, where a nutrient content claim is being made, provided that, if claim of higher nutrient content is made, the nutrient content shall not be less than thirty per Page 9 of 76 cent of the recommended daily allowance and shall not exceed one RDA in any case. In case such standards are not specified, the standards laid down by an international food standards body namely, Codex Alimentarius Commission shall apply.
(d) Delivery format(s)	Shall comply with general requirements 5(1).
(e) Additive(s)	(i) For products in tablet/capsule/pills/liquid format: Only additives as specified by the FA from time to time. (ii) For products other than tablet/capsule/pills/liquid format: Only additives within the limits specified as permitted for category 13.6 and GMP table of Appendix ‘A’ of FSS (FPS & FA) Regulations, 2011 are permitted
(f) Labelling requirement(s)	Shall comply with general requirements 5(11).
(g) Any other requirement not covered above -	

The said Notification dated 29th March, 2022 was further revised by FSSAI by a Notification dated 10th May, 2022 being Std/SP-05/T(Nutraceutical-2022)[E-5148] to permit additional food additives and enzyme/proteins for Health Supplements.

Subsequently, by a further Notification dated 24th June, 2022 being No.F.No.Std/SP-05/T(Nutraceutical-2022) FSSAI has published Draft Regulations, 2022 called FSS (Health Supplements, Nutraceuticals, Food for Dietary Use, Food for Special Medical Purpose and Prebiotic and Probiotic Food) Regulations, 2022 inviting objections/suggestions from any person with respect to the draft Regulations, 2022 before expiry of the period 60 days from the date of publication of the same in the Official Gazette. The Regulations of 2022 as notified by FSSAI by the Notification dated 24th June, 2022 has not yet been finalized .In the meantime by a further Notification dated 18th October, 2022 being No. Std/SP-05/T(Nutraceutical-2022)(part-1)-(Part-1) FSSAI has re-operationalized the provisions of the said Regulations,2022 as specified in the Notification dated 29th March, 2022 together with the provisions specified in the Notification dated 10th May, 2022 with effect from 1st October, 2022. Therefore ,unless the draft Regulations of 2022 is notified by FSSAI, the provisions of the said Regulations, 2022 as notified by FSSAI on 29th March, 2022 shall apply to all Nutraceuticals. Therefore, the provisions of the said Regulations 2022 should be considered for determining whether a particular food can be considered as Nutraceuticals.

According to the said Regulation 6(2)(b) Nutraceutical consists of molecules/isolates/extract from the Schedule III to the said Regulations, 2022 as specified by Food Authority from time to time. In addition to the molecules/isolates/extract from the Schedule III to the said Regulations, 2022, Nutraceutical may also contain nutrients and ingredients from the other Schedules to the said Regulations 2022 i.e. Schedule I, II and IV as approved and specified by the Food Authority from time to time as an optional ingredient. For the sake of convenience the Schedules I to IV to the said Regulations, 2022 are annexed hereto and marked as “A”.