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Evulation of FSSAI Guidelines on Functional Food and Health Supplements

Ayush Panchal[1*], Harshala Patil[1], Anand S. Deshmukh[1], M. N Noolvi[1]
Department of Regulatory Affairs, Shree Dhanvnatary Pharmacy College, Kim (E), Olpad, Surat, Gujarat, India
ayushpanchal360@gmail.com&dranandeshmukh@gmail.com
ORCID ID: 0000-0003-4803-4894

Abstract: *India, with its rich tapestry of biodiversity and indigenous knowledge systems, stands at the crossroads of modern development and traditional conservation practices. The interplay between Intellectual Property Rights (IPR) and the conservation of biodiversity and traditional knowledge is pivotal in ensuring sustainable development. This paper delves into the significance of IPR in safeguarding India's biodiversity, the challenges posed by biopiracy, and the role of traditional knowledge in sustainable practices. Through an examination of existing legal frameworks and case studies, this study aims to highlight the need for a balanced approach that respects indigenous knowledge while promoting innovation and conservation.*

Keywords: *biodiversity*

I. INTRODUCTION

FSSAI

The Food Safety and Standards Authority of India is a statutory body under the administration of the Ministry of Health and Family Welfare, Government of India. It regulates the manufacture, storage, distribution, sale, and import of food articles, while also establishing standards to ensure food safety. The FSSAI was established by the Food Safety and Standards Act, 2006, which consolidated all former acts and orders related to food safety that were previously handled by various ministries and departments. The FSSAI has its headquarters at New Delhi. The authority also has four regional offices located in Delhi, Mumbai, Kolkata, and Chennai. There are 22 referral laboratories notified by FSSAI, 72 State/UT laboratories located throughout India and 112 laboratories are NABL- accredited private laboratories notified by FSSAI. The FSSAI is headed by a non-executive chairperson, appointed by the central government, either holds or has held the position of not below the rank of Secretary to the Government of India. Ms. Punya Salila Srivastava is the current chairperson for FSSAI and Rajit Punhani is the current chief executive officer for FSSAI. The FSSAI provisions are enforced by Food Safety Officers.

FSSAI was established on 5 September 2008 under Food Safety and Standards Act, 2006 which was operationalized in year 2006. The FSSAI consists of a chairperson and 22 members. The FSSAI is responsible for setting standards for food so that there is one body to deal with and no confusion in the minds of consumers, traders, manufacturers, and investors. Ministry of Health & Family Welfare, Government of India is the Administrative Ministry of Food Safety and Standards Authority of India. The following are the statutory powers that the FSS Act, 2006 gives to the Food Safety and Standards Authority of India (FSSAI).

- Framing of regulations to lay down food safety standards
- Laying down guidelines for accreditation of laboratories for food testing
- Providing scientific advice and technical support to the Central Government
- Contributing to the development of international technical standards in food
- Collecting and collating data regarding food consumption, contamination, emerging risks, etc.
- Disseminating information and promoting awareness about food safety and nutrition in India.

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REGULATORY FRAMEWORK:

The Food Safety and Standards Authority of India is a statutory body under Food Safety and norms Act, 2006. The Food Safety and norms Act(FSS), 2006 is the primary law for the regulation of food products. This act also sets up the expression and enforcement of food safety norms in India. The FSSAI appoints food safety authorities on the state position.(16)

The FSSAI functions under the executive control of the Ministry of Health and Family Welfare. The main end of FSSAI is to

1. Lay down wisdom- grounded norms for papers on food
2. To regulate themanufacture, storehouse, distribution, import, and trade of food

. To grease the safety of food

FUNCTIONAL FOOD

A functional food is a food claimed to have an fresh benefit beyond just nutrition(frequently one related to health creation or complaint forestallment) by modifying the civilization of the native food or by adding constituents during manufacturing.

The term applies to traits deliberately bred into being comestible shops, similar as grandiloquent or golden potatoes having increased anthocyanin or carotenoid contents, independently. Functional food manufacturing has the intent" to have physiological benefits and/ or reduce the threat of habitual complaint beyond introductory nutritive functions, and may be analogous in appearance to conventional food and consumed as part of a regular diet".

Common constituents intended to be functional when added to foods include polyunsaturated adipose acids, probiotics, prebiotics, vitamins with antioxidant parcels, and protein.

As of 2025, leading product trends and provocations for choosing functional foods are for energy drinks, healthy aging, active living, and weight loss, among several others.

Presumed benefits of making foods more functional or healthy have n't been scientifically established, and specific statements of health claims are regulated on food markers in the European Union, United States and Canada.

Functional foods are generally high in important nutrients, including vitamins, minerals, healthy fats, and fiber.

Filling your diet with a variety of functional foods — including both conventional and fortified foods — can help insure you get the nutrients you need and cover against nutrient scarcities.

In fact, since the preface of fortified foods, the frequence of nutrient scarcities has significantly dropped around the globe.

For case, after iron- fortified wheat flour was introduced in Jordan, rates of iron insufficiency anemia among children were nearly cut in half(5Trusted Source).

Bastion has also been used to help other conditions caused by nutrient scarcities, including rickets, goiter, and birth blights(6Trusted Source).

May cover against complaint

Functional foods give important nutrients that can help cover against complaint.

numerous are especially rich in antioxidants. These motes help neutralize dangerous composites known as free revolutionaries, helping help cell damage and certain habitual conditions, including heart complaint, cancer, and diabetes(7Trusted Source).

Some functional foods are also high in omega- 3 adipose acids, a healthy type of fat shown to reduce inflammation, boost brain function, and promote heart health(8Trusted Source).

Other types are rich in filaments, which can promote better blood sugar control and cover against conditions like diabetes, rotundity, heart complaint, and stroke. Fiber may also help help digestive diseases, including diverticulitis, stomach ulcers, hemorrhoids, and acid influx

Salutary SUPPLEMENT

A salutary supplement is a manufactured product intended to condense a person's diet in the form of a lozenge, capsule, tablet, greasepaint, or liquid. A supplement can give nutrients either uprooted from food sources, or that are synthetic(to increase the volume of their consumption). The classes of nutrient composites in supplements include vitamins,

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minerals, fiber, adipose acids, and amino acids. Salutary supplements can also contain substances that have n't been verified as being essential to life, and so are n't nutrients per se, but are retailed as having a salutary natural effect, similar as factory colors or polyphenols. creatures can also be a source of supplement constituents, similar as collagen from cravens or fish for illustration. These are also vended collectively and in combination, and may be combined with nutrient constituents. The European Commission has also established harmonized rules to help ensure that food supplements are safe and meetly labelled.

Creating an assiduity estimated to have a value of$ 151.9 billion in 2021, there are further than 50,000 salutary supplement products retailed in the United States, where about 50 of the American adult population consumes salutary supplements. Multivitamins are the most generally used product among types of salutary supplements. The United States National Institutes of Health states that some supplements may help give essential nutrients or support overall health and performance for those with limited salutary variety.

II. AIM AND OBJECTIVES

Aim

To understand the *Food Safety and Standards Authority of India (FSSAI)* guidelines related to functional foods and health supplements, focusing on their role in ensuring safety, quality, labelling, and regulatory compliance within the Indian nutraceutical sector.

Objectives

- To study the key provisions of the FSSAI (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, 2022.
- To evaluate how these regulations ensure the safety, efficacy, and labelling accuracy of functional foods and health supplements.
- To identify the gaps and challenges faced by manufacturers and consumers in implementing these guidelines.
- To assess the impact of FSSAI regulations on the growth and standardization of the nutraceutical and health supplement industry in India.
- To suggest possible recommendations or improvements for strengthening the regulatory framework.

Food Safety and Standards (Health Supplements, Nutraceuticals) Regulations, 2022. [FSSAI (Nutra) Regulations, 2022]

1. Title	Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022
2. Scope and categories covered	Articles of food falling under these regulations are specially processed or formulated for specific nutritional or dietary purpose and shall be clearly distinguishable from foods intended for normal consumption by their special composition. These foods are intended for population above the age of 2 years[1] and shall fulfill the characteristics as laid down in these Regulations. They are intended to be consumed orally in defined quantities and duration and shall not include products intended for parenteral use. Categories covered under these regulations include the following: Health Supplements (HS) Nutraceuticals (Nutra) Food for Special Dietary Use (FSDU) Food for Special Medical Purpose (FSMP) Prebiotic food and Probiotic food (Pre-Pro) Food or ingredients referred to in Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, and for which standards are provided, and the plants and botanicals specified in these regulations offered in normal or naturally occurring forms shall

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	not constitute a health supplement or nutraceutical, or food for special dietary use or food for special medical purpose. The products falling under these regulations shall not include a drug as defined in clauses (a), (b) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder. The products falling under these regulations shall not contain hormones or steroids or a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act,1985 (61 of 1985) and rules made thereunder and substances listed in Schedules E and E- 1 of the Drugs and Cosmetics Rules,1945. The Products claiming cure, prevention or mitigation of any specific disease, disorder or condition shall also not fall under these regulations, unless specifically permitted by Food Authority under FSS regulations. Mere food forms such as vegetables, for example, bhindi, karela and other vegetables; cereals, for example, ragi, jowar, millets and other cereals; legumes, for example, rajmah and other legumes; spices, for example, pepper, jeera, turmeric and other spices; fruits, for example, amla, jamun, grapes and other fruits; and other plants or botanicals, minimally processed (cleaned, de-weeded, sorted, dried or powdered), in either as juice or cooked form, shall not constitute 'health supplement' or 'nutraceutical' or 'food for special dietary use' or 'food for special medical purpose'. Note 1: Foods intended for infants up to the age of 2 years shall comply with FSS (Food for Infant Nutrition) Regulations, 2020.
3. Definitions:- In these regulations, unless the context otherwise requires	Act means the Food Safety and Standards Act, 2006 (34 of 2006); Food Authority means the Food Safety and Standards Authority of India established under section 4 of the Act; Food for special dietary use is a category of foods, which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist. FSDU which are intended to be used as an adjunct for the management of diseases/disorders only under medical prescription and supervision shall normally be categorized under FSMP. Food for special medical purpose is a category of foods for special medical uses, which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two. Health supplement is a category of foods, which consists of a concentrated source of nutrients (like proteins, minerals, vitamins, amino acids) and/or other ingredients with nutritional or physiological effects, singly or in combination, whose purpose is to supplement the normal diet.

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	Ingredient means plant or botanicals and their extracts, probiotics, prebiotics, and molecules/isolates as listed by FA in its Schedule II, III and IV. Nutraceutical is a category of foods which consists of extracts, isolates and purified chemical compounds having a physiological benefit and help to maintain health Nutrient means vitamins, minerals, amino acids and other nutrients as specified by FA from time to time. Premix means a combination of two or more ingredients specified in the Schedules in a specific proportion with or without additives, packed and meant for use in formulating a product falling under any category of these regulations. Prebiotic food means food that contains added ingredients which are non-viable food components that confer health benefits to the consumer by modulation of gut microbiota. Probiotic food means food with live micro-organisms beneficial to human health, which when ingested in adequate numbers as a single strain or as a combination of cultures, confer one or more specified or demonstrated health benefits in human beings. Schedule means the Schedules to be specified by the FA through executive orders under these regulations. Sportsperson means an individual who regularly participates in various types of sports activities as approved by Sports Authority of India (Ministry of Youth Affairs & Sports)
4. Applicability. - No person shall manufacture, pack, sell, offer for sale, market or otherwise distribute or import any food products referred to in these regulations unless they comply with the requirements laid down in these regulations. (1) Delivery format	The products covered under these regulations may be in the form of powders, granules, tablets, capsules, liquids, semi solids, drops, pills, gummies, jelly, chewable and mouth dissolving strips, bars, biscuits, candies that are intended to be consumed orally in defined quantities and duration unless otherwise restricted for specific categories under these regulations. In addition, Food Authority may also specify any other formats from time to time. In case the delivery format is in conventional form (like bar, biscuit, candy, etc.), information on the label shall not represent the product as conventional and clear differentiation in this regard is to be made on the label. Ingredients not adhering to conventional delivery formats (or as described in Section 22 of FSS Act, 2006) including Nano derived ingredients and modified drug delivery format shall need prior approval under FSS (approval of non-specified food and food ingredients) Regulations, 2017
(2) Ingredients	The products shall contain approved ingredients as applicable to different categories of foods to be specified separately by the Food Authority in the form of Schedules as listed below: Schedule I: Nutrients (vitamins, minerals, amino acids and other nutrients) Schedule II: Plant or botanicals* Schedule III: Molecules/isolates/extracts other than Schedule II Schedule IV: Prebiotics and Probiotics and *(Ingredients of plant or botanical origin specified in Schedule II may be used either in the given form, or their extract. In case of extract, the same shall be subject to the extractive ratios in relation to the daily usage value and shall be obtained only from the part of the plant listed in the schedule). In addition, categories covered under these regulations may also contain such additional ingredients, other than additives, which are either standardized or permitted for use in preparation of the other standardized foods as specified in the FSS (Food Products Standards and Food Additives) Regulations, 2011 [FSS(FPS&FA)]. Products covered under these regulations may also contain cereal grains, legumes, fruits and vegetables mentioned in the latest edition of the Indian Food Composition Tables (IFCT)

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	published by ICMR-National Institute of Nutrition (ICMR-NIN) and spices included in the list published by the Spices Board of India either as such or as processed ingredients including extracts. Non-specified foods including novel foods and non-specified ingredients, even if intended for use as any of the above categories, are not covered under these regulations. Such ingredient/product shall need approval in accordance with Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017.
(3) Provision for inclusion of ingredients with incident free history of safe use (HoSU)	(a) Ingredients including plant or botanicals or their extracts which are not provided in these regulations but have documented incident free history of safe use (at least thirty years in the country of origin or fifteen years in India) may be allowed, with prior approval by the Food Authority through representation by submitting relevant evidence. (b) For inclusion of any other new ingredient which does not fall under scope of above provision, the Food Business Operator (FBO) shall apply to the Food Authority as per FSS (approval of non-specified food and food ingredients) Regulations, 2017 [FSS (NSF&FI)]. In such cases, Food Authority may, after proper scientific evaluation, include and notify the nutrients or other ingredients approved under NSF regulations from time to time.
(4) Additives, processing aids and flavours	Additives and processing aids as specified in Appendix A and C of FSS (FPS&FA) regulations for categories under these regulations are permitted for use, unless specifically restricted. * The list of additives/excipients intended specifically for tablet/capsule/syrup/pills format shall be specified separately by the Food Authority from time to time. ** Flavours: FBO may use the natural, nature identical or artificial flavours in accordance with regulation 3.3.1 of FSS (FPS&FA). Use of any additive and processing aid that are not specified under these regulations shall be allowed only with the prior approval of the Food Authority or under FSS (approval of Non-Specified Food and Food Ingredient) regulations,2017. Esters and salts of any vitamins in particular Vitamin C & Vitamin E mentioned under Additives schedules with the usage level as GMP are permitted in product formulations subject to maximum level specified for usage by Food Authority. In case, levels are not specified by Food Authority the total level shall not exceed RDA specified by ICMR. *(Till the time the additives are notified in the FSS (FPS&FA) Regulations, 2011, the FBO shall use the additives permitted for different food categories as given in Annexure 3 and the additives given in GMP Table (Appendix 'A') of the FSS (FPS&FA) Regulations, 2011). **(FBO shall refer to Annexure 3 for additives/excipients intended specifically for tablet/capsule/syrup/pills format).
(5) Purity criteria for the ingredients	The purity criteria for the ingredients used in the categories of articles of food covered under these regulations shall be specified separately by the Food Authority from time to time. * In case such standards are not specified, the purity criteria generally accepted by pharmacopoeias (namely, Indian Pharmacopoeia, Ayurvedic Pharmacopoeia of India, United States Pharmacopoeia & British Pharmacopoeia), relevant BIS Specifications, Quality Standards of Indian Medicinal Plants as published by ICMR, Joint FAO/WHO Expert Committee on Food Additives or Codex Alimentarius may be adopted by FBO. The FBO shall provide information on the purity criteria adopted for ingredients at the time of licensing and any subsequent changes. *(FBO shall refer to Annexure 3 for purity criteria for the ingredients).
(6) Provision on single	Any single purified chemical entity listed in these regulations, except extracts of plant or

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purified chemical entity	botanicals and vitamins and minerals, amino acids and nucleotides, are not permitted to be sold as HS, Nutra, FSDU, FSMP or Pre-Pro, without prior approval of the Food Authority.
(7) Ingredient combination rationale	Any combination of ingredients in a formulation shall be based on available scientific and technical evidence; and such evidences shall be made available to the Food Authority as and when called for.
(8) Quality requirements for tablet, capsule format	The quality requirements for tablet, capsule format shall be specified separately by the Food Authority from time to time. In case such standards are not specified, the same shall comply with general monograph and quality requirements specified for them in Indian Pharmacopoeia, if applicable.
(9) Process to obtain plant or botanical extracts	Food grade solvent, either singly or in combination shall only be used for extraction of plant or botanicals. Ingredient prepared by extraction and fractionation using any other solvent shall require prior approval by the Food Authority under NSF & FI regulations.
(10) Products for 2 to 5 years of age	The products covered under these regulations intended for children of 2 to 5 years of age, shall only be given under medical advice by a recognized medical doctor or dietician or nutritionist.
(11) Overages & Tolerance limit	Addition of appropriate overages to ensure adequate availability of vitamins and minerals in the products shall be permitted based on scientific rationale; and, such overages shall be specified by the Food Authority from time to time. The tolerance limit for variation in case of articles of food covered in these regulations during analysis of samples of finished products, shall be in accordance with FSS (L&D) regulations, 2020.
(12) Labelling	In addition to the general labelling requirements specified under FSS (Labelling and Display) Regulations, 2020 [FSS (L&D)], categories specified under these regulations shall carry the following information on the label: Front of the Pack The words “HEALTH SUPPLEMENT/ NUTRACEUTICAL” as applicable to the concerned category, in capital and bold letters in the immediate proximity of the name or brand name of the product; A prominent statement indicating the target consumer group and/or age group if the product has been formulated for a specific age group;
	Front or Back of the Pack The statement “NOT FOR MEDICINAL USE” in capital and bold letters prominently written on label, unless exempted for specific categories under these regulations; ‘Recommended usage level’; ‘Duration of usage, where applicable’; ‘Not to exceed the recommended daily usage’ prominently written. An advisory warning in cases where a danger may exist with excess consumption; Warning on any other precautions to be taken while consuming, known side effects if any, contraindications and published product or drug interactions, as applicable; statement or warning stating, ‘product is not to be used as a substitute for a varied diet’ except for FSDU and FSMP category; A warning statement ‘product is required to be stored out of reach of children’; The quantity of nutrients, expressed in terms of percentage of the relevant recommended daily allowances, unless exempted by any other regulations in force; Front or Back of the Pack or Accompanied Leaflet.

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	A declaration on the amount of the nutrients or substances with a nutritional or physiological effect present in the product; The label, accompanying leaflet or other labelling and advertisement of each type of article of food, referred to in these regulations shall provide sufficient information on the nature and purpose of the article of food and detailed instructions and precautions for its use, and the format of information given shall be appropriate for the intended use of the consumer; (b) In addition to the above, the labels shall also comply with any other requirements mentioned specifically against the applicable category under these regulations.
(13) Claims and its approval process	The products falling under these regulations by means of labelling, presentation and advertisement shall not claim to treat, cure, mitigate or prevent any specific disease, disorder or condition or refer to such properties, unless specifically permitted by Food Authority. The statement by FBO relating to structure, function or general well- being of the body may be allowed by the Food Authority if the statement is supported by the generally accepted scientific data. FBO may make nutritional or health claims or reduction of disease risk claims (DRR) that are listed under FSS (Claims and Advertisements) Regulations, 2018 [FSS (C&A)]. For making any other claims or any exemption to 10(1) of FSS (C&A), prior approval of the Food Authority shall be obtained in accordance with FSS (C&A) Regulations,docs fees.
(14) Other regulations for compliance	Unless otherwise specified, categories under these regulations shall comply to the following regulations also - Chemical Contaminants: FSS (Contaminants, Toxins and Residues) Regulations,2011. Microbial contaminants: Appendix B of FSS(FPS&FA). Packaging: FSS (Packaging) Regulations,2018 (b) The products shall be prepared and handled in accordance with the requirements specified in Schedule 4, or as applicable, under the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and such other guidelines as specified from time to time under the provisions of the Food Safety and Standard Act, 2006.
(15) Other provisions including explanatory notes	An article of food which has not been particularly modified in any way but is suitable for use in a particular dietary regimen because of its natural composition, shall not be designated as 'health supplement' or 'special dietary' or 'special dietetic' or by any other equivalent term, and such food may bear a statement on the label that 'this food is by its nature X' ('X' refers to the essential distinguishing characteristic as demonstrated by the generally accepted scientific data), provided that the statement does not mislead the consumer. The Food Authority may suspend or restrict sale of such articles of food as have been placed in the market that are not clearly distinguishable from articles of food for normal consumption and are not suitable for their claimed nutritional purpose, or may endanger human health, in accordance with the provisions of the Act. Food Authority may also advise the FBO to alter or modify or stop claims which are not supported by scientific evidence. The articles of food or formulation shall consist of a composition delivering the desired level of energy, protein, vitamins and minerals, and other essential nutrients required for respective age group, gender and physiological stage in accordance with the guidelines made by the ICMR from time to time.
6. Category specific requirements	
(1) Health supplements	
(a) Scope	Health supplements are meant to supplement the normal diet of a person

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	and not intended to treat or cure any deficiency.
(b) Nutrients/Ingredients allowed	Proteins, vitamins, minerals, amino acids or other ingredients with nutritional or physiological effects, singly or in combination, specified under schedules (except Schedule III) by the Food Authority from time to time.
(c) Nutrients/Ingredients usage level	(i) 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 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
	Alimantarius Commission shall apply. (ii) Ingredients: Limits as specified in schedule. 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. FBO shall submit such data to the Food Authority, as and when called for.
(d) Delivery format(s)	Shall comply with general requirements 5(1)
(e) Additive(s)	For products in tablet/capsule/pills/liquid format: Only additives as specified by the FA from time to time. 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(12). In addition, FA may allow Health supplements term on the label may be interchangeably use by the terms, namely, Dietary supplements or Food supplements.
(g) Any other requirement not covered above	NA
(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	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. 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
	cent of the recommended daily allowance and shall not exceed one RDA in any case. In case

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	such standards are not specified, the standards laid down by an international food standards body namely, Codex Alimantarius Commission shall apply.
(d) Delivery format(s)	Shall comply with general requirements 5(1).
(e) Additive(s)	For products in tablet/capsule/pills/liquid format: Only additives as specified by the FA from time to time. 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	N/A
(b) Essential Composition	Energy: FSDU presented as a replacement for all meals of the daily diet- Minimum 800 kcal (3,350 kJ); not more than 1,200 kcal (5,020 kJ). The individual portions or servings contained in the formula food shall provide approximately one-third or one-fourth of the total energy of the food in the pack depending on whether the recommended number of portions or servings per day is three or four, as the case may be, respectively. FSDU presented as a replacement for one or more meals of the daily diet - Minimum 200 kcal (835 kJ); not more than400 kcal (1,670 kJ) per meal. When such products are presented as a replacement for the major part of the diet, the total energy intake shall not exceed 1,200 kcal (5,020 kJ). Protein: Not less than 25 per cent and not more than 50 per cent of the energy available from the food, when ready-to-serve, shall be derived from its protein content; and the total amount of protein shall not exceed 125 g per day. The quality of protein shall have- the protein digestibility corrected amino acid score of 1.0 known as, the reference protein; the protein digestibility corrected amino acid score where less than 1.0, the minimum level shall be increased to compensate for the lower protein quality; the protein with a protein digestibility corrected amino acid score of 0.8 or more shall be used in a formula food for use in a weight control diet; and D. for improving the protein quality, the FBO shall add only L- forms of essential amino acids except for methionine where DL form is allowed. Fat and linoleate: Not more than 30 per cent of the energy available from fat and not less than 3 per cent of the energy from linoleic acid in the form of a glyceride. Vitamins and minerals: FSDU represented as a replacement for all meals per day, shall contain at least one RDA of vitamins and minerals in the daily intake. However, usage level beyond RDA are permitted only with prior approval of FA by providing adequate scientific evidence to the FA. Dietary fiber: These products shall have adequate dietary fiber.
(c) Additive(s)	Only additives within the limits specified as permitted for category 13.5 of Appendix 'A' and GMP table of FSS (FPS & FA) Regulations, 2011 are permitted.
(d) Labelling requirement(s)	In addition to 5(12) and 6(3)(f), every package of Food for Special Dietary Use intended for weight management shall carry the following information on the label–

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III. CONCLUSION

FSSAI's guidelines on functional foods and health supplements ensure product safety, quality, and truthful labelling. The 2022 regulations promote scientific validation and protect consumers from misleading claims. Overall, these guidelines strengthen public trust and support the safe growth of the nutraceutical industry in India

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