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Current Regulations and FSSAI Requirements for Registration, Import, and Manufacture of Dietary Supplements / Nutraceuticals in India

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ABSTRACT

The main aim of this article was to study the various dietary supplement registration processes, regulations in imports, and requirements by the Indian Regulatory Authorities. The study emphasizes the challenges faced by stakeholders entering into the Indian market without difficulty by demonstration of strategy arrived from the established guidelines, regulations, and expert opinion. The study was undertaken to identify the challenges in dietary supplements and evaluate the available guidelines and map the general requirements for registration.

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INTRODUCTION

A nutraceutical is a food or food component that claims to have health benefits, including treatment and prevention of disease. The term nutraceutical has no regulatory definition and is not recognized by the U.S. Food and Drug Administration, which uses instead the term 'dietary supplements. The Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, of 2006 which consolidates various acts & orders that have hitherto handled food-related issues in various Ministries and Departments.

New Nutraceutical Regulations by FSSAI to Make Import Easy for Firms

A set of new nutraceutical regulations started by the Food Safety and Standards Authority of India (FSSAI) very recently will make it easier for companies to innovate and import a broader range of supplements, although there are still some ‘bottlenecks’ to overcome. The new set of regulations is known as the FSS (Health Supplements, Nutraceuticals, and Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022.

The regulation policy is still in the process of draft publication and is open for comments from the industry stakeholders. Despite this, the FSSAI started the new regulations on April 1 without any transition period given. Also known as the FSS (Nutra) Regulations, 2022, the new framework will replace the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, and Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, 2016. According to the sources from FSSAI, the new regulations aim to remove ambiguity and bring more clarity among the stakeholders.

The new regulations would benefit the industry by expanding the scope for new product innovation and imports. This is due to several key reasons, such as a greater range of permitted dosage formats and a higher permissible limit for certain ingredients.

Also, the regulations now cover supplement guidelines for kids over two years old. Previously, the regulations only stated the supplement guidelines for individuals over the age of five. The additional formats covered under the new regulations are drops, gummies, chewable and mouth-dissolving strips, bars, biscuits, and candies. This is an expansion from the tablets, capsules,

liquids, semi-solids, pills, jelly or gel, and sachets allowed in the 2016 regulations. This set of new regulations will benefit the stakeholders. The manufacturers earlier were not able to manufacture and import some supplement products because there were no relevant guidelines. And so, they had to obtain permission from the FSSAI for every single product that was not covered under the regulations. Now, they just have to comply with the regulations.

While the new regulations would benefit the industry, there are still limitations to overcome. One of the regulatory bottlenecks lies in the recommended dietary allowance (RDA) for vitamins and minerals.

In the case of vitamin C, the maximum permissible limit as per the 2010 guidelines of NIN-ICMR was only 40mg. Now it has been revised to 80mg and both these guidelines are valid until June 30, 2023.

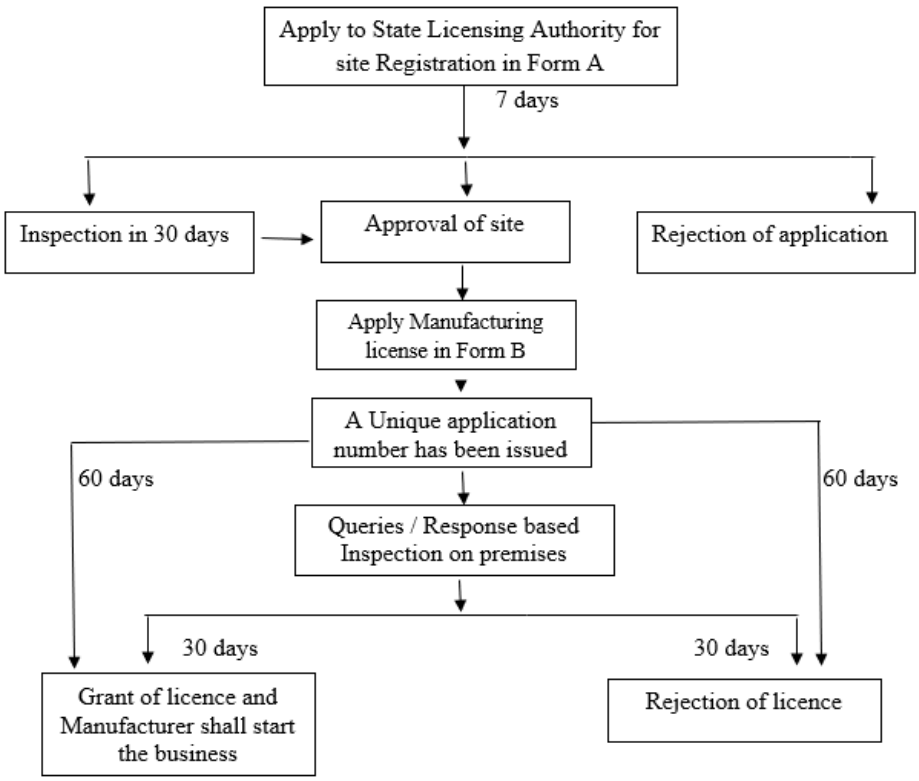
Importance of the Proposed Work

The Food Safety Standards Authority India (FSSAI) is the approving authority that approves the registration of food products and food businesses for the sale of products in the country. It also promotes general awareness of food safety standards in the country. The food safety standard and standards act is laid down in 2006 to form the statutory body which regulates the manufacture, storage, distribution, sale, and import, to ensure the availability of food and food products within the country. Nutraceuticals are grouped under the umbrella of foods by the FSS act 2006, rules and regulations 2011. The Food Safety and Standard Authority has issued regulations[3] concerning Licensing and registration of food businesses, manufacturing, packing and labeling, food product standard, etc. The FSSA has 12 chapters with 101 sections and two schedules. The FSSA incorporates the salient provisions of the prevention of Food Adulteration Act 1954 to establish a single reference point for all matters relating to food safety and standards.[4] The FSSA establishes the Food Safety and Standards Authority of India (FSSAI) as an apex regulatory authority, consisting of a Chairperson and 22 members. In their endeavor to carry out the provisions of the FSSA, the FSSAI shall be assisted by a Central Advisory Committee (CAC), Scientific Panels (SPs), and a Scientific Committee (SC); each with specific responsibilities. [4] The Food Authority may enlist specific Nutraceuticals as approved from time to time after undertaking proper scientific evaluation. Labeling of Nutraceuticals shall comply

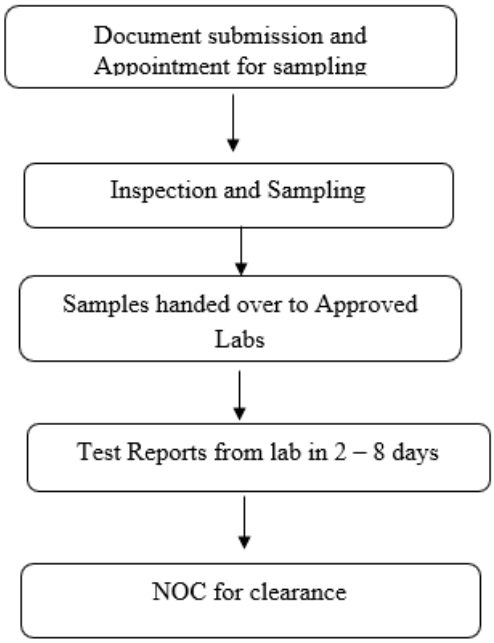
with the packaging and labeling requirements as laid down under Food Safety and Standards (Packaging and Labelling) Regulations, 2011.[3]The Food Safety and Standard act will encourage manufacturers to Product Research and Development; develop reliable protocols, and carry out clinical studies. Foreign Direct Investment Act will also provide new opportunities for international firms to manufacture and sell nutraceutical products in India.

For a better understanding of the updated requirements for Imports, Exports, and Registration of Dietary Supplements/Nutraceuticals with FSSAI in detail and to ensure regulatory compliance in India this research work has been carried out. The FSSAI started the new regulations on April 1, 2022, without any transition period given. Also known as the FSS (Nutra) Regulations, 2022, the new framework will replace the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, and Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, 2016. According to the sources from FSSAI, the new regulations aim to remove ambiguity and bring more clarity among the stakeholders.

The licensing process is done in two steps (i.e.) site registration and product registration[2].



Food Import Clearance Process



Clearance of Imported Food by the Food Authority[7]

Upon the arrival of the food consignments at the port, the importer or Custom House Agent shall file an Integrated Declaration Form as specified by the Customs. The Form forwarded from Customs to the Food Import Clearance System of Food Safety and Standards Authority of India shall be processed in the following manner, namely:-

(a)the Authorised Officer shall scrutinize the Form and may seek clarification if required

(b)upon satisfactory scrutiny, the applicant shall pay the fees as specified by the Food Authority for scrutiny of documents, visual inspection, and drawing of the sample

(c)where a single bill of entry is made up of articles of food consignment consisting of multiple categories of articles of food, an inspection fee shall be paid for each category of articles of food

(d) the Food Authority shall specify and review the inspection fee from time to time

(e)on receipt of the fees, the Authorised Officer shall intimate the details of the date and time of inspection to the Food Importer to facilitate the presence of the Food Importer or his Customs House Agent/Authorised representative at the time and place of inspection.

The Food Importer or his authorized representative shall remain present at the customs area at the appointed time to participate and facilitate visual inspection, assist in drawing of samples, if required, and assist in the import clearance proceedings as instructed by the Authorised Officer or his representative and witness proceeding, sealing of samples by the Authorised Officer or his representative and affix his counter signatures on the sealed samples.

If the Food Importer or his Customs House Agent is not present to facilitate the inspection and sampling despite two opportunities having been granted, the Authorised Officer may refuse to grant further opportunities for inspection and sampling of the food consignment: provided that any further opportunity in this behalf may be granted by the CEO or his authorized representative after levy of suitable fee on the Food Importer as may be specified by the Authority from time to time.

Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purposes, and Prebiotic and Probiotic Food) Regulations, 2022[9]

Scope and categories covered:

(1)Articles of food falling under these regulations are specially processed or formulated for specific nutritional or dietary purposes and shall be distinguishable from foods intended for normal consumption by their special composition. These foods are intended for the population above the age of 2 years and shall fulfil 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.

(2)Categories covered under these regulations include the following:

i. Health Supplements (HS)

ii. Nutraceuticals (Nutra)

iii. Food for Special Dietary Use (FSDU)

iv. Food for Special Medical Purposes (FSMP)

v. Prebiotic food and Probiotic food (Pre-Pro)

(3)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 not constitute a health supplement or nutraceutical, or food for special dietary use or food for special medical purpose.

(4)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.

(5)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.

(6)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 the Food Authority under FSS regulations.

(7)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, rajma 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.

Definitions[9] as per the new Act:

(i) **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. FSDUs 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.

(ii) **Food for special medical purposes** 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.

(iii) **The health supplement** is a category of foods, which consists of a concentrated source of nutrients (like proteins, minerals, vitamins, and amino acids) and/or other ingredients with nutritional or physiological effects, singly or in combination, whose purpose is to supplement the normal diet.

(iv) **Nutraceutical** is a category of foods that consists of extracts, isolates, and purified chemical compounds having physiological benefits and help to maintain health.

Category-specific requirements[9]:

1. Health supplements: Health supplements are meant to supplement the normal diet of a person and are not intended to treat or cure any deficiency.

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.

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, the usage level shall be a minimum of 15 % of RDA as specified by ICMR, where a nutrient content claim is being made, provided that, if the claim of higher nutrient content is made, the nutrient content shall not be less than thirty percent 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.

(ii) Ingredients: Limits as specified in the 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.

2. Nutraceutical: Nutraceuticals are meant to provide a physiological benefit and help maintain good health and are not intended to treat or cure any medical condition, disease, or disorder.

Nutrients/Ingredients allowed: Molecules/ isolates/extract from 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.

Nutrients/Ingredients usage level:(i) Ingredients: Limits as specified in Schedule III with standardization 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 standardization of the marker compound has not been specified shall comply with manufacturer specifications or quality requirements and purity criteria as specified in the 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, the usage level shall be a minimum of 15 % of RDA as specified by ICMR, where a nutrient content claim is being made, provided that, if

the claim of higher nutrient content is made, the nutrient content shall not be less than thirty percent 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.

3. Food for Special Dietary Use[9] :

(i) This standard applies to all pre-packaged foods for special dietary uses, in case of weight management, obesity, diabetes, high blood pressure, pregnant and lactating women, geriatric population, celiac disease, sleep management, food for Sportspersons and other health conditions.

(ii) Any other special dietary use products containing the approved ingredients shall need prior approval from the Food Authority by submitting the representation along with scientific justification.

(iii) FSDU shall not include the normal food which is merely enriched or modified with nutrients and meant for mass consumption, intended for improvement of general health for day-to-day use, and do not claim to be targeted to consumers with specific disease conditions and also not include the article of food intended to replace complete diet covered under food for special medical purpose.

Nutrients/Ingredients allowed: Carbohydrates, proteins, vitamins, minerals, amino acids, fats/essential fatty acids, fiber including dietary fiber and other ingredients such as botanicals and their extracts, enzymes, probiotics, prebiotics, and other dietary substances (singly or in combination) as specified in different Schedules by Food authority from time to time.

4. Food for Special Medical Purposes:

(i) This standard applies to the foods specially meant for the dietary management of persons with specific medical conditions or diseases or disorders.

(ii) The articles of food for special medical purposes, other than those intended for infants, may either be nutritionally complete food which, when used following the manufacturer's

instructions, shall constitute the sole source of nourishment for the persons for whom they are intended or nutritionally incomplete food with formulation specific for a disease, disorder or medical condition, but are not suitable to be used as the sole source of nourishment. Accordingly, FSMP may be classified into the following three categories.

A. 'Nutritionally complete food with a standard nutrient formulation', which when used following the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended.

B. 'Nutritionally complete food with a nutrient-adopted formulation specific for a disease, disorder or medical condition', which when used following the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended; and 'Nutritionally incomplete food with a standard formulation or a nutrient adopted formulation specific for a disease, disorder or medical condition', which is not suitable to be used as the sole source of nourishment. Note - the food specified in items (B) and (C) of sub-clause (ii) may be used as a partial replacement or as a supplement to the person's diet.

C. 'Nutritionally incomplete food with a standard formulation or a nutrient adopted formulation specific for a disease, disorder or medical condition, which is not suitable to be used as the sole source of nourishment.

Note - the food specified in items (B) and (C) of sub-clause (ii) may be used as a partial replacement or as a supplement to the person's diet.

Nutrients/Ingredients allowed: Carbohydrates, proteins, vitamins, minerals, amino acids, fats/essential fatty acids, fiber including dietary fiber and other ingredients such as botanicals and their extracts, enzymes, probiotics, prebiotics, and other dietary substances (singly or in combination) as specified in different Schedules by Food Authority from time to time.

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, the usage level shall not exceed one

RDA as specified by ICMR in any case. However, usage level beyond those specified by FA or RDA in food format (except tablet, capsule, syrup) is permitted only with prior approval of FA by providing adequate scientific evidence to the FA.

ii. Ingredients: Limits as specified in the schedule. In case no 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.

5. Prebiotic and Probiotic Food (Pre-Pro) :

i. Prebiotic Food: These are non-viable food components that confer health benefits by modulating gut microflora.

ii. ii. Probiotic Food: The foods with added viable microorganisms which when consumed in adequate amounts confer health benefits. Provided that the presence of the commonly used starter cultures of lactic acid-producing bacteria such as Lactococcus spp., earlier known as Streptococcus spp., Lactobacillus spp., and other such microorganisms used in the preparation of fermented milk (dahi) and related products shall not be considered as probiotics if the probiotic properties have not been substantiated.

Nutrients/Ingredients allowed:

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, the usage level shall not exceed one RDA as specified by ICMR in any case. However, usage levels beyond those specified by FA or RDA in food format (except tablet, capsule, syrup) are permitted only with prior approval of FA by providing adequate scientific evidence to the FA.

ii. Ingredients: Limits as specified in the schedule. In case no 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.

CONCLUSION:

The new regulations would benefit the industry by expanding the scope for new product innovation and imports. The new regulations cover supplement guidelines for kids above two years old. Previously, the regulations only stated the supplement guidelines for individuals above the age of five. The additional formats covered under the new regulations are drops, gummies, chewable and mouth-dissolving strips, bars, biscuits, and candies. This is an expansion from tablets, capsules, liquids, semi-solids, pills, jelly or gel, and sachets allowed in the 2016 regulations. The manufacturers earlier were not able to manufacture and import some supplement products because there were no relevant guidelines. So they had to obtain permission from FSSAI for every single product that was not covered under the regulations, now they have to just comply with the regulations.

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