



# A STUDY ON FUTURE REGULATORY ASPECTS RELATED TO NUTRACEUTICALS IN INDIA

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**Abstract:** The nutraceuticals enterprise has gone through large transformations over the years, pushed by using a developing international attention of the significance of fitness and wellness. As we step into 2024, the enterprise is poised for exceptional growth, with developments in science, technology, and client preferences shaping its trajectory. This assignment explores the modern-day panorama and future potentialities of the nutraceuticals industry, focusing on key elements such as growth, profits, market trends, lookup initiatives, and job opportunities.

**Keywords:** Nutraceuticals, Market trends

## INTRODUCTION

Nutraceutical is an advertising and marketing time period used to mean a pharmaceutical impact from a compound or meals product that has now not been scientifically demonstrated or accredited to have medical benefits. They are bioactive compounds and factors of herbs and minerals, as nicely as dietary supplements with medicinal properties. Vitamins, minerals, fatty acids, pre- and probiotics, natural supplements, and different dietary supplements are an increasing number of substantially used for preventive and therapeutic functions throughout the world, making it essential to preserve protection and first-class standards. [1,2]

This is a fast-developing enterprise in India, and several initiatives have been launched to function India as an outstanding participant in the discipline of Nutraceuticals in the subsequent years. The Indian enterprise and customers continue to be involved and regulatory scenario are nevertheless in their early stages, however they have the potential to compete with different worldwide organizations. [3] Nutraceuticals are merchandise derived from meals sources that are purported to supply more fitness benefits, in addition to the fundamental dietary cost observed in foods. Depending on the jurisdiction, merchandise may additionally declare to stop persistent diseases, enhance health, extend the getting older process, expand lifestyles expectancy, or help the shape or characteristic of the body. [4]

### **CLASSIFICATION OF NUTRACEUTICALS**

**DIETARY SUPPLEMENTS:** A dietary complement is a product taken by means of mouth that carries a 'dietary ingredient' meant to complement the diet. The 'dietary ingredients' in these merchandise can also encompass vitamins, minerals, herbs or different botanicals, amino acids, and elements such as enzymes, organ tissues, glandular, and metabolites. Dietary supplements can additionally be extracts or concentrates, and may also be observed in many types such as tablets, capsules, smooth gels, gel caps, liquids, or powders. [5,6]

### **EXAMPLES OF DIETARY SUPPLEMENTS**

- Vitamins (such as multivitamins or individual vitamins like vitamin D and biotin).
- Minerals (such as calcium, magnesium, and iron).
- Botanicals or herbs (such as Echinacea and ginger).
- Botanical compounds (such as caffeine and curcumin).
- Amino acids (such as tryptophan and glutamine).

**FUNCTIONAL FOODS:** Functional foods are elements that provide fitness advantages that lengthen past their dietary value. Some kinds include dietary supplements or different extra components designed to enhance health. The notion originated in Japan in the Nineteen Eighties when authority's corporations began approving ingredients with validated advantages in an effort to higher the fitness of the customary population. Some examples encompass meals fortified with vitamins, minerals, probiotics, or fiber. [7]

#### EXAMPLES OF FUNCTIONAL FOODS

- Fruits: berries, kiwi, pears, peaches, apples, oranges, bananas
- Vegetables: broccoli, cauliflower, kale, spinach, zucchini
- Nuts: almonds, cashews, pistachios, macadamia nuts, Brazil nuts
- Seeds: chia seeds, flax seeds, hemp seeds, pumpkin seeds
- fortified dairy products, such as milk and yogurt
- fortified milk alternatives, such as almond, rice, coconut, and cashew milk

#### **GLOBAL MARKET SIZE OF NUTRACEUTICALS**

The Nutraceuticals Market size is estimated at USD 488.41 billion in 2024, and is expected to reach USD 626.02 billion by 2029, growing at a CAGR of 5.09% during the forecast period (2024-2029).

[8]

STUDY PERIOD	2019-2029
MARKET SIZE[2024]	USD 488.41 BILLION DOLLARS
MARKET SIZE[2029]	USD 626.02 BILLION DOLLARS
CAGR	5.09%



Figure:1 Global Market Size according to CAGR

### **LIST OF FEW TOP NUTRACEUTICAL COMPANIES IN INDIA:**

- United Laboratories
- SwissChem Healthcare
- Bionova Lifesciences
- Venistro Biotech
- Kabir Lifesciences
- Lifecare Neuro
- Associated Biotech
- Nutriberry Nutraceuticals

### **MARKET SIZE OF NUTRACEUTICALS IN INDIA**

According to 6Wresearch, the India Nutraceuticals Market measurement is projected to develop at a CAGR of 29.5% at some stage in 2021-2027. With the rising health enterprise owing to an amplify in fitness recognition amongst humans and covid-19, demand for supplements, healthful ingredients & drinks is growing and will see a massive soar in coming years as human beings are focusing greater on enhancing their immunity. Growing center of attention on preventive healthcare and growing disposable profits additionally contributed to India nutraceutical market increase trajectory. Offers and reductions supplied by way of e-commerce structures appeal to human beings to purchase a range of merchandise from these systems (especially the younger generation) together with nutraceuticals. <sup>[9]</sup>

# India Nutraceuticals Market Overview

6W  
research

India Nutraceuticals Market Revenues, 2017-2027F (INR Thousand Crore)

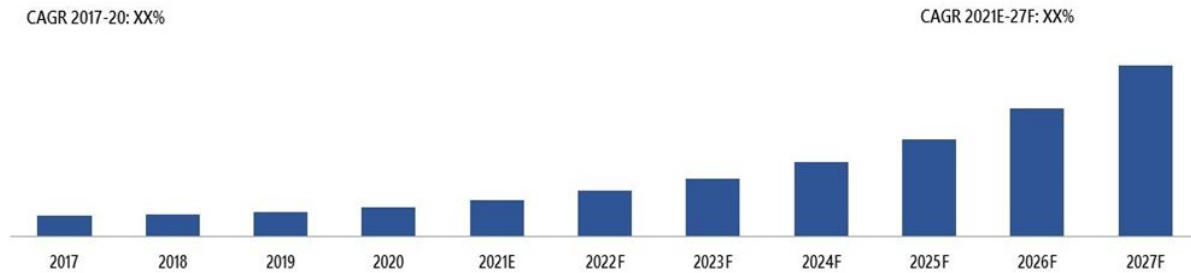


FIGURE 2: INDIAN NUTRACEUTICAL MARKET

## METHODOLOGY

### A) FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

- The Food Safety and Standards Authority of India (FSSAI) 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. <sup>[10,11,12]</sup>
- 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 holding or has held the position of not below the rank of Secretary to the Government of India. <sup>[13,14,15]</sup>

### B) FOOD SAFETY AND STANDARDS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022

- 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.



**C) CATEGORIES COVERED UNDER THESE REGULATIONS INCLUDE**

- 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 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
- 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.
- Foods intended for infants up to the age of 2 years shall comply with FSS (Food for Infant Nutrition) Regulations, 2020.

**D) 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.

**E) GENERAL REQUIREMENTS FOR ALL CATEGORIES**

- i) 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.

- ii) **Ingredients:** 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.
- iii) **Provision for inclusion of ingredients:** 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
- iv) **Additives, processing aids and flavours:** 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.
- v) **Purity criteria for the ingredients:** FBO shall refer to Annexure 3 for purity criteria for the ingredients. 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.
- vi) **Quality requirements for tablet, capsule format:** quality requirements specified for them in Indian Pharmacopoeia
- vii) **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.
- viii) **Labelling:** The words “HEALTH SUPPLEMENT/ NUTRACEUTICAL/ FOOD FOR SPECIAL DIETARY USE/ FOOD FOR SPECIAL MEDICAL PURPOSE/ PREBIOTIC FOOD /PROBIOTIC FOOD” 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. The statement “NOT FOR MEDICINAL USE” in

capital and bold letters prominently written on label, unless exempted for specific categories under these regulations. A declaration on the amount of the nutrients or substances with a nutritional or physiological effect present in the product

## **RESULTS**

### **REGISTRATION OF NUTRACEUTICALS IN INDIA:**

- Before beginning a business, the manufacturer has to be registered or been licensed in a legitimate manner.
- The inspection of premises has been accomplished after the trouble of ID wide variety in the way which is ordered via the act of FSSAI by using the protection officer.
- Under the regulations, the license which is granted shall be valid, except it is now not specified, for the length of 15 years.
- Manufacturers have to register with the country workplace commissioner and these producers whose turnover is higher than 12 lakhs to have to validly get a license from FSSAI office.
- The identical shall goes to the petty meals manufacturer.
  - An application for the grant of the license shall be made in form B of schedule 2.
  - The application must be filled so that the license can be granted.
  - This license should be issued within 60 days from the date of issue of application ID number.

### **FSSAI LICENSING SYSTEM:**

Food makers have to be registered or licensed through neighborhood authorities, and transient license holders ought to register their association with the neighborhood municipality. There are three classes of licensing: fundamental FSSAI registration, nation FSSAI license, and central FSSAI license. The license is legitimate for 1-5 years, relying on the choice of the meals facility owner, and is legitimate for 30 days from the date of expiry.



**DOCUMENTS NEEDED:** <sup>[10,11,12]</sup>

STATE FSSAI DOCUMENTS	CENTRAL FSSAI DOCUMENTS
Form B with signature	Form B with signature
Lay out plan of manufacturing unit	Complete equipment list with details
Contact details and address of unit	All government authority ID proofs
List of food products manufactured	In case of export a certificate from Ministry of Commerce is needed
Analysis report of public health laboratory	Sources of raw materials and their permissions
Sources of raw materials	NOC certificate for raw materials

Table 1: List of Documents

**CONCLUSION**

In 2024, the nutraceuticals enterprise is poised for amazing growth, pushed by using elements such as an ageing population, a shift towards preventive healthcare, and evolving customer preferences. The industry's monetary affect is substantial, with organizations navigating an aggressive landscape, adapting to regulatory changes, and leveraging digitalization to join with consumers. Research and innovation stay at the forefront, using the improvement of personalized, sustainable, and evidence-based nutraceutical products. As the enterprise expands, numerous job possibilities will emerge, attracting gurus throughout lookup and development, regulatory affairs, marketing, sales, excellent control, and provide chain management. The nutraceuticals enterprise in 2024 is now not simply a reflection of contemporary tendencies however a manifestation of the ongoing dedication to advancing science, merchandising wellness, and assembly the numerous fitness wants of an international population.

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