

# Nutraceuticals: Regulatory Landscape and Market Dynamics in the Indian Scenario

Lakshmi Prasanthi Nori, Potti Sowmya, Tippa Madhusree, Kalidindi Venkateswara Raju\*

Department of Regulatory Affairs, Shri Vishnu College of Pharmacy, Kovvada, Andhra Pradesh, INDIA.

## ABSTRACT

Numerous diseases can be prevented and treated with the help of Nutraceuticals. They have become an integral part of daily food intake for every human due to the increase in lifestyle-related health issues. Ensuring the enforcement of safety and quality standards is of utmost importance, particularly considering the widespread global usage of vitamins, minerals, fatty acids, prebiotics, probiotics, and herbal supplements for both preventive and therapeutic purposes. The necessity for the development of such regulatory guidelines has been further highlighted by the fast-growing global Nutraceutical business. Even though rules in the US, UK, and Europe have been simplified and made more conducive to growth of Nutraceutical product ecosystem, the Indian Nutraceutical companies and the regulatory landscape are still in their nascent stage and have a lot of room to grow and compete with other international organisations. India's Nutraceuticals industry is expanding quickly, and several measures have been made to position the country as a major role in the future of the sector.

**Keywords:** Nutraceuticals, Vitamins, Minerals, Global Nutraceutical business, International organisations.

## Correspondence:

**Dr. K. Venkateswara Raju** M. Pharm, Ph.D

Department of Regulatory Affairs, Shri Vishnu College of Pharmacy, Kovvada, Andhra Pradesh, INDIA.

Email: venkateswararaju.k@svcp.edu.in

**Received:** 27-06-2023;

**Revised:** 20-07-2023;

**Accepted:** 20-08-2023.

## INTRODUCTION

Dr. Stephen DeFelice coined "Nutraceuticals" as a term in 1989, and in 1994, he defined them as substances that can be considered part of food or food and provide relief for medical ailments as well as health benefits, that includes disease prevention and treatment. Nutraceuticals encompass a wide range of substances, including minerals, amino acids, vitamins, herbs, botanicals, essential oils, dietary substances, and natural substances of plant and animal origin. These nutritional supplements are limited to the products which are to be administered through the oral route as tablet, capsule, granules, and powder, liquid, or soft gel.<sup>1</sup> Nutritional supplements are used in the following disease treatment or their prevention, and they include;

**Anti-diabetic:** Nutritional supplements are used to manage diabetes by providing additional nutrients that support blood sugar regulation and improve insulin sensitivity.

**Anti-cancer:** Certain Nutraceuticals have been studied for their potential anticancer properties. They may possess antioxidant, immune-enhancing anti-inflammatory properties, and that help in the treatment and prevention of cancer.

**Chronic heart disease:** Nutritional supplements can play a supportive role in managing chronic heart disease by providing essential nutrients that support cardiovascular health. They may help regulate blood pressure, improve cholesterol levels, and reduce inflammation.

**Arthritis:** Some Nutraceuticals, such as glucosamine and chondroitin, are commonly used for managing symptoms of arthritis. These substances are believed to promote joint health, reduce inflammation, and alleviate pain associated with arthritis.

**Hypertension:** Certain nutritional supplements, including coenzyme Q10, omega-3 fatty acids, and potassium, have been studied for their potential blood pressure-lowering effects. They may be used as adjuncts to lifestyle modifications and conventional treatments for hypertension.

It is important to note that while Nutraceuticals can offer potential health benefits, their effectiveness and safety may vary. It is advisable to consult with healthcare professionals before starting any new dietary supplement regimen, especially for individuals with pre-existing medical conditions or those taking other medications.

## Advantages of Nutraceuticals

**Enhanced Health Benefits:** Nutraceuticals offer additional health benefits beyond basic nutrition. They are designed to provide specific nutrients, bioactive compounds, or herbal extracts that



DOI: 10.5530/jyp.2023.15.84

### Copyright Information :

Copyright Author (s) 2023 Distributed under Creative Commons CC-BY 4.0

Publishing Partner : EManuscript Tech. [www.emanuscript.in]

can support overall health, boost immunity, improve bodily functions, and address nutritional deficiencies.

**Preventive Approach to Healthcare:** Nutraceuticals promote a preventive approach to healthcare. They can be used proactively to support health and well-being, potentially reducing the risk of chronic diseases and improving overall quality of life.

**Natural and Plant-Based Ingredients:** Many Nutraceutical products derive their ingredients from natural sources such as plants, herbs, fruits, and vegetables. These products often contain bioactive compounds, antioxidants, and phytochemicals that may have beneficial effects on health. The use of natural ingredients appeals to individuals seeking alternative or complementary healthcare options.

**Convenience and Accessibility:** Nutraceuticals come in various forms such as capsules, tablets, powders, liquids, and functional foods or beverages. They are readily available and can be easily incorporated into daily routines without significant lifestyle changes.

**Personalized Nutrition:** Nutraceuticals offer the flexibility of personalized nutrition. With a wide range of products available, individuals can select supplements that target specific health concerns or nutritional requirements. This customization allows for tailored approaches based on factors such as age, gender, lifestyle, and specific health conditions.

## Disadvantages of Nutraceuticals

**Limited Regulation:** The Nutraceutical industry lacks stringent regulation compared to the pharmaceutical industry. This can result in inconsistencies in quality, safety, and efficacy among different products. Some Nutraceuticals may make unsubstantiated claims or contain adulterated or low-quality ingredients.

**Insufficient Scientific Evidence:** While certain Nutraceuticals have shown health benefits through scientific research, many products lack adequate clinical trials and long-term studies to support their claims. Limited scientific evidence makes it challenging for consumers to evaluate the effectiveness and safety of various Nutraceutical products.

**Potential Interactions and Side Effects:** Nutraceuticals, like any other bioactive substances, have the potential to interact with medications or other supplements. Consulting with a healthcare professional before starting a new Nutraceutical regimen is crucial to ensure compatibility and minimize the risk of adverse effects or interactions.

**Cost Considerations:** Nutraceuticals can be more expensive compared to regular dietary supplements or traditional food products. The higher cost may limit accessibility for individuals with lower incomes or in developing regions.

**Ethical Concerns:** Some Nutraceutical products raise ethical concerns due to misleading claims, exaggerated marketing tactics, or inadequate transparency regarding ingredients and manufacturing processes. Such practices can undermine consumer trust and pose ethical dilemmas.

**Bioavailability:** Due to issues in bioavailability, even before having any therapeutic effect, they are quickly evacuated from the human body.<sup>2</sup>

**Impact of the placebo effect:** Consumers may sometimes misinterpret the effectiveness of dietary supplements in treating illnesses, especially when the body has a natural ability to heal itself.

**Product quality concerns:** Nutraceuticals marketed internationally often make claims of using organic ingredients and natural chemicals. However, the safety and effectiveness of these products may be compromised due to a lack of regulation and oversight.

**Potential for Interactions:** Their impact on pre-existing medical conditions and potential interactions with prescribed medications is often not adequately communicated to consumers. This lack of information poses potential risks to individuals who rely on Nutraceuticals for their health.

When considering Nutraceuticals, it is important to approach them critically, seek reliable information, and make informed decisions based on individual needs and consultation with healthcare professionals. Nutraceuticals should be viewed as a complementary approach to a balanced diet and healthy lifestyle, rather than a substitute.

## HISTORY OF FOOD REGULATIONS IN INDIA

Regulations for Food products in India started in the early 20th century when the British colonial government introduced several laws and regulations aimed at control of food quality and ensuring safety. Here is a concise summary of the key milestones in emergence and evolution of regulations for Food Products in India:

“Prevention of Food Adulteration Act, 1954”: This act touted as the first comprehensive legislation in post-independence India that aimed to prevent food adulteration and establish standards for food quality. It also mandated the establishment of Central Food Laboratory and State Food Laboratories for testing purposes.

Food Safety and Standards Act, 2006: Replacing the Prevention of Food Adulteration Act, this act modernized India's food regulatory framework. It established the FSSAI as the central authority responsible for setting standards, regulating food safety, and overseeing enforcement across the country.

Food Safety and Standards (Amendment) Act, 2011: This amendment act brought significant changes to the FSS Act, 2006. It introduced stricter penalties for food adulteration and non-compliance, expanded the scope of FSSAI's authority, and enhanced its regulatory powers.

“Food Safety and Standards (Labelling and Display) Regulations, 2011”: These provided guidelines for labelling and display of “packaged food products”. They mandate the disclosure of information such as nutritional content, ingredients, allergens, and vegetarian/non-vegetarian symbols on food labels.

“Food Safety and Standards (Packaging and Labelling) Regulations, 2011”: These specify packaging requirements for food products, including use of food-grade materials, proper labelling, and guidelines for packaging design and printing.

“Food Safety and Standards (Contaminants, Toxins, and Residues) Regulations, 2011”: These guidelines establish maximum limits for contaminants, toxins, and residues in food products to ensure consumer safety. They cover substances such as heavy metals, pesticides, mycotoxins, and veterinary drug residues.

“Food Safety and Standards (Import) Regulations, 2017”: These guidelines govern the import of food products into India. They establish standards and procedures for inspection, sampling, and testing of imported food items to ensure compliance with Indian food safety standards.

These milestones represent key developments in the history of food regulations in India. Additional regulations, standards, and guidelines have been introduced over the years to address specific aspects of food safety, labelling, hygiene, and quality control. The FSSAI plays an important role in regulation of food industry and safeguarding the safety and quality of food consumed by the Indian population.

India, faces challenges in the growth of its food market, the reasons being inadequate infrastructure, logistical issues, and stringent food regulations. These barriers are particularly evident in the low level of processing of perishable agricultural products, which stands at only around 2% compared to 80% in the United States.

During the mid-1990s, India's food processing sector became entangled in a complex web of regulations, including various state laws and national legislation such as:

- “Export Act, 1963”
- “Solvent extracted oil control order, 1967”
- “The insecticide Act, 1968”
- “Meat food products order, 1973”
- “Prevention of food adulteration Act, 1954”
- “Bureau of Indian standards Act, 1986”
- “Environmental protection Act, 1986”
- “Milk and milk products order, 1986”
- “Pollution control Act, 1986”
- “Agriculture produce act”
- “Industrial license”
- “Vegetable oil product control order, 1998”

In 1998, the Prime Minister's council on trade and industry established a working group on food and agriculture industries, which recommended the establishment of a unified legislation under a single food regulatory authority. Experts and members of the Standing Committee of Parliament also advocated for the consolidation of existing food laws under a single regulatory body responsible for public health and food safety in India. This move aimed to streamline the regulatory landscape and eliminate multiple layers of control over food. Furthermore, there was a specific emphasis on addressing the Nutraceutical and functional food segment, which had great potential but lacked clear definitions and implications for consumer health. In 2002, a national nonprofit association was formed with the primary objectives of ensuring that every food manufacturing company provides scientific-based support for their products to protect consumers and promoting a regulatory environment that fosters the growth of the industry while safeguarding consumer interests.

The “Indian Food Safety Standard Bill” in 2005 eventually became into law, having an important impact on our nation's food processing business. This led to the enforcement of the “Indian Food Safety and Standards Act in 2006”, which aimed to achieve two main objectives: the implementation of a single comprehensive statute governing the food sector and the promotion of scientific advancements in the food processing industry.

## INDIAN NUTRACEUTICAL MARKET

The Nutraceutical market is currently dominated by the USA, Japan, and Europe, which collectively hold over 90% of the global market. However, as these markets get closer to maturing, industry participants are turning their attention to emerging markets, specifically those in the Asia Pacific area, among them India. The Indian Nutraceutical sector had only 2% of the worldwide market in 2017 and is expected to be worth \$5 billion by the year 2019. However, significant growth is anticipated in the coming years, with projections indicating that the Indian market will expand to \$11 billion by 2023, exhibiting a Compound Annual Growth Rate (CAGR) of 21%. By 2023, India is anticipated to hold a minimum of 3.5% of the worldwide market for Nutraceuticals. The Nutraceutical industry in India encompasses the entire ecosystem involved in the manufacturing, distribution, and consumption of Nutraceutical products within India. Nutraceuticals are products that combine the benefits of nutrition and pharmaceuticals, often

**Table 1: Top Nutraceutical companies in India.**

Company	Description
Himalaya Drug Company	A leading Indian company offering a wide range herbal and natural healthcare products.
Dabur India Ltd.,	Well-known consumer goods company with a diverse Nutraceutical portfolio based on ayurvedic principles.
Amway India Enterprises	Global direct-selling company with a wide range of health and wellness products, including Nutraceuticals.
Patanjali Ayurved Ltd.,	Renowned Indian brand specializing in ayurvedic products; including a range of Nutraceutical offerings.
Baidyanath Group	Trusted ayurvedic company manufacturing various Nutraceuticals and herbal supplements for over a century.
Sun Pharmaceuticals Industries	One of India's largest pharmaceutical companies offering Nutraceutical products adhering to high quality standards.

providing health benefits beyond basic nutrition. The Indian Nutraceutical market has been experiencing significant growth in recent years. Factors such as increasing health consciousness, rising disposable incomes, changing lifestyles, and a growing middle class have contributed to the market's expansion. Additionally, the COVID-19 pandemic has further accelerated the demand for Nutraceutical products as people have become more focused on boosting their immunity and overall well-being. The market includes various types of Nutraceutical products, including dietary supplements, functional foods, functional beverages, and herbal extracts. Dietary supplements, such as vitamins, minerals, and protein powders, are among the most popular products in the market. Functional foods and beverages are fortified with additional nutrients or bioactive ingredients to provide health benefits beyond basic nutrition. Herbal extracts, derived from traditional Indian medicinal plants, are also widely used in Nutraceutical products.

Several domestic and international companies operate in the Indian Nutraceutical market. Some prominent Indian companies include Himalaya Drug Company, Dabur India Ltd., Amway India Enterprises Pvt. Ltd., and Patanjali Ayurved Ltd., International players such as Abbott Laboratories, Nestlé, and Herbalife are also actively involved in the market. The top nutraceutical companies in India can be seen in Table 1. The Food Safety and Standards Authority of India (FSSAI) is responsible for regulating Nutraceuticals in India. Under its authority, the FSSAI establishes guidelines and regulations pertaining to the manufacturing, labeling, and marketing of Nutraceutical products. The primary objective of these regulations is to ensure the safety and quality of

Nutraceuticals available in the Indian market. Overall, the Indian Nutraceutical market presents significant opportunities for both domestic and international companies due to the growing consumer demand for health and wellness products. The market is expected to continue its growth trajectory in the coming years as more consumers prioritize preventive healthcare and seek natural and holistic approaches to well-being. Functional foods and drinks and dietary supplements make up the two main segments of the virtually two-billion-dollar Indian Nutraceutical industry.

**Functional Beverages and Foods:** 60% of the market share is made up by this segment. The World Health Organisation (WHO) defines fortified food as processed food that has had micronutrients added. Sports beverages that are fortified juices, fortified beverages, fortified foods and energizers are just a few examples of the many products that fall under the category of functional foods and beverages. The nutraceutical segments data in India is given in Table 2.

**Dietary Supplements:** The remaining 40% of the Indian Nutraceutical business is made up of dietary supplements. This category includes various types of supplements such as vitamins and minerals, herbal supplements, protein supplements, and even traditional products like CHAWANPRASH.

The two major manufacturers and consumers are the United States of America and Europe. Due to rising disposable incomes and thus greater living standards in these nations, demand is, however, expanding strongly in other emerging markets as well. According to a report by Variant Market Research, the global Nutraceuticals market is projected to reach a value of \$340 billion by 2024. From 2016 through 2024, this Corresponds to an Annualised Growth Rate (CAGR) of 7.2%. According to Grand View Research's Global Nutraceuticals Industry Report, the industry will grow at an 8.3% Annualised Growth Rate (CAGR) to reach \$722.49 billions of dollars by 2027.

### Critical problems faced by India's Nutraceutical market

Various existing laws pertaining to food and Nutraceutical hygiene and regulations have been integrated under the FSSAI. However, specific restrictions have not yet been put into place, and the government actively seeks for thoughts on how to establish them. Currently, the tax rate on Nutraceuticals and health supplements is 18%, with some categories being taxed at a rate of 28%. Compared to the prior tax rate of 12%, the additional levying has led to higher expenses for these goods.

Additionally, the absence of a streamlined system for establishing new plants for Nutraceutical product manufacturing poses challenges for new entrants in this field. The lack of regulations also hinders their eligibility for subsidies and incentives, further complicating their entry into this relatively uncharted territory.

**Table 2: Nutraceutical Market Segments in India.**

Segment	Description
Dietary supplements	Includes vitamin, minerals, herbal supplements, protein powders, and other Nutraceuticals designed to supplement the diet and provide additional nutrients.
Functional foods	Food products fortified with additional nutrients or bioactive ingredients to offer health benefits beyond basic nutrition. Examples include fortified cereals.
Functional beverages	Beverages formulated with added functional ingredients such as probiotics, antioxidants, and herbal benefits. Examples include fortified.
Herbal extracts	Extracts derived from traditional Indian medicinal plants used in various Nutraceutical products, including herbal supplements, oils, and tonics.

### Trends and demand changes

The market for Nutraceuticals has surpassed that for supplements, which was previously dominated by pharmaceuticals, with a significant 67% share. The growing consumer preference for Nutraceuticals can be attributed to the increased awareness and responsiveness of the public towards health-related issues. Recent estimates suggest that the southern and eastern regions of India have the highest concentrations of the Nutraceutical market, which is also slowly gaining appeal in rural areas. This pattern has been influenced by the rural population's increasing awareness about diseases arising from flawed lifestyle habits. The demand for Nutraceuticals is expected to experience substantial growth due to the rising emphasis on preventive healthcare and the increasing need for medical treatments. As a result, there is a growing demand for products that incorporate Nutraceutical ingredients. Manufacturers and marketers within the Nutraceutical industry are assuming the role of educating consumers by offering comprehensive information about their products, including their benefits and their contributions to promoting overall health and wellness. This approach aims to establish transparency and credibility among consumers, ultimately strengthening the Nutraceutical category as a segment of the market for health and wellness. Players in the industry are actively pursuing a variety of activities. To further enhance the Nutraceutical market. These include focusing on improving product quality standards, increasing transparency, and offering competitive pricing for innovative products. These efforts contribute to the overall development and growth of the Nutraceutical industry.

### OPPORTUNITIES

Due to an increase in bad eating habits, sedentary lives, low levels of physical exercise, the prevalence of lifestyle-related diseases has increased. This in turn, has led to a significant growth in the

Nutraceutical market. However, there are several other factors and opportunities that are poised to further boost the Nutraceutical market in the future. These include:

**Growing awareness about preventive healthcare:** There is an increasing awareness among individuals about the importance of preventive healthcare, given the rising prevalence of lifestyle-related diseases. Nutraceuticals, which offer health benefits and disease prevention through natural ingredients, are being recognized as a valuable tool for proactive health management. This heightened awareness contributes to the growth of the Nutraceutical market.

**Aging population and demand for healthy aging solutions:** The global population is experiencing rapid aging, resulting in a higher demand for solutions that promote healthy aging and address age-related health issues. Nutraceuticals catering to joint health, cognitive function, cardiovascular health, and overall vitality are likely to witness significant growth as the aging population seeks natural and safe alternatives to maintain their health.

**Consumer preference for natural and organic products:** Consumers are increasingly inclined towards natural and organic products across various sectors, including healthcare. Nutraceuticals produced from natural resources, like herbs, botanicals, and plant extracts, are perceived as safer and more desirable than their synthetic counterparts. This consumer preference for natural and organic products will act as a driving force for the growth of the Nutraceutical market.

**Technological advancements in product development:** Ongoing advancements in technology, such as encapsulation techniques, Nano emulsion, and novel delivery systems, are revolutionizing the Nutraceutical industry. These technological innovations enhance the stability, bioavailability, and targeted delivery of Nutraceutical ingredients, making them more effective and appealing to consumers. The integration of technology in product development fuels expansion in Nutraceutical market.

**Personalized nutrition and customization:** The concept of personalized nutrition is gaining momentum as individuals recognize that their nutritional needs vary based on factors like age, genetics, and lifestyle. Nutraceuticals offer the potential for customization, allowing individuals to address their specific health concerns and optimize their well-being. The ability to tailor Nutraceutical products to individual needs will drive their demand and further market growth.

**E-commerce and direct-to-consumer channels:** The rise of e-commerce platforms and direct-to-consumer channels has significantly facilitated access to a wide range of Nutraceutical products. Consumers can now conveniently purchase Nutraceuticals online, bypassing traditional retail channels. This enhanced accessibility, coupled with the convenience of home

delivery, has expanded the consumer base and contributed to the expansion of the Nutraceutical industry.

**Government support and regulations:** Governments worldwide are increasingly acknowledging the prospective advantages of dietary supplements in promoting public health and wellness. Consequently, there is a growing emphasis on implementing regulations and policies to guarantee the security, effectiveness, and standard of Nutraceutical items. Such support from regulatory authorities instills consumer confidence and fosters market growth.

**Integration of Nutraceuticals in conventional healthcare:** Nutraceuticals are progressively being integrated into mainstream healthcare as complementary or alternative therapies. Physicians and healthcare professionals are recognizing the potential benefits of Nutraceuticals in preventing and managing certain health conditions. This integration provides additional avenues for the growth of the Nutraceutical market.

### Registration process of Nutraceuticals in India

In India the registration of Nutraceutical is required for the marketing of the product in Indian market. The FSS act (2006) gives the procedure for the registration of the Nutraceutical products, but there is no standard format is available for the purpose.<sup>3</sup> The Nutraceutical companies in India struggles a lot for the approval of the product due to the lack of the proper roadmap for the registration of the products.<sup>4</sup>

The Food Safety and Standard Rules, 2011 were released in May 2011 by the Food Safety and Standards Authority of India (FSSAI). These regulations include thorough guidelines for numerous facets of the food industry, such as standards for food additives and products, packaging and labelling practises, and licencing and registration of food firms and goods. On August 5, 2011, these regulations were put into effect throughout the nation. This implementation created a single legal framework with competent authorities in charge of regulating the nation's production, distribution, and sale of food items. According to FSS regulations, 2011.

a) To market food items in India, it is necessary to register a manufacturing facility and receive a manufacturing licence (Form A/B; obtained from the state licencing authority, except for those listed under Schedule I).

b) Any food or food product import into the nation requires an import permit, which must be secured from the Central Licencing Authority. The following are the documents required for registration approval:<sup>5</sup>

#### Application form A for registration

Self-attested declaration form license for manufacturing/ import license.

Application form B of schedule 2 and license obtained in form C. Self-attested declaration form.

#### Copies of the following documents

There is a chance that some of the content is contradicting or confusing as India's Nutraceutical regulation develops with the recent introduction of FSSA, but this needs to be streamlined for the Indian sector to take shape.<sup>6-11</sup> Documents need to be submitted with new licence or import licence applications to the State or Central Licensing Authority.

- Form A.
- Form B.
- Blueprint/layout plan of the processing unit.
- List of directors.
- Name and list machineries to be used in the process.
- Photo id and address proof.
- List of food category desired to be manufactured.
- Authority letter with name and address of responsible person analysis report.
- Proof of possession of premises.
- Partnership deed/affidavit/memorandum and articles.
- NOC from manufacturer.
- Food safety management system plan or certificate.
- Source materials.
- Pesticide residues report of water.
- Recall plan.
- NOCs.

Despite the implementation of various regulations and standards in the food industry, there remains a lack of clarity regarding the registration process for Nutraceuticals and their additives. Therefore, business owners intending to market Nutraceutical products in the country are facing several obstacles and challenges, according to the current definition of drugs, regulatory authorities are categorizing Nutraceutical products, particularly those available in tablet form or as liquid orals containing vitamins and minerals, under the drug category. Any product contained in a gelatin capsule is viewed as a drug since the empty gelatin capsule is thought to meet the definition of a drug. The list of permitted food additives does not include all of the additives and colourants used in the production of Nutraceutical goods. The registration process for Nutraceuticals in India involves complying with the regulations set by the Food Safety and Standards Authority of India (FSSAI). Here is a general outline of the registration process:

**Determine the category:** Identify the specific category of the Nutraceutical product based on its formulation and intended use. Nutraceuticals can fall under various categories such as dietary supplements, functional foods, functional beverages, or herbal extracts.

**Formulate the product:** Develop the formulation of the Nutraceutical product, ensuring it meets the necessary safety and quality standards. This may involve sourcing appropriate ingredients, conducting research and development, and ensuring compliance with applicable regulations and guidelines.

**Obtain manufacturing license:** If you plan to manufacture the Nutraceutical product, obtain a manufacturing license from the State Licensing Authority or Central Licensing Authority, depending on the scale of production. The license ensures compliance with Good Manufacturing Practices (GMP) and other manufacturing standards.

**Conduct safety and efficacy assessment:** Before seeking registration, conduct appropriate safety and efficacy assessments of the Nutraceutical product. This may involve conducting toxicological studies, clinical trials, or gathering scientific evidence to support the product's claims.

**Submit the application:** Prepare the registration application in accordance with the requirements specified by the FSSAI. The application should include details such as product composition, manufacturing process, labeling information, scientific data, and safety assessments.

**Submit the product samples:** Along with the application, provide representative samples of the Nutraceutical product to the designated laboratory for testing. The samples will undergo analysis to ensure compliance with quality and safety standards.

**Review and approval:** The FSSAI will review the application and supporting documents, including the test reports. If the application meets all the requirements, the FSSAI will grant registration for the Nutraceutical product. The registration may include specific conditions, labelling requirements, or limitations, depending on the product category.

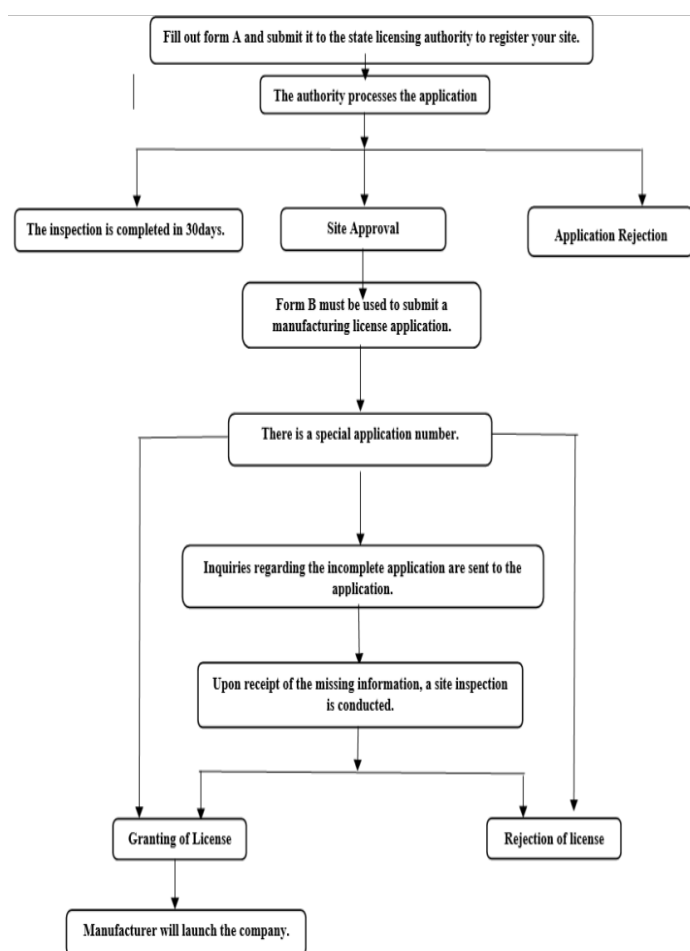
**Compliance with labelling regulations:** Once the registration is obtained, ensure that the Nutraceutical product complies with the labelling regulations specified by the FSSAI. This includes providing accurate and comprehensive information on the product label, such as ingredients, nutritional content, allergens, and any specific claims or warnings.

It is important to note that the registration process and requirements may vary depending on the specific category of the Nutraceutical product. It is advisable to consult the FSSAI website and seek professional guidance to ensure compliance with the latest regulations and guidelines during the registration process. The process is shown in Figure 1.

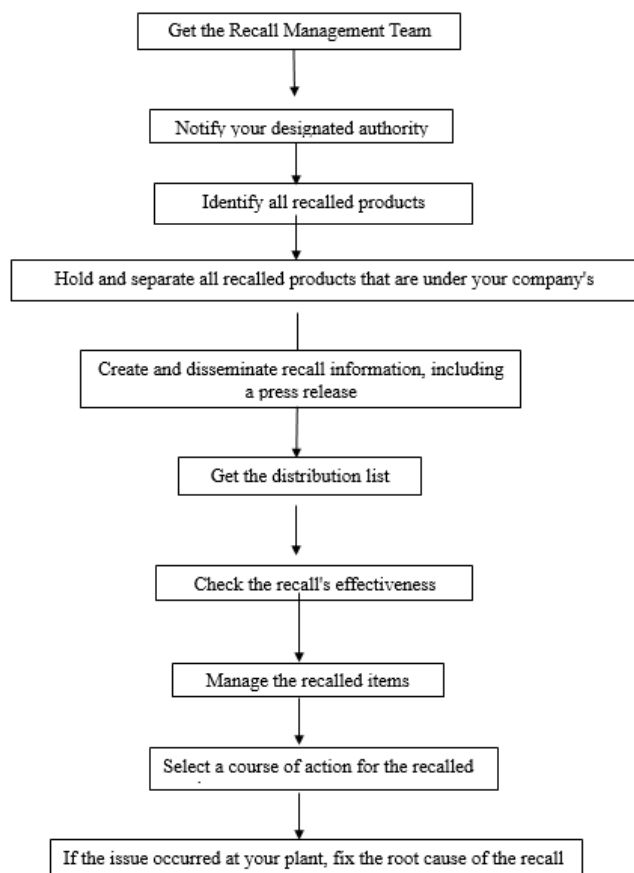
## Food Recall

Food available for human consumption should meet the standards of being wholesome, free from adulteration and contamination, suitably labelled and safe for consumption by people. Regulations under the Act, or rules and regulations adopted thereunder, may be taken against the relevant FBO for violating the laws in this regard. Food recalls serve as an efficient approach to eliminate or rectify non-compliant food products from the market under the supervision of regulatory authorities. They involve the proactive removal of food items from all stages of the food supply chain, including those already in consumers' possession, in cases where there is a potential risk to public health or when they don't adhere to the conditions established in the relevant laws, rules, or regulations. A food recall is generally thought to be in the best interests of the industry, the government, and, most importantly, the consumers. Its main goal is to ensure consumer safety.

Recalls offer a more efficient and prompt means of safeguarding consumers, especially in cases where a widely distributed product is involved, compared to formal administrative or civil actions. This mechanism ensures that necessary actions are taken swiftly to address potential risks or non-compliance, thereby providing enhanced protection for consumers. Manufacturers



**Figure 1:** Registration Process for nutraceuticals in India.



**Figure 2:** Food Recall plan.

and distributors bear the responsibility of proactively initiating a recall whenever necessary to fulfil their obligation of ensuring public health and safety. This obligation applies to products that may pose risks such as injury, deception, or any other form of defect.

The initiation of a food recall is an essential step in ensuring consumer protection and maintaining the integrity of the food supply chain. It demonstrates the commitment of food manufacturers, distributors, and regulatory authorities to promptly address and rectify any potential issues that could compromise public health and safety. The initiation of a food recall process involves several key steps and stakeholders. Here is a general outline of the process:

**Identification of the Issue:** The first step is to identify a problem or issue with a food product that poses a potential risk to public health or violates food safety regulations. This can be done through various means, including consumer complaints, routine inspections, laboratory testing, or notifications from regulatory authorities.

**Investigation and Evaluation:** Once the issue is identified, a thorough investigation is conducted to assess the nature and extent of the problem. This may involve gathering information,

examining product samples, conducting laboratory tests, and evaluating the potential risks associated with the product.

**Notification and Communication:** The responsible party, which can be the manufacturer, distributor, or retailer, should promptly notify the relevant regulatory authority about the issue. They should also establish effective communication channels to inform consumers, retailers, and other stakeholders about the recall and the associated risks. Clear and concise messaging is crucial to ensure that the recall information reaches the intended recipients.

**Product Retrieval:** The next step is to retrieve the affected product from the market, including distribution centers, retailers, and potentially consumers' possession. The responsible party should develop a plan for the efficient and comprehensive retrieval of the recalled product. This may involve working closely with distributors, retailers, and other supply chain partners to facilitate the removal of the product from the market.

**Disposal or Corrective Action:** Once the recalled products are retrieved, proper disposal methods are implemented to ensure they are safely and securely disposed of to prevent any further risk to public health. In some cases, corrective actions may be taken, such as reworking or reprocessing the product to address the identified issues.

**Evaluation and Review:** After the recall process is completed, a thorough evaluation and review of the entire process should be conducted. This includes assessing the effectiveness of the recall, identifying any areas for improvement, and implementing corrective measures to prevent similar issues in the future.

It is important to note that the specific procedures and requirements for initiating a food recall may vary by jurisdiction and the nature of the issue. The responsible party should closely follow the guidelines and regulations provided by the relevant regulatory authority to ensure compliance and effective recall management. Additionally, businesses may decide to start a recall of goods in response to alerts from the Food and Drug Administration or a state agency, in compliance with official requests from the authority, or as directed by the regulatory organisation. The process is shown in Figure 2.

## CONCLUSION

In conclusion, the nutraceuticals market in India has witnessed substantial growth in recent years, propelled by various factors including a growing awareness of health, higher disposable incomes, and evolving lifestyles. The nutraceuticals market in India comprises diverse segments such as dietary supplements, functional foods, functional beverages, and herbal extracts. The nutraceutical business in India is governed by the Food Safety and Standards Authority of India (FSSAI). It is in charge of setting standards, maintaining food safety, and managing the application of laws in this industry. The rules guarantee the nutraceutical products' safety, quality, and labelling requirements.



