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Review Article

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Nutraceutical Regulations in India: A comprehensive Review

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Abstract

The term "nutraceutical" was coined from "nutrition" and "pharmaceutical" in 1989. A nutraceutical is any substance considered as a food or its part which, in addition to its normal nutritional value provides health benefits including the prevention of disease or promotion of health. Due to the adverse effects of drugs, consumers are preferring food supplements to improve health. Nutraceutical demand will grow with increasing risk of diseases is expected to boost product demand over the forecast period. High cost associated with healthcare treatments has resulted in rising consumer interest in nutraceuticals. The Food Safety and Standards Authority of India (FSSAI) has been established, which consolidates various acts and orders that were in existence to handle food related issues in various Ministries and Departments. FSSAI has been created for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. The regulatory framework of nutraceuticals in India needs attention from the relevant authorities. Globally, the regulatory authorities are aware of changing needs of consumers and proactively protect consumers by amending existing laws to accommodate changes but in India old laws such as Prevention of Food adulteration Act, 1954, which regulates packaged foods, still exist for manufacturers.

Keywords: Nutraceutical, FSSAI, Nutrition and Pharmaceutical, Regulations, Acts and Laws, FSSA (Food Safety and Standards Act)

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1. Introduction

Nutraceuticals are bioactive compounds and elements of herbs and minerals, as well as dietary supplements with medicinal properties. In addition to the fundamental nutritional content contained in foods, they are delivered as dose formulations and have developed as a key component of the diet for the average consumer. Vitamins, minerals, fatty acids, pre- and probiotics, herbal supplements, and other nutritional supplements are increasingly extensively used for preventive and therapeutic purposes across the world, making it critical to maintain safety and quality standards. The rapidly growing worldwide nutraceutical business has emphasized the importance of developing such regulatory norms. Despite the fact that rules in the United States, the United Kingdom, and Europe have been simplified and made more favourable to the production of nutraceutical goods, the Indian industry and consumers remain concerned and regulatory situation are still in their early stages, but they have the ability to compete with other international organizations. This is a fast-developing business in India, and numerous initiatives have been launched to position India as a prominent participant in the field of Nutraceuticals in the next years. (1)

Stephen DE Felice, MD, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ, developed the phrase “nutraceutical” from the word’s “nutrition” and “pharmaceutical” in 1989. Nutraceutical, according to DE Felice, is “a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease.”

A nutraceutical is any item or portion of a food that, in addition to its typical nutritional value, provides health advantages such as illness prevention or health promotion. Because of the negative side effects of medications, customers are turning to dietary supplements to improve their health. This sparked a worldwide revolution in the field of Nutraceuticals.

In addition to the fundamental nutritional content present in meals, Nutraceuticals give additional health advantages. Depending on the jurisdiction, items may promise to prevent illnesses, promote health, slow the ageing process, extend life, or support the body's structure or function.

Nutraceutical is a wide word for any product generated from food sources that provides additional health advantages in addition to the nutritional content present in meals. Carbohydrates, fats, proteins, vitamins, minerals, and other nutrients are all included in these goods. Dietary supplements are the most popular form of nutraceutical product. (2)

1.1 Nutraceutical Concept

It is a prerequisite in the pharmaceutical development process to obtain clinical test findings from animal experiments and studies for verification of the effects. In the case of nutrition, on the other hand, there was no verification technique for foods in avoiding illnesses in the past. (3)

1.2 Global Market Overview

The study on Global Market Growth & Demand suggests that worldwide nutraceutical industry has been developed at a compound annual growth rate (CAGR) of 7.5% to $285.0 billion from 2016 to 2021. The functional beverages market is reached $105.5 billion by 2021, up from $71.5 billion in 2016, at an 8.1% CAGR from 2016 to 2021. The functional food industry is reached $92.3 billion by 2021, up from $64.6 billion in 2016, at a 7.4% CAGR from 2016 to 2021. By 2025, the globe will have 1 billion people aged 60 and up. While the industry expanded at 7% per year between 1999 and 2002, the next several years up to 2010 experienced double that growth at 14% per annum. Currently, roughly $12-15 billion is contributed each year. Nutraceutical demand is predicted to rise as the prevalence of disorders such as high blood pressure, obesity, diabetes, and cholesterol rises throughout the forecast period. The high expense of healthcare services has led in increased public interest in nutraceuticals in recent years. (4)

1.3 The Indian market and health

The worldwide nutraceutical industry was projected to reach $117 billion in 2008, with India accounting for just 0.9% of that figure. The global market is expected to reach $177 billion by next year, with a 7% compound annual growth rate (CAGR). With increased penetration of preventative health care products in the Indian market, rising health awareness, more disposable income, and other reasons, the Indian nutraceutical business has grown at an 18% CAGR over the previous three years. According to one research, the overall Indian nutraceutical industry is anticipated to reach around $5 billion in 2015. As indicated in the image below fast-moving consumer goods and pharmaceutical businesses are important players in the Indian nutraceutical sector. (5)

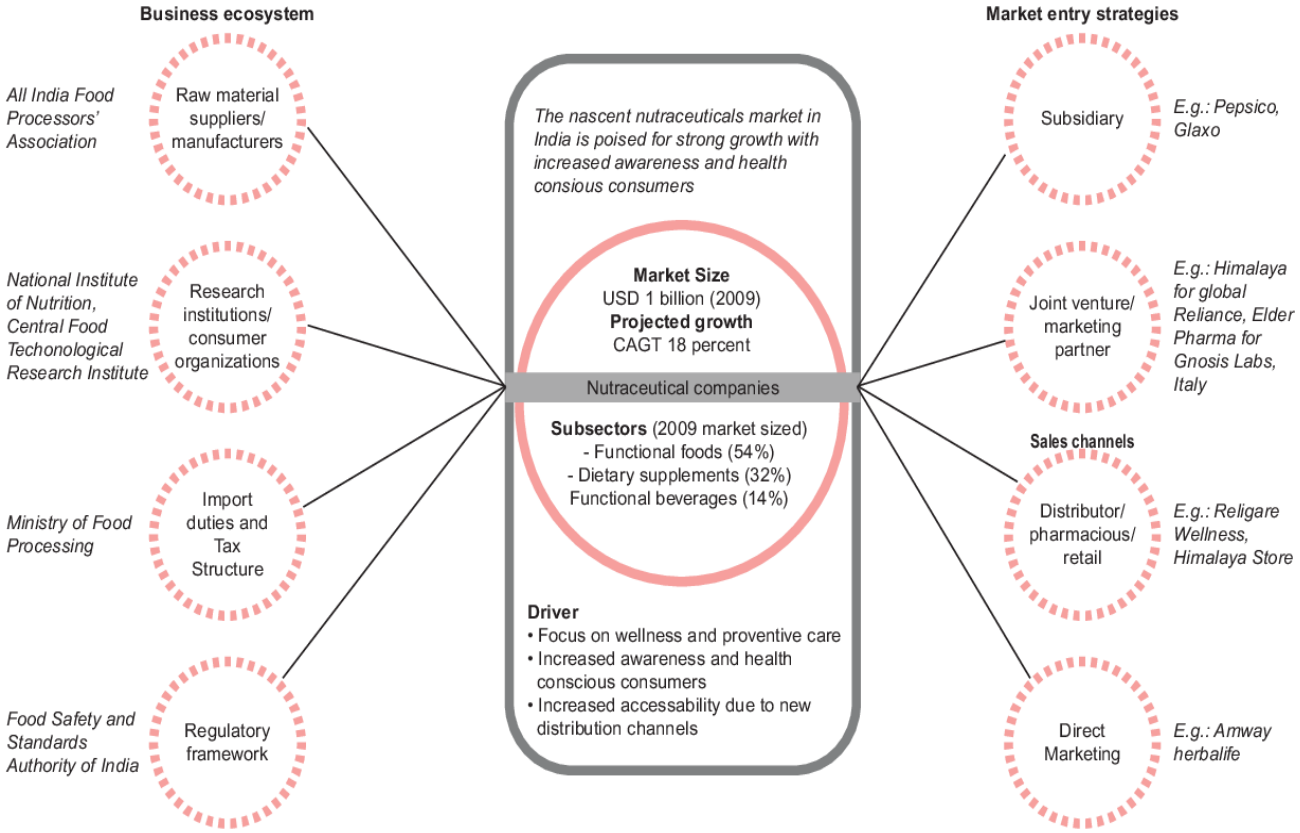

Figure 1. Global Market Size of Nutraceutical Companies (6)

2. FSSA (Food Safety and Standards Act): 2006

This act was enacted in 2006 to establish the statutory body FSSA, which controls the manufacturing, storage, distribution, sale, and import of food and food products in order to ensure the availability of food and food products inside the country.

The FSS act of 2006, rules and regulations of 2011, classify Nutraceuticals as foods. According to Section 22(1) of the FSSA, "foods for special dietary uses or functional foods or Nutraceutical or health supplements" are defined as:

a) Foods that are specially processed or formulated to meet specific dietary requirements that exist as a result of a specific physical or physiological condition or specific diseases and disorders and are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist, and may contain one or more of the following ingredients:

- Plants or botanicals or their parts in the form of powder, concentrate, or extract in water, ethyl alcohol, or hydro alcoholic extract, single or in combination;
- Minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);
- Substances of animal origin;

b) A product labelled as a "Food for special dietary uses or functional foods or Nutraceuticals or health supplements or similar such foods" that is not intended for use as a conventional food and may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly, and other dosage forms but not parenteral, and is intended for oral administration;

- Such product does not include a drug as defined in clause (b) and Ayurvedic, Siddha, and Unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder; does not claim to cure or mitigate any specific disease, disorder, or condition (except for certain health benefit or such promotion claims as may be permitted by FSSA regulations;

3. Nutraceutical regulatory authority in India: FSSAI

In 2006, parliament approved the Food Safety and Security Act. The FSSAI was established in 2008. In order to execute the FSSAI Act, a prepublication consultation procedure was initiated in 2006, during which several rules and regulations were written. As a result, these draught regulations will be forwarded for notification by the end of September 2010.

- As outlined in the FSSA Act of 2006, several laws and regulations pertaining to Nutraceuticals have been established.
- Food acquired from organic production processing and their standards, taking into account proprietary and innovative foods that are not safe but are also not listed in the act. Food components made of or comprising obtained via contemporary biotechnology the food obtained similar, genetically modified or altered organisms which may also include the same has also been included in the act.
- This FSSAI act has twenty-one chapters, and the fourth article, or 22 of the acts, talks about Nutraceuticals, dietary supplements, and various functional foods, and these products can be produced/manufactured, marketed (sold), or distributed (imported) by any company. Nutraceuticals, nutritional supplements, functional food, organic food, unprocessed food, canned food, innovative foods, and irradiated foods are examples of such items.
- Articles 23 and 24 cover the packaging and labelling of Nutraceuticals, as well as their claims and limits on Nutraceutical advertising.
- These Nutraceuticals are permissible under the Act's rules since they do not promise to treat or alleviate any specific illness, problem, or condition.
- The chemicals mentioned in schedules E and E1 of the D&C Rules, 1945; it does not contain a narcotic drug or a psychotropic substance as defined in the schedule of the Narcotic Drugs and Psychotropic chemicals Act, 1985.
- The FSSAI Authority would also be tasked with the amusing duty of establishing laws of varied minimal degrees of food conformity.
- The rules and regulations developed under the new system by each state's food safety commissioner will be difficult to regulate both claims and quality, and their force function should be hastened.
- Food Ingredients made of or comprising of or including obtained via contemporary biotechnology the food obtained such as, genetically modified or altered organisms which may also include the same has been included in the act.
- "Food for special dietary uses" These labels are intended for functional food or Nutraceuticals dietary supplements that are not primarily for acquiring as traditional food. Such items may be manufactured in the following form: Powders, Granules, Tablets, Capsules, Liquids, Jelly and other dosage forms, but not parenteral.
- With the aid of developed guidelines, there may be provisions for various tests and tracking the origin of food goods all the way back to farm level.

FSSAI is also involved in:

- Manufacturing Process Standardization, Validation, and Intellectual Property Protection
- It defines the different allowed health claims and the amount of such components necessary to make the claims.
- Resulting in the establishment of a Regulatory Framework and its standards.
- Active participation of government and private sector organizations in educating consumers about the benefits of Nutraceuticals.
- The sector is waiting for improved RDA values that are appropriate for the present lifestyle of the Indian populace.

- Recognize a list of dietary elements that have been shown to have health advantages.
- Improved coordination between Indian manufacturers on R&D. (7)

Increased demand for Nutraceuticals products in India demonstrates their potential success rate in illness prevention and treatment. As a result, regulatory authorities on product quality and safety are required to reduce adverse events, toxicity, adulteration, abuse, and overdose during human consumption. As food goods travel from one nation to another, it is critical to maintain safety and quality standards in accordance with the numerous regulatory rules established by the separate governments. To preserve the quality and safety issues of Nutraceuticals, all new and current firms should follow the FSSAI regulatory advice for better use. (7)

4. Regulatory Aspects reared to Nutraceutical in India

Nutraceuticals are classified as "Foods for Special Dietary Uses" in India. "Foods for special dietary uses or functional foods or Nutraceuticals or health supplements," according to the Food Safety and Standards Authority (FSSA). The Food Safety and Standards Authority of India (FSSAI) was founded in India under the Food Safety and Standards Act, 2006, which consolidates different statutes and regulations that were previously in place to address food-related matters in various Ministries and Departments. FSSAI was established to establish science-based standards for food items and to regulate their manufacturing, storage, distribution, sale, and import in order to assure the availability of safe and healthy food for human consumption. As a result, it also applies to items such as dietary supplements and Nutraceuticals. Various central Acts like

- Prevention of Food Adulteration Act, 1954,
- Fruit Products Order, 1955,
- Meat Food Products Order, 1973,
- Vegetable Oil Products (Control) Order, 1947,
- Edible Oils Packaging (Regulation) Order 1988,
- Solvent Extracted Oil, De- Oiled Meal and Edible Flour (Control) Order, 1967,
- Milk and Milk Products Order, 1992 etc., have been repealed after commencement of FSS Act, 2006.

Health Claims: A "health claim" is a link between a food or a component of that food and health. Health claims are further classified as follows:

a. Nutrient content assertion

b. Disease claim reduction

c. Claim of Structure/Function

a) Nutritional Claims: A nutritional claim implies that a meal has positive nutritional features, such as "low fat," "no added sugar," or "high in fibre." A claim is a statement that implies a link between diet and health. A food, for example, can "help lower cholesterol," "reinforce the body's natural defences," or "improve learning ability."

b) Illness Reduction Claim: Any claim that asserts or suggests that taking dietary supplements or one of their ingredients significantly reduces the risk factor in the development of human illness.

c) Structure/Function Claim: A structure claim is a statement on the label of a food or dietary supplement that describes how that product affects the structure of the human body.

5. India's Regulatory Requirements

a) Product Evaluation:

Analyse each active component and additive. Among the several phases in product evaluation are:

- Creating document extracts
- Collecting samples (in the presence of witnesses)
- Sample delivery to the appropriate authorities (various processes for bulk and single packages)
- Food analysis
- Adjudication proceedings (holding enquiry, appeal procedure, hearing, etc.)
- Adjudication proceedings (holding enquiry, appeal procedure, hearing, etc.)

b) Licenses:

To get a product registered in India, a number of licenses (almost 4 - 5) may be required, which include:

- Import licensing
- Manufacturing licensing
- Marketing licensing and
- Other state and national level regulatory clearances/licenses required before launching these products in India.

c) Health and label claims:

"Health claims" are any representations that assert, indicate, or imply that there is a link between a product or a constituent of that food and health. This includes:

- India-specific labelling and packaging regulations;
- packaging of the consignment composition and marketing approach;
- need for sample goods and declaration for registration; and
- label text and claim.
- Claim about structure and function. (8)

The regulatory framework for Nutraceuticals in India requires attention from the appropriate authorities. Globally, regulatory agencies are aware of evolving consumer requirements and actively safeguard consumers by modifying current rules to meet developments; but, in India, outdated legislation such as the Prevention of Food Adulteration Act, 1954, which controls packaged goods, remain in force for producers. They must also comply with a slew of additional onerous laws, such as: Standards of Weights and Measures Act,

1976, and the Standards of Weights and Measures (Packaged Commodities) Rules, 1977 (SWMA) Infant Milk Substitutes, Feeding bottles and infant foods (regulation of production, Supply and Distribution) Act, 1992 with Rules, 1993 (IMS) Edible Oils Packaging (Regulations) Order,1998 Fruit Products Order 1955 (FPO) Meat product Order 1973 Milk and Milk Products Order 1992 Vegetable Oils Products (Regulation) Order 1998 (VOP) Atomic Energy Act, 1962 and Atomic Energy (Control or irradiation of Food) Rules 1996 Consumer Protection Act 1986 and the Consumer Protection (Amendment) Act, 2002 and Rules 1987 Environment Protection Act, 1986 and Rules 1986 Agricultural Produce (Grading and Marking) Act, 1937 (as amended up to 1986) and 49 General Grading and Marking Rules 1986 and 1988 (AG Mark) Bureau of Indian Standards (BIS) Act 1986. (9)

6. Registration Process in India

- Before starting a business, the manufacturer must be registered or been licensed in a valid manner
- The inspection of premises has been done after the issue of ID number in the way which is ordered by the act of FSSAI by the safety officer.
- Under the regulations, the license which is granted shall be valid, unless it is not specified, for the period of 15 years.
- Manufacturers have to register with the state office commissioner and those manufacturers whose turnover is greater than 12 lakhs to have to validly get a license from FSSAI office. The same shall goes to the petty food 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.

7. FSSAI Licensing System

Food makers must be registered or licensed by local authorities, and temporary license holders must register their firm with the local municipality. There are three categories of licensing: basic FSSAI registration, state FSSAI license, and central FSSAI license. The license is valid for 1-5 years, depending on the option of the food facility owner, and is valid for 30 days from the date of expiry.

7.1 Documents required for registration of Nutraceuticals (10-12)

Table 1. Various Registration process for Nutraceuticals in India

BASIC FSSAI REGISTRATION	STATE FSSAI REGISTRATION	CENTRAL FSSAI REGISTRATION
Application in Form A issued by the proprietor	Form B (in duplicate) completed and signed	Form B (in duplicate) completed and signed
Photo identity of FBO (Food business operator)	Blueprint/ layout plan of the manufacturing unit	Names of the equipment and machinery with the numbers
Rental agreement of premises	Contact details and full address of the premises	Address and identity proof issued by the government authority
Certificate of incorporation/ partnership deed	Names of the equipment and machinery name with the numbers	List of directors/ partners/ proprietors
List of food products	Address and identity proof issued by the government authority	List of food categories to be manufactured
Food safety management system plan	List of food categories to be manufactured	In case the unit is export-oriented, a certificate from the Ministry of Commerce in this regard
The Authority letter with the name and address of the proprietor	Authority letter which includes the name and address	Proof of premises possession
Supporting documents such as NOC (No objection certificate) by the municipality	The Analysis report issued by a recognized public health laboratory	Source of raw materials used
The power consumption of the equipment used	Proof of premises possession	IE code document issued by FSSAI
NOC certificate	Source of raw materials used	NOC certificate
Identity proof documents such as PAN card, passport, Aadhaar card	Certificate of food safety management	Authority letter which includes the name and address
Proof of premises possession	NOC certificate	Self-declaration of the number of vehicles used

7.2 Process for Registration of License

The basic FSSAI registration is necessary for all small-scale food enterprises with an annual income of less than '12 lakhs, cottage industries, and temporary stakeholders. Following approval, the FSSAI emblem and license number can be shown on the product label; this mark is not a certification, but rather a legal license for food company operators under the Food Safety and Standards Act of 2006. The FSSAI license is valid for one to five years and must be renewed 30 days before it

expires. If the renewal is filed after the expiry date, the applicant must pay a penalty of '100 for each day of delay.

License Registration Steps:

- File the application to the licensing authority
- The supporting documents are uploaded along with the application
- Application received by the licensing authority and the submitted documents will be verified
- Inspection is done by the licensing authority
- If rejected, the applicant should send the application again with relevant documents to the licensing authority
- Approval of the application
- Filing of the application to the licensing authority
- Issuing of unique application number
- For complete application, the queries are forwarded
- Inspection is done after receiving the missing information
- If yes, then the license is granted and the manufacturers shall start the business.
- If no, the license is rejected.

7.3 Benefits of FSSAI license

Aids in company expansion; ensures food safety in storage, distribution, sale, and import, among other things; FSSAI logo, which enhances consumer goodwill; and creates customer awareness. (13)

8. Labelling and Claims in Nutraceuticals

Most products still do not need labelling, as well as stringent regulation over formulas and branding. Health claims on Nutraceuticals serve to inform customers that, when combined with a good diet, they may lessen the risk of certain diseases. As part of the 1990 Nutrition Labelling and Education Act (NLEA), the FDA first authorized seven health claims in 1993. Six further claims have been approved by the FDA since 1993. To help consumers get this information faster, the Food and Drug Administration Modernization Act of 1997 contained a provision to expedite the process of establishing the scientific foundation for health claims.

Despite the fact that food producers may make health claims to advertise their products, leads to benefit customers by offering information on healthy eating habits that may help lower the risk of heart disease, cancer, osteoporosis, high blood pressure, dental cavities, or certain birth abnormalities. Structure /function statements, which may also appear on standard food or dietary supplement labels, are not the same as health claims. Structure/function claims, unlike health claims, do not address illness risk reduction. Furthermore, the FDA neither pre-approves nor authorizes structure / function claims. When a manufacturer makes a structure/function claim, the firm is responsible for ensuring that the claim is accurate and not misleading.

Many academic, scientific, and regulatory organizations are examining how to establish the scientific foundation for claims (other than health claims) for nutraceutical functional components. The following are the five categories of health-related statements that can be found on food and dietary supplement labels:

- Nutrient-content claims show the existence of a certain nutrient at a given level.
- Structure and function claims explain the impact of dietary components on the body's normal structure or function.
- Dietary-guidance claims address the health advantages of certain food groups.
- Qualified health claims reflect a growing link between dietary components and illness risk, as recognized by the FDA and substantiated by a substantial body of reliable scientific data.
- Health claims demonstrate a link between dietary components and the risk of illness or health condition, as approved by the FDA and backed by considerable scientific consensus. (14)

9. Conclusion

To enhance the regulatory framework and promote the growth of the functional food/nutraceutical industry in India, these recommendations are aimed at fostering collaboration, standardizing processes, expanding standards, amending laws, and focusing on research and development.

- Encouraging Indian producers to unite and form a platform to market India as a brand in the nutraceutical industry can enhance visibility and competitiveness in the global market.
- Increased collaboration in manufacturing and research and development can lead to synergies, shared resources, and accelerated progress in the industry.
- Standardization in manufacturing, validation, research and development, and intellectual property protection is crucial to ensure consistent quality and safety of nutraceutical products.
- Coordinated efforts among policy makers, regulators and manufacturers are essential for developing and implementing effective standards.
- Expanding Indian standards, like the Indian Pharmacopoeia, to include regulations for Nutraceuticals ensures that manufacturing complies with safety and quality standards set by the nation.
- Compliance with recognized standards enhances consumer trust and facilitates international trade.
- Updating laws related to nutrition labelling, similar to the U.S. Nutrition Labelling Education Act 1990, can help educate consumers about the safe and healthy aspects of Nutraceuticals.

- Transparent and informative labelling is essential for informed consumer choices.
- Joint efforts between the government and private agencies, along with support from food scientists, can drive suitable legislation that supports the growth of the Nutraceutical industry.
- Clear and supportive legislation encourages innovation, investment, and adherence to quality and safety standards.
- Initiatives such as new retailing programs, increased validation and clinical research, heightened awareness through media and government focus, and greater corporate responsibility through health awareness programs can significantly contribute to industry growth.
- Investing in research, educating the public, and promoting responsible practices are essential for building a sustainable and trusted industry.

It can be concluded that FSSA was a significant milestone as it consolidated these diverse regulations into a single statute. It aimed to bring systematic and scientific development to the food processing industry in India by categorizing food products into different heads, including novel foods, genetically modified food, proprietary food, standardized food, foods for special dietary use, and Nutraceuticals. Passing of the Food Safety and Standards Act 2006 marked a crucial initial step towards streamlining and modernizing food safety and standards regulation in India. Prior to the FSSA, there existed a complex web of various laws and regulations governing food safety and standards, leading to confusion and inefficiencies.

The subsequent introduction of the Food Safety and Standards Regulations in 2011 was a pivotal moment, as it provided detailed guidelines and rules for the manufacture, distribution, and sale of Nutraceuticals in India. These regulations were designed to ensure the safety and quality of these products, thereby safeguarding the health and interests of consumers.

While these steps were significant, it's important to acknowledge that there is still work to be done. Efforts should continue to eliminate any remaining overlaps with older laws and regulations, enhance regulatory clarity, and promote compliance within the food industry. This ongoing process will contribute to the growth and maturation of the functional food and nutraceutical sector in India, aligning it with international standards and facilitating its development as a thriving and innovative industry.

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