



**IJPPR**

INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH  
An official Publication of Human Journals

ISSN 2349-7203



Human Journals

**Review Article**

July 2020 Vol.:18, Issue:4

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## Nutraceutical Regulations and Market in India: Current Opportunities and Challenges



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**Submission:** 26 June 2020

**Accepted:** 02 July 2020

**Published:** 30 July 2020



HUMAN JOURNALS

[www.ijppr.humanjournals.com](http://www.ijppr.humanjournals.com)

**Keywords:** Challenges, FSSAI initiatives, Nutraceuticals, Opportunities, Regulations

### ABSTRACT

Nutraceuticals are treated broadly as food products, subject to manufacturing/quality standards, and restrictions on claims to prevent or mitigate disease. Even though Indian regulatory authority has come a long way by addressing many challenges, with the current lack of clarity and standardization issues such as definition, claims, and manufacturing standards, the mainstream industry complains that the Indian market is counterfeit and unregulated. Market players say the lack of carved-out nutraceuticals regulations leads to confusion and expediency. Nonetheless, India offers considerable potential for the growth of nutraceuticals from a modest base. It is currently estimated at 1-2% of global nutraceutical sales. To reach its full potential, food and pharmaceutical companies along with regulatory authorities need to address several regulatory, cultural, economic, and structural challenges in the Indian market.

## **1. INTRODUCTION:**

Food is recognized as medicine in the 5th century BC by Hippocrates (father of western medicine), who said, “Let food be thy medicine” [1]. Few civilizations that have used food as medicine are Indians, Egyptians, Chinese, and Sumerians. Later in 1989, the word ‘Nutraceutical’ was coined by Stephen L. Defelice, which is a combination of words, “nutrition” & “pharmaceutical” is a food or food product that reportedly provides health and medical benefits, including the prevention and treatment of disease [2- 3].

The benefits of the food have been re-established with the advancements of science and technology. The awareness among the consumers had increased about the ability of nutraceuticals to prevent, treat and manage the illness created the demand for nutraceuticals in India. As the consumption of nutraceuticals has increased there is a need to regulate these products. To create and regulate the nutraceuticals various laws were formed in India. The multiplicity of laws created confusion among the stakeholders [4]. To establish a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command Food Safety and Standard Authority of India (FSSAI) established under Food Safety and Standard Act, 2006. Food Safety and Standard Rules came into force on Aug 5, 2011, after notification in the Gazette of India on May 5, 2011. The main objective of FSSAI was to create science-based standards and to regulate manufacture, sale, import, processing, and distribution of food and to ensure the availability of safe food for human consumption [5].

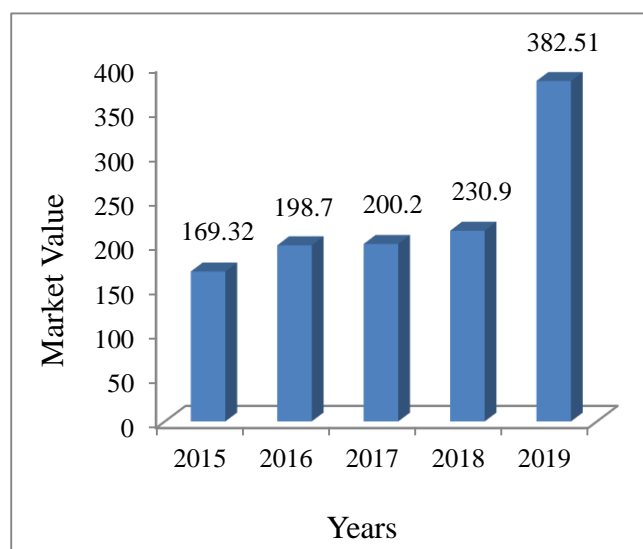
The current review focuses on the regulations regarding registration and licensing, import, labelling, and claims of nutraceuticals. This article aims to highlight some opportunities and challenges present in the nutraceutical sector of India and disclose some initiatives FSSAI has taken. This review also provides some recommendations to increase the quality, safety, and market of nutraceuticals in India.

## **2. MARKET:**

The global nutraceuticals market was estimated at US \$230.9 billion in 2018 [6]. The United States and Europe are the major manufacturers as well as consumers. However, demand is growing quite significantly in other emerging markets as well, as a result of increasing disposable incomes which have further led to higher standards of living in these countries [7]. Global Nutraceuticals Market Report, published by Variant Market Research, forecast that the

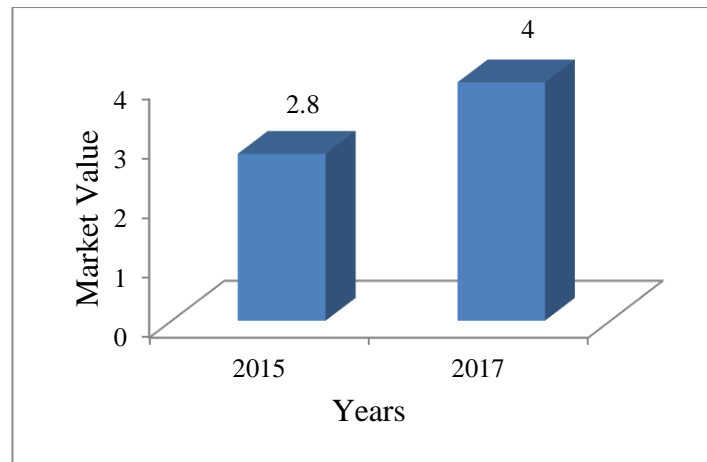
global market is expected to reach \$340 billion by 2024; growing at a Compound Annual Growth Rate (CAGR) of 7.2% from 2016 to 2024. Global Nutraceuticals Market Report, published by Grand View Research, forecast that the global market is expected to reach \$722.49 billion by 2027; growing at a Compound Annual Growth Rate (CAGR) of 8.3% [8].

Figure No.1 shows the growth of the global nutraceutical market from 2015 to 2019 [6][9][10][11][12].

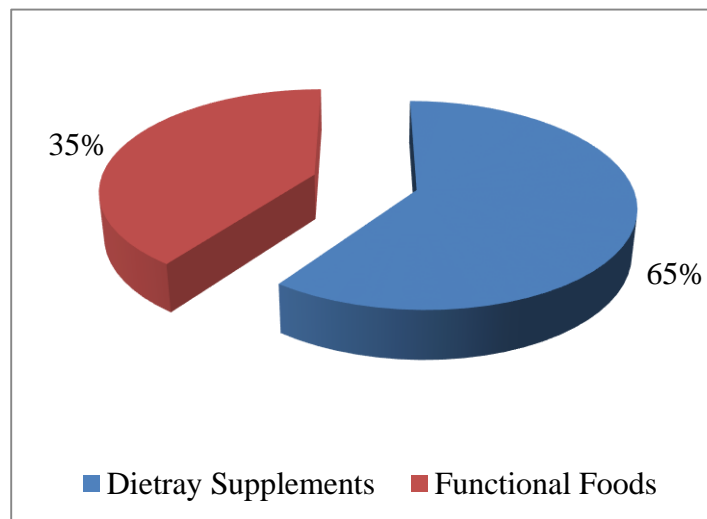


**Figure No. 1: Global Nutraceutical market (Billion US\$).** Data of 2015 from Smergers, 2016 from Research and Markets (Mar 2017), 2017 from Zion Market Research (June 2018), 2018 from Bcc Research (July 2018), and 2019 from Grand View Research (Apr 2020).

In comparison to global standards, in 2015, India accounted for a share of around 2% of the global market with US \$2.8 billion (refer Figure No.2) [13][14]. By 2022, this share is anticipated to increase to a value of approximately 3% owing to the countries large population base, increasing urban density and awareness [7][13]. The Indian nutraceuticals market was worth around US \$4 billion in 2017 and is expected to grow at 21% CAGR to US\$ 10 billion by 2022. Dietary supplements are the fastest growing sector in India (refer to Figure No.3) [13].



**Figure No. 2: Indian Nutraceutical Market (Billion US\$).** Data of 2015 from Business standard (Apr 2017), and 2017 from Australian Trade and Investment Commission.



**Figure No. 3: Indian Nutraceutical Market Segmentation (%), 2017.** Adapted from Rise in health awareness to take nutraceuticals market to \$ 8.5 bn by 2022, by Business Standard, 9 Apr 2017, retrieved from [https://www.business-standard.com/content/b2b-pharma/rise-in-health-awareness-to-take-nutraceuticals-market-to-8-5-bn-by-2022-117041900637\\_1.html](https://www.business-standard.com/content/b2b-pharma/rise-in-health-awareness-to-take-nutraceuticals-market-to-8-5-bn-by-2022-117041900637_1.html).

### 3. REGULATIONS:

In India, the body which legalizes the Nutraceuticals is Food Safety and Standard Authority of India (FSSAI) established under the Food Safety and Standard Act, 2006 [15].

Food Safety and Standard Rules of 2011 came into force on Aug 5, 2011, after notification in the Gazette of India on May 5, 2011.

The regulations include [16]:

1. Food Safety and Standard (Licensing and Registration of Food Businesses) Regulations, 2011.
2. Food Safety and Standard (Food products standard and Food Additives) Regulations, 2011.
3. Food Safety and Standard (Prohibition and Restriction of Sales) Regulations, 2011.
4. Food Safety and Standard (Packaging and Labeling) Regulations, 2011.
5. Food Safety and Standard (Contaminants, Toxins & Residues) Regulations, 2011.
6. Food Safety and Standard (Laboratory and Sampling Analysis) Regulations, 2011.
7. Food Safety and Standard (Food or Health Supplements, Nutraceuticals, Food for Special Dietary purpose, Functional Food, and Novel Food) Regulations, 2016.
8. Food Safety and Standard (Food Recall Procedure) Regulations, 2017.
9. Food Safety and Standard (Import) Regulations, 2017.
10. Food Safety and Standard (Approval for Non-Specific Food and Food Ingredients) Regulations, 2017.
11. Food Safety and Standard (Organic Food) Regulations, 2017.
12. Food Safety and Standard (Alcoholic Beverages) Regulations, 2018.
13. Food Safety and Standard (Fortification of Food) Regulations, 2018.
14. Food Safety and Standard (Food Safety Auditing) Regulations, 2018.
15. Food Safety and Standard (Recognition and Notification of Laboratories) Regulations, 2018.
16. Food Safety and Standard (Advertising and Claims) Regulations, 2018.
17. Food Safety and Standard (Packaging) Regulations, 2018.

### **3.1 Licensing and registration:**

The Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations came into force on 5 Aug 2011.

According to the regulations, all Food Business Operators in the country will have to be registered or licensed following the procedures laid down in Food Safety and Standards (Licensing and Registration of Food Businesses), Regulations 2011 [17].

- Petty food manufacturer whose annual turnover is less than 12 lakhs have to be registered with the commissioner.
- A Manufacturer whose annual turnover is more than 12 lakhs have to obtain a license from the FSSAI office.
- A manufacturer who already has registrations/licenses should be converted into FSSAI registrations/licenses.
- If the Food business is operating in more than 1 state, one additional Central License for Head/Registered Office is required [18].

#### **3.1.1 Registration of Petty food manufacturer:**

A Petty food manufacturer cannot start his/her business unless registered with the commissioner (Figure 4).

Documents required for registration:

- a) Application in Schedule-1.
- b) Fees 100 Rs per annum.
- c) Address proof (government documents like Voter ID card).
- d) Photograph of applicant [19].

Procedure [17]:

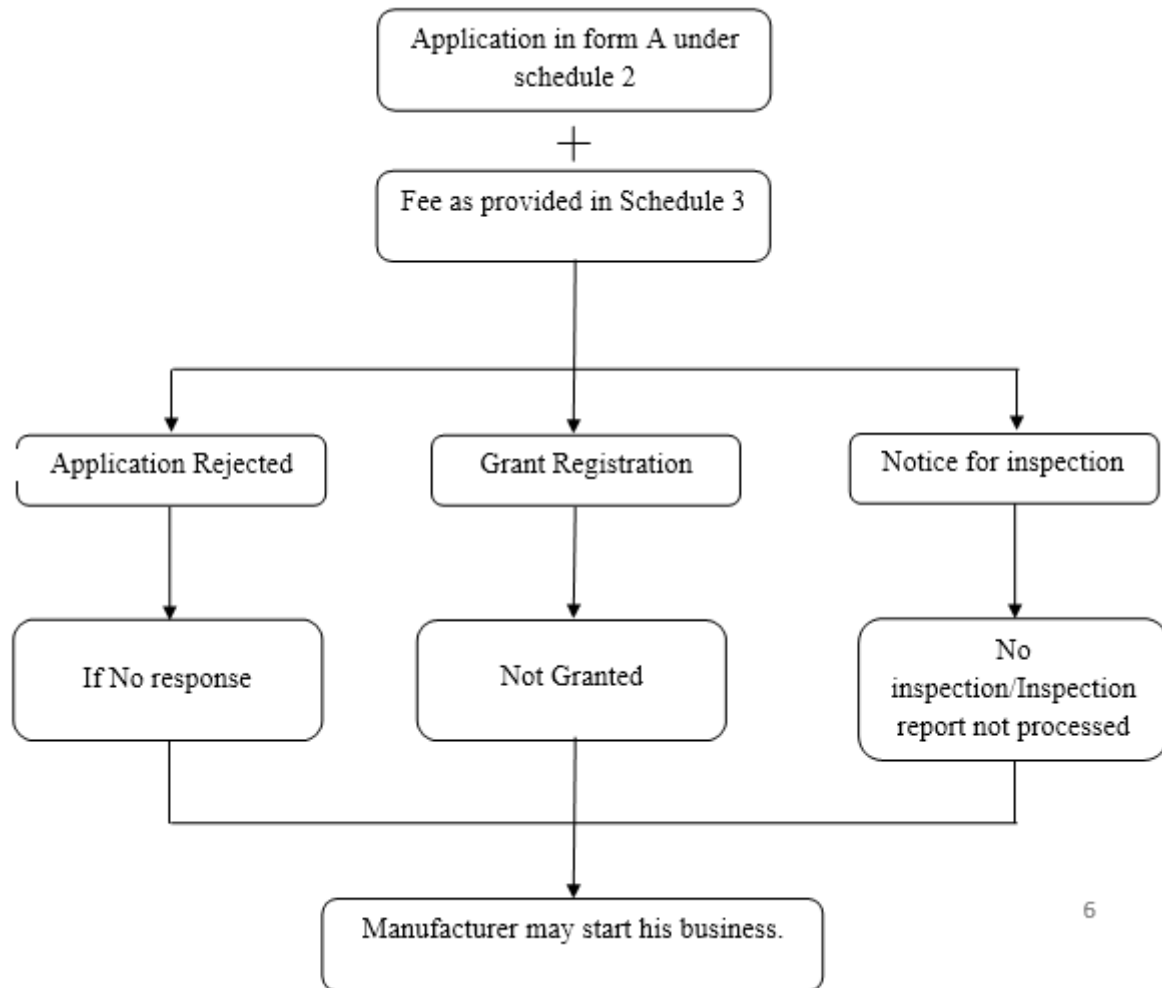


Figure No. 4: Registration process for a petty food manufacturer.

Adapted from FSSAI regulations, retrieved from [https://www.fssai.gov.in/upload/uploadfiles/files/Licensing\\_Regulations.pdf](https://www.fssai.gov.in/upload/uploadfiles/files/Licensing_Regulations.pdf).

Food safety inspection of the registered establishments should be conducted at least once in a year [17].

**3.1.2 License for food business:**

No person shall commence any food business unless he possesses a valid license through the licensing procedure as mentioned in Figure 5.

Documents required for application:

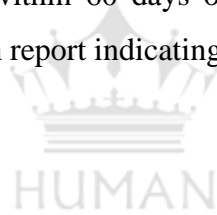
- a) Application for the grant of license in form B of Schedule 2.
- b) Self-attested declaration in the format provided in the Annexure-1.
- c) Copies of documents mentioned in Annexure 2 of schedule 2.
- d) An Applicable fee as per Schedule 3 [19].

State license: Rs. 2000 to 5000.

Central license: Rs. 7500.

**Commencement of Business:**

An applicant may commence his food business and the concerned Licensing Authority shall not deny the applicant to commence such business if, from the date of making the completed application, a license is not issued within 60 days or the applicant has not received any intimation of inadequacy or inspection report indicating defects from the concerned Licensing Authority [17].





Procedure [17]:

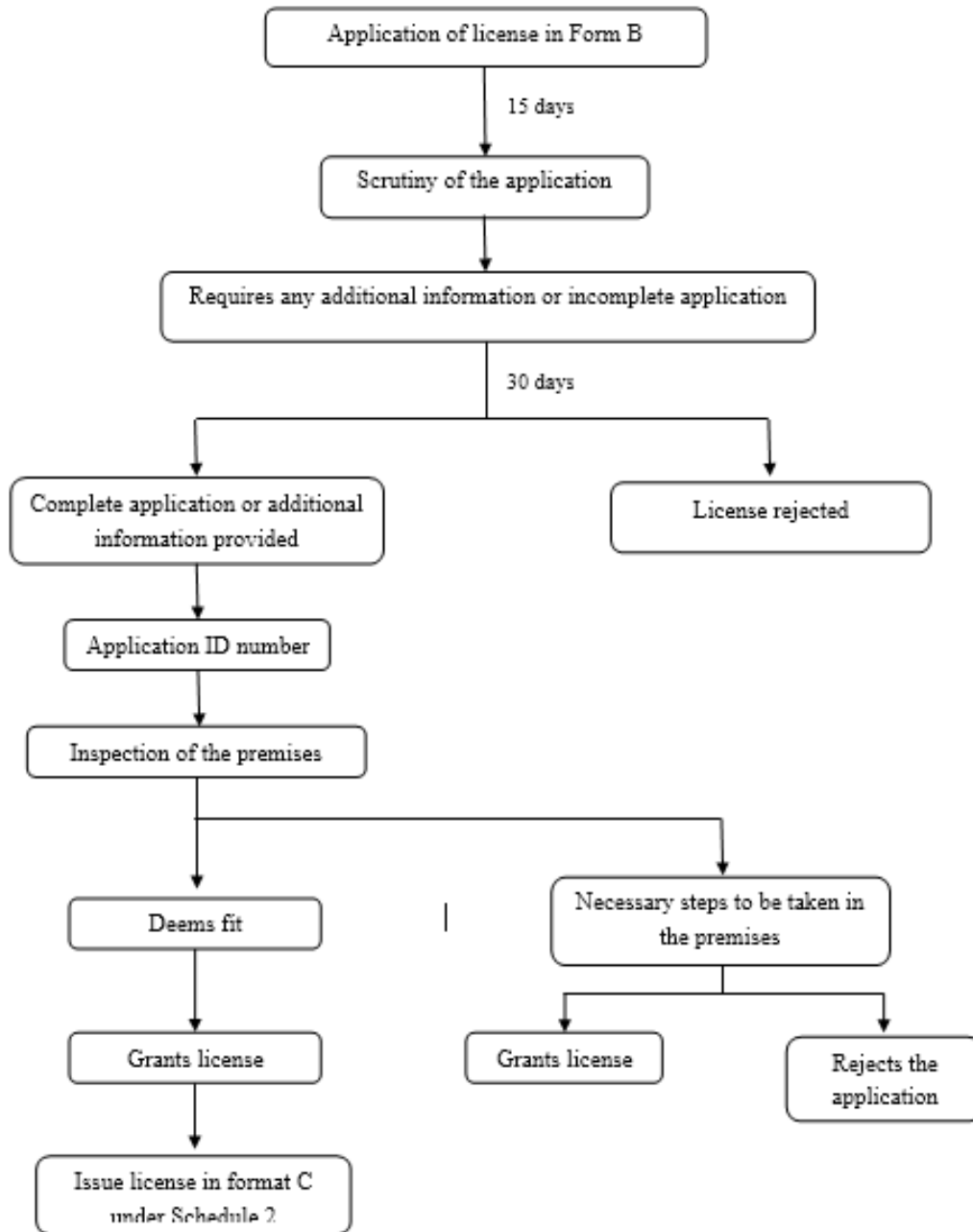
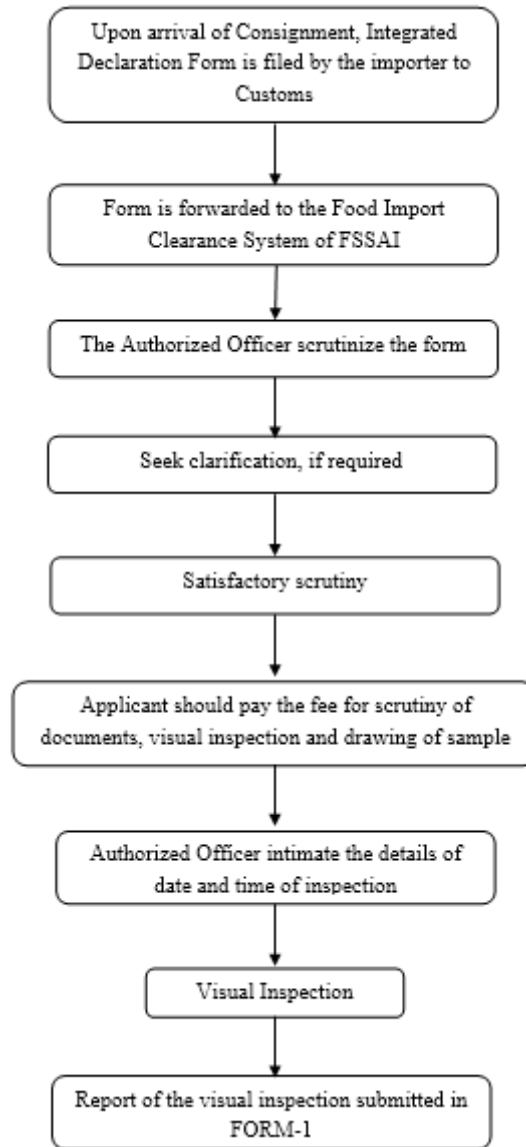


Figure No. 5: Licensing process for Food Business Operator.

Adapted from FSSAI regulations, retrieved from [https://www.fssai.gov.in/upload/uploadfiles/files/Licensing\\_Regulations.pdf](https://www.fssai.gov.in/upload/uploadfiles/files/Licensing_Regulations.pdf).

3.2 Food Imports Regulations:

The Food Safety and Standards (Import) Regulations came into force in 2017.



**Figure No. 6: Food Import process.**

Adapted from FSSAI regulations, retrieved from <https://archive.fssai.gov.in/home/fss-legislation/fss-regulations.html>.

No person shall import any article of food without an import license from the Central Licensing Authority following the provisions of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 as shown in Figure 6 [20].

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 not present despite of two opportunities having been granted, the Authorized Officer may refuse to grant further opportunity for inspection and sampling [20].

### 3.3 Claims [21]:

FSSAI has finalized the regulations about claims and advertisements by food business operators in respect of their food products on 19 Nov 2018. According to the regulations every Food Business Operator may make nutritional or health claims in respect of an article of food.

Health claims components:

- a) Nutrient or Nutritional ingredients.
- b) Health-related benefits.

Health claim Types:

- a) Ingredients (nutrient or nutritional) function claims.
- b) Enhanced function claims.
- c) Disease risk reduction claims.
- d) Health maintenance claims.
- e) Immunity claims- increase resistance (excluding vaccines) &
- f) Anti-aging claims.

Nutritional Claims:

- a) Nutritional content claims or
- b) Nutrient comparative claim.

#### 3.3.1 Approval of claims:

Claims which are listed in the regulations are permitted to be made by food business operator without any prior approval from the food regulator. However, other types of claims not standardized under these regulations may require approval from the Food Authority and should be supported with a sound scientific basis.

### 3.3.1.1 Procedure for approval of claims:

- The food business operator shall submit an application along with applicable fees as prescribed by FSSAI consisting of following information, namely:-

- a) Claim to be made;
- b) Name of the ingredient, nutrient or substance based on which the claim is to make;
- c) Validated Method of analysis of ingredients or substance for which the claim is to be made;
- d) Scientific information or material substantiating the claims;
- e) How the claim clear and meaningful and help consumers to comprehend the information provided;
- f) Well-designed human intervention studies in case of health claims conducted by or under the guidance of established research institutions; and
- g) Any other useful information.

- The agency or panel appointed by the authority carries out preliminary scrutiny of the application submitted by FBO.

- Within 90 days deficiencies shall be informed to the applicant and the applicant shall provide information within 30 days to the food authority.

- After scrutiny, the food authority may pass a speaking order either for approval or rejection and may suggest an amendment for the concerned claims.

- An amendment should be submitted within 30 days for reconsideration.

- In case of rejection, the FBO shall not use that claim.

## 4. OPPORTUNITIES:

Due to an increase in unhealthy food habits, lifestyles, decreased physical activities and an increase in the number of people employed in sitting jobs have increased the occurrence of lifestyle-related diseases, which increased the nutraceutical market growth. Not only these

factors, but there are also some other opportunities that will increase the nutraceutical market in the future. They include:

**a) Affordability testing protocols:**

Administrations are trained to establish strict, but affordable testing protocols to make the consumption of nutraceuticals much safer. The major ingredients are elemental detection of heavy metals that require proper digestion methodology and modern analytical instruments. In the coming year, we can see more quality awareness for nutraceuticals and competitive quality for the export as well as domestic consumption [22].

**b) Awareness:**

Rapid digitalization and increased social media usage have increased awareness and access to vital information regarding nutrition, holistic health and wellness [23]. According to the survey conducted by Via Media in 2015, revealed that 49% of Indians use the internet for accessing health information [24]. These increased the consumption of nutraceuticals for gaining wellness and maintaining good health.

**c) Diversifying into nutraceutical space:**

Many companies including Pharma companies (such as Novartis, GlaxoSmithKline, Cadila Healthcare, etc.), Fast-moving Companies (Cadbury, Dabur), Ayurvedic and Herbal Manufacturing companies (Himalaya), Multi-National Companies (Amway, Nestle) have diversified their business into nutraceutical space in India. Thus, giving a boost to the already growing nutraceutical market [25].

**d) Affordability:**

Hospitalization costs have increased from US\$177 in 1995 to US\$316 in 2014 (an increase of 79%). Hospitalization costs for communicable diseases were US\$175 compared with US\$316 for non-communicable diseases in 2014 [26].

A Survey conducted by National Sample Survey Organization (NSSO) said that: “the average total medical and other related non medical expenditure per hospitalization in rural and urban areas is Rs 16,956 and Rs 26,455 respectively.” The average total medical expenditure for non-

hospitalized treatment per ailing person in rural and urban areas is Rs 509 and Rs 639 respectively.

Thus, increasing hospitalization cost was driving the consumers towards nutraceuticals. Therefore, people are shifting from cure to prevention to gain the ability to control their health by improving their present health and fight against future diseases [27].

**e) Rapid retail growth:**

In 2015, India's retail market was US\$ 600b which is expected to double to US \$1.3t by 2020. Also increasing the number of supermarkets would increase the accessibility of nutraceutical products to consumers [12].

**f) Increasing co-prescription:**

In conditions like chronic alcohol, liver cirrhosis, stroke, pregnancy, and others, multi-vitamins are mostly prescribed. In India, about 16% of the prescriptions are with multi-vitamins products [12].



**g) Increased urbanization:**

Urbanization is taking place at a relatively rapid rate in India. In 1901, the percentage of urbanization is 11.40% which has increased to 34% in 2017 [28]. This has resulted in an increase in the working population of India resulting in a large base of informed consumers in India who have the disposable income to spend on a healthier life.

Due to the change in consumption patterns and urbanization taking place at a rapid rate has increased the utilization of nutraceuticals.

**h) Demand for specialized nutraceuticals:**

It is also driving by prevalent hereditary disorders such as widespread lactose intolerance in the Indian population. In a study conducted in 2015, 74% of Indians were found to be lactose malabsorbers [12].

**i) Changing trends in dosage forms:**

New dosage formulations have been developing to increase product effectiveness. Such as Liquid Encapsulation Technology which allows multiple ingredients to be encapsulated in a

single capsule. As a result, chewable and traditional tablets are slowly being replaced by capsules and liquid-filled capsules. This has the scope to increase the nutraceutical market in India [29].

## **5. CHALLENGES:**

Even though nutraceuticals has huge market demand in India, it has several challenges that preventing it to reach its true market potential in both global and domestic markets. Some of them are [30]:

### **a) Regulatory challenges:**

#### **i) Lack of clear unified definition:**

The definition of nutraceuticals varies from country to country according to their regulations. Example: The US defined nutraceuticals as Dietary supplements and Europe as Food supplements.

Still, now there is no internationally accepted definition for nutraceuticals. Hence, there is a need for global regulatory synchronization. At present, the ASEAN (Association of Southeast Asian Nations) countries are leading the path by following common regulations.

#### **ii) Complicated regulatory landscape:**

Products defined in India as nutraceuticals can be regulated as different products in other countries such as dietary supplements, traditional medicine, food supplements, etc., which creates a challenge for both manufacturers and exporters of India to comply with other importing country regulations and also monitoring of nutraceuticals based on the claims by three agencies FSSAI, (Ayurvedic, Yoga and Naturopathy, Unani, Siddha, and Homeopathy) AYUSH and (Central Drug Standard Control Organization) CDSCO makes it complicated for the manufacturer to market the nutraceutical product.

#### **iii) Claims allowed:**

Health claims allowed by different countries vary based upon the regulations which make it difficult to reach the product for the global market.

Example: FSSAI regulation does not allow prevention claims, whereas other countries allow prevention claims.

**iv) Need for more legal classification:**

More legal classification is needed to prevent different players from applying different categories for various products. On one end, the products they are said to be of medical nature and at the other end, they maintain health. The problem lies in defining nutraceuticals as curative or preventive.

**b) Difficulties faced by new players:**

It is difficult for new players to enter the nutraceutical territory and to avail subsidies as there is no regulatory system for setting up manufacturing plants. The quality and pricing also become an issue as nutraceuticals are categorized as either foods or drugs.

**c) Adulteration:**

**i) Economic adulteration:**

Undercutting of ingredients mentioned on the label, wholly or partially, and replacing them with cheaper and easier to attain, and they are undeclared by the manufacturer in the claims which may cause risk to the consumer who could have an adverse reaction to it [31].

**ii) Pharmaceutical adulteration:**

To improve the efficacy of the nutraceutical, active chemical pharmaceutical ingredients were added without declaring the ingredient on the label. Worldwide, there are several scandals reported the use of undeclared Active Pharmaceutical Ingredients in the nutraceutical product [31].

**d) Online pharmacies:**

As most of the products are Over The Counter (OTC) in nature there is no need for prescription uploads as pharmaceutical products, and moreover, regulatory oversight is far lower in e-retail pharmacies for nutraceuticals. Consumers also tend to choose higher concentration products as there are unaware of stipulated permissible limits [30].



**e) Lower consumer awareness on Micronutrient Supplementation:**

While there is no denying that there is growing health consciousness among the Indian population and people are moving towards healthy living, but when it comes to knowledge about specific nutritional deficiencies, daily limits of macro and micronutrients that are not met through regular diet is quite low [30].

**6. INITIATIVES THAT ARE TAKEN BY FSSAI:**

To boost, food safety culture in India, the FSSAI has taken many initiatives. Some key initiatives are:

a) On 31 Dec 2019, FSSAI had finalized the regulations for approval of rapid testing devices, kits, and methods to strengthen the food testing ecosystem in the country. FSSAI has so far approved 30 rapid food testing kits/devices under these regulations.

These devices ensure “faster, better, cheaper” real-time testing of food. These are expected to become an integral part of quality assurance/quality control programs in the food industry and also for regulatory and surveillance purposes in 2020 [32].

b) In order to earn consumer trust, the country’s food regulator has decided to get food testing done through the consumer organisations. Food safety law provides for reimbursement of testing fees if a consumer sample fails. This provision has however never been used due to some practical difficulties. Intending to address these difficulties, on 13 Dec 2019 FSSAI has decided to authorize credible Voluntary Consumer Organisations (VCOs) to assist consumers in getting such tests done. Reimbursement of testing fees in such cases will be done even if the sample does not fail [33].

c) Swasth Bharat Yatra is a pan-India movement called ‘Eat Right India’, which was aimed to create consumer awareness about eating safe and nutritious food.

On 29 Dec 2019 FSSAI presented the second edition of the ‘National Eat Right Mela’. The Hon’ble Minister will also launch the “Network for Scientific Co-operation for Food Safety and Applied Nutrition” (NetSCoFAN), a network of research in academic institutions working in different areas. They are responsible for carrying out the activities i.e., conduct horizon-scanning of information/data on existing and emerging food safety risks and issues in the

respective areas; conduct surveys, research work and related activities; sharing of testing facilities and instrumentation, testing protocols, and so on.

The Hon'ble Minister will also launch 'The PURPLE Book' a handbook on diets for diseases. The book provides general guidelines for hospitals to on suitable diets for common medical conditions such as diabetes, hypertension, cancer, gut disorders, and so on in a sample format and has been developed and vetted by experts in the field of food and nutrition [34].

d) Heart Attack Rewind is an initiative by FSSAI to eliminate trans-fat from India by the year 2022. This initiative was campaigned across India [35].

e) FSSAI-CHIFSS (CII-HUL Initiative on Food Safety Sciences) is a collaboration between FSSAI and CII-HUL (Confederation of Indian Industry (CII) and Hindustan Unilever (HUL)), it aims to promote collaboration between Industry, Scientific Community, and Academia for food safety [35].

f) FSSAI launched Food Product Identity Verification System (FPIVS) and "eplatform for Comments" on 5 Nov 2018.

FPIVS enables FBOs to identify applicable food regulations for any product or whether such food requires product approval. The "eplatform for Comments" will facilitate stakeholders for online submission of their views for upcoming food standards and regulations [36].

g) It will be mandatory for food outlets to put up color-coded food safety display boards on the premises of the outlet. It has to include FSSAI license number, instructions for safety practices and food hygiene and, a customer feedback form [37].

h) Integration of food standards to avoid confusion, strengthening food testing labs, partnering with food companies to promote self-regulation among businesses are other key initiatives [37].

All these FSSAI initiatives are a part of the mechanism to revitalize the FSS act, which is already in process. It is a beginning of the bigger task ahead of the FSSAI, of building a collective approach for food safety in India.

## 7. A RECENT REPORT ON NON-CONFORMITIES:

Food safety issues extend beyond food adulteration. Even though the government has been taking so many steps to prevent food safety issues, the non-conformities of nutraceuticals have been increasing from the past few years. When compared with 2018 non-conformities have increased by 25% in 2019.

According to the Food Enforcement report during the year 2018-19, a total of 1,06,459 samples were analysed. While 3.7 % of these samples were found to be unsafe, 15.8% were found to be sub-standard and 9% of samples had labelling defects.

There has been a 7% increase in the number of samples analysed during 2018-19 as compared to 2017-18. 25% more samples were found non-conforming compared to the previous year. There has been a 36% increase in civil cases launched and a 67% increase in the number of cases where penalties were imposed. The amount of penalty imposed has increased by 23% during 2018-19 compared to the previous year. A total amount of Rs. 32.58 crore has been realised during 2018-19. As far as criminal cases are concerned there has been an 86% increase in criminal cases launched.

Among all the states and union territories, the states which occupied the top 5 places in the percentage of unsafe food are Tamil Nadu (12.7%), Assam (8.9%), Jharkand (8.8%), West Bengal (7.6%) and Odisha (6.7%) among 3.7% of the total unsafe food found in India [38].

No. of samples, non-conformities, unsafe food has also increased from the past years (Table 1).

**Table No. 1: Enforcement report from the past three years [38]**

Year	No. of samples analysed	No. Of samples found Non-conforming	No. of Cases launched		No. of Convictions/Penalties		
			Criminal	Civil	Convictions	Penalties	Penalties amount Rs
2016-2017	78,340	18,325	1,727	11,353	1,605	4,757	17,01,93,266
2017-2018	99,353	25,262	1,506	13,615	5,198	7,627	26,35,41,067
2018-2019	1,06,459	30,415	2,813	18,550	701	12,734	32,57,78,087

## 8. CONCLUSION & RECOMMENDATIONS:

The Indian nutraceutical industry is growing, due to an increase in disposable income, growing health awareness, the emergence of specialized nutraceuticals, and other factors. Due to these players of other industries diversifying their business into nutraceutical space. Therefore, it is necessary to have effective regulations in place to look over safe and effective use of nutraceuticals. Although there are many challenges, currently available FSSAI has come a long way with the intention to provide unique and transparent regulations. To increase the food safety FSSAI has developed so many initiatives such as FSSAI- CHIFSS, Heart Attack Rewind, FPIVS, and e-Platform for Comments, and many others. Even though FSSAI has taken many initiatives there are still some challenges that need to get resolved, such as complicated regulatory landscape, lack of clear unified definition and classification, adulteration, and unsafe food products. According to the food safety enforcement report (2018-2019): out of 1,06,459 samples analyzed, 3900 samples were found unsafe and 16,870 were found sub-standard. So, there is a need for FSSAI to develop a few more initiatives to resolve the challenges.

To further improve the Nutraceutical quality, safety, and also the market, the regulatory agencies need to take consider the following recommendations:

- Harmonization of global nutraceutical regulatory bodies can help to develop standard definition and regulation of nutraceuticals, similarly as Global Harmonization Task Force (GHTF) for medical devices and International Regulatory Cooperation for Herbal Medicines (IRCH) for herbal medicine.
- The manufacturer should provide data on the safety, efficacy, and mechanism of action supporting their claims.
- To address the adulteration issue more stringent regulations are needed.
- To prevent unregulated nutraceutical products in the e-commerce websites, more stringent regulations should come in the place that evaluates sellers for their FSSAI license code for their shop before they enter into the websites.
- FSSAI should develop new programs to create awareness, increase research and development and product development skills.

## Summary

- The word ‘Nutraceutical’ was coined by Stephen L. Defelice, which is a combination of words “nutrition” & “pharmaceutical” is a food or food product that reportedly provides health and medical benefits, including the prevention and treatment of disease. India defines them as food for “special dietary uses”.
- In India, FSSAI regulates the nutraceuticals through Food and Safety Standards Act, 2006, and the regulations framed thereunder. No person shall manufacture, sell, or commence any food business unless following the regulations laid under FSSA.
- Ideally, the intake of nutrients through food should be sufficient to prevent curative measures such as pharmaceuticals and traditional medicines being used in large quantities. However, in the absence of the requisite nutrition through food, external intervention in the form of health supplements and nutraceuticals have become imperative in India. However, demand is growing quite significantly over the past few years owing to 2% of global nutraceutical market.
- There are key demand drivers that have resulted in the need for nutraceuticals in India are:
  1. Affordability: Due to an increase in hospitalization cost people are shifting from cure to prevention, thus driving towards nutraceuticals.
  2. Increased urbanization: This has resulted in an increase in the working population of India resulting in a large base of informed consumers in India who have the disposable income to spend on a healthier life.
  3. Awareness: Rapid digitalization and increase in social media usage have increased awareness and access to vital information regarding nutrition, holistic health, and wellness.
  4. Manufacturers diversifying into nutraceutical space: Many companies including Pharma companies, fast-moving Companies, Ayurvedic and Herbal Manufacturing companies, Multi-National Companies have diversified their business into nutraceutical space in India.
- Along with the opportunities, they are challenges that are preventing the market from reaching its true market potential in both the global and domestic markets. Some of them were:
  1. Lack of clear unified definition and classification.

2. False claims.
3. Adulteration.
4. Sale of unregulated products on online pharmacies.
5. Availability of unsafe food products.

- Although there are many challenges, currently available FSSAI has come a long way with the intention to provide unique and transparent regulations. To increase the food safety FSSAI has developed so many initiatives such as **FSSAI- CHIFSS**, Heart Attack Rewind, FPIVS, and e-Platform for Comments and many others. Even though FSSAI has taken many initiatives there are still some challenges that need to get resolved. And also harmonization of nutraceutical regulations can prevent confusion, and also reduce the time and efforts of the manufacturers who wish to export their products to multiple countries.

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