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Scope and Opportunity of Nutraceuticals and Dietary Supplements Market in India



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ABSTRACT

Nutraceutical food or food components that help in treatment and prevention of diseases are made from herbal/botanical raw material. This is rapidly growing industry (7 – 12% per year) with more than millions of peoples using these natural products. According to recent analysis from Euro monitor, international global sales of health and wellness products are on track to reach a record of about \$1 trillion by 2017, fuelled by functional/fortified products designed to offer specific health benefits. The nutraceuticals industry in India is anticipated to grow around 20 per cent over the period to reach USD 6.1 billion by 2019 – 2020. The Food Safety and Standard Authority have issued regulations with respect to Licensing and registration of food business, manufacturing, packing and labeling, food product standard etc. The Food Authority may enlist specific nutraceuticals as approved from time to time after undertaking proper scientific evaluation. Labelling of Nutraceuticals shall comply with the packaging and labelling requirements as laid down under Food Safety and Standards (Packaging and Labelling) Regulations, 2011. The Food Safety and Standard act will encourage manufacturers for product Research and Development; develop reliable protocols and carryout clinical studies. Foreign Direct Investment Act will also provide new opportunities for international firms to manufacture and sale nutraceutical products in India.



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INTRODUCTION:

For better understanding of the updated requirements for Imports, Exports and Registration of Dietary Supplements/Nutraceuticals with FSSAI in detail and to ensure the regulatory compliance in India, this project work is initiated. Food or Health Supplements are foods which are intended to supplement the normal diet of a person and which are concentrated sources of one or more nutrients, like minerals, vitamins, proteins, mineral complexes, amino acids or enzymes, other dietary substances, plants or botanicals, prebiotics and probiotics substances from animal origin or other similar substances with known and established nutritional or beneficial physiological effect, and which are presented as such and are offered alone or in combination, but are not drugs as defined in the Section 3(b) of Drugs and Cosmetics Act, 1940 and the rules made there under.

1. Drugs defined under Section 3(b)(i) of the Drugs and Cosmetics Act, 1940¹ and also ayurvedic, siddha and unani drugs are specifically excluded from the scope of the definition of nutraceutical, health supplement etc. under Section 22 of the Act. The definition of drug under Drugs Act is very exhaustive. Taking recourse to the definition of drug, regulatory officers are categorizing nutraceuticals, especially manufactured, and marketed in tablet, capsule or liquid oral dosages form containing vitamin and minerals as drugs on the basis of even structure function claims.

2. Some commonly used colors and additives such as binding agents, granulating agents used in formulating tablets do not find place in the list of permitted food additives under the regulations.

3. Though the structure function claims are permitted, there is no clarity as to the permitted structure function claims for nutraceuticals and dietary supplements. To overcome these difficulties, it would be necessary to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to provide for specific exemption to nutraceuticals, dietary supplements, health supplements from the scope of Drugs and Cosmetics Act, 1940 and Rules, 1945.

It is also necessary to have specific regulations for product approval, approval of claims, permitted additives, quantity of vitamins for nutraceuticals, as it is necessary to treat this segment as an independent and unique entity under the Food Safety Standard Act, 2006. In 2012, the

Indian Nutraceutical industry was estimated at US \$ 2 Billion, roughly 1.5 percent of the global nutraceutical industry.

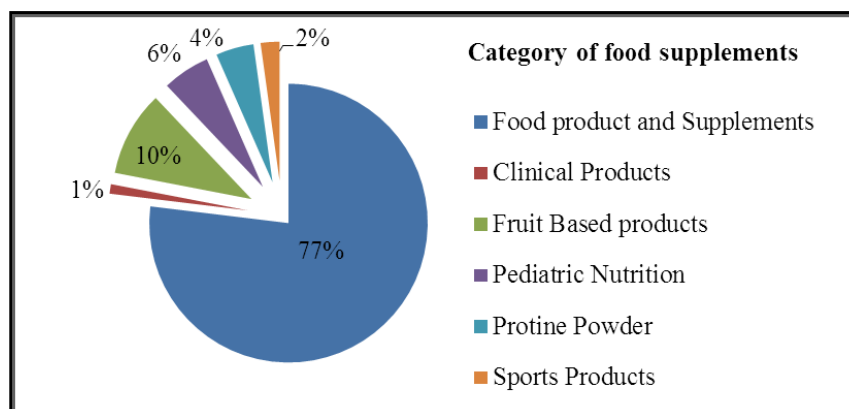


Fig. No. 1. Category of food supplements

In India, market of nutraceutical² over a broad spectrum of categories of food supplements which is shown in fig1, which are approaching the higher degree of accuracy and growth through innovative approaches. A host of pharmaceutical and Fast Moving Consumer Goods (FMCG) companies are entering this market, other than Nutraceutical and Herbal/ Ayurvedic companies. Pharmaceutical companies consider nutraceuticals as an extension of the healthcare sector and lead the dietary supplement category. Meanwhile, FMCG companies are expanding by launching products in the functional food and beverage category. The domestic companies have a strong foothold with 55% of market share and international companies occupying 45%.

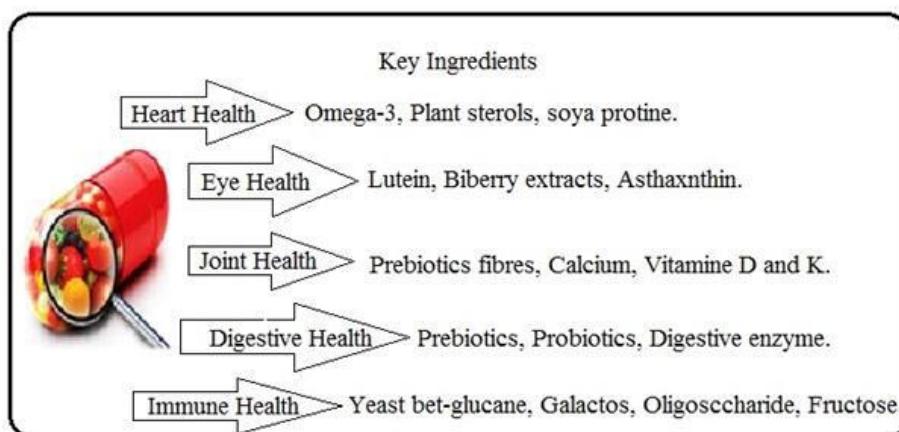
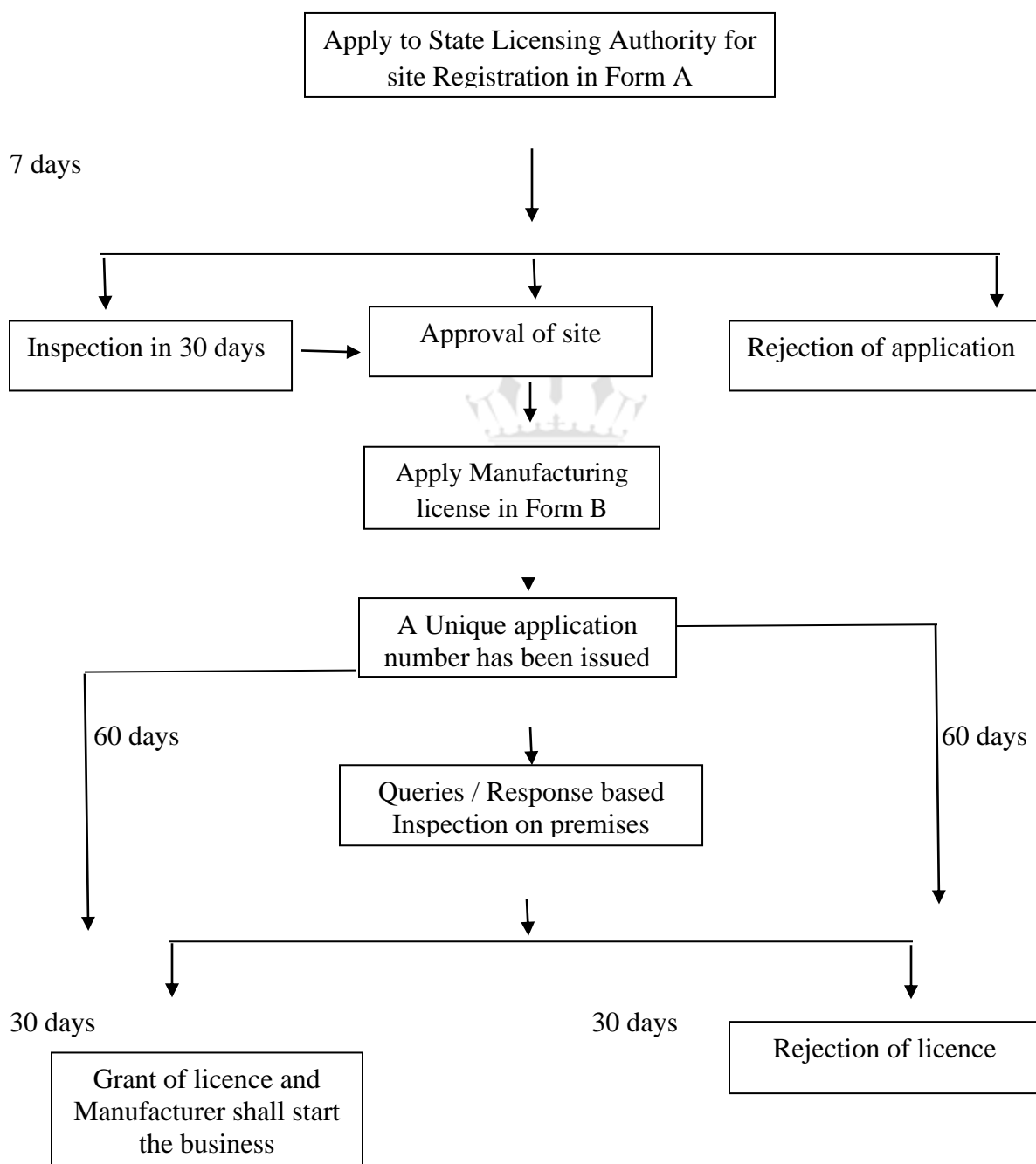


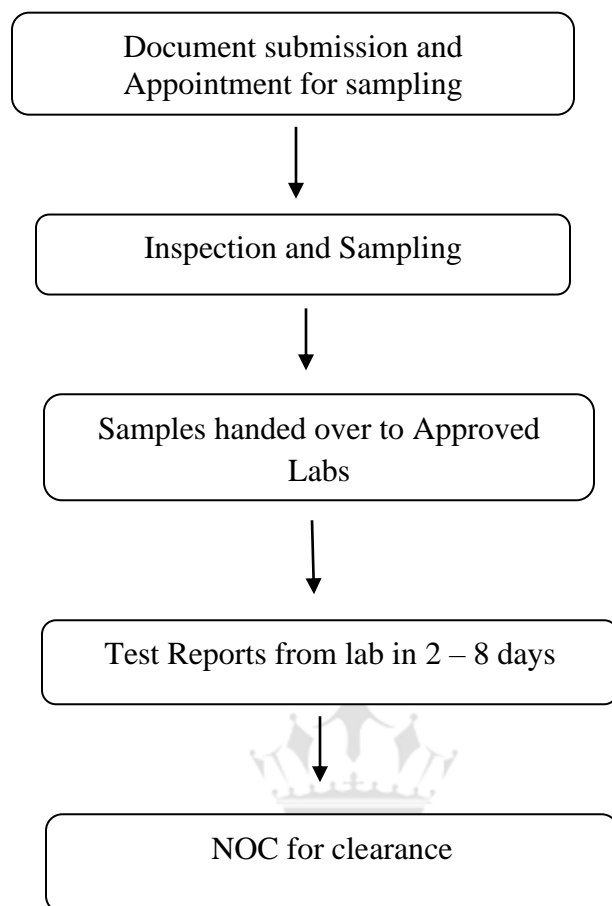
Fig. No. 2. Various nutrients used in various health issues

The potential for cultural customization and inclusion of natural ingredients is high in the region, given the high acceptance of alternative herbal medicines. Many of the natural products or their synthesized products used in various health issues, some of them are illustrated in fig 2. Moreover, India has emerged as a key sourcing destination for natural ingredients, thereby, allowing manufacturers easy access to their ingredients.

The flowchart explaining the registration process³ of the Nutraceutical in India is as follows:



Food Import Clearance Process



Web based Food Import Clearance System

- It facilitates CHA's / Importers to:
 - To Register online
 - Apply for NOC without visiting any FSSAI Office and make payments for testing
 - Track status of their application
- It facilitates FSSAI Authorized Officers / Inspectors to:
 - Process applications for NOC
 - Ensure timely sampling and inspection

- Generate No Objection Certificate (NOC)
- It facilitates Labs to:
 - Update test results in the system
 - Invoice FSSAI for payment
 - Communicate with other labs
- It facilitates FSSAI HQ to:
 - To monitor the overall operations of the ports
 - Analyze the risk associated with importing countries
 - Generate MIS reports

Nutraceutical food or food components that help in treatment and prevention of diseases are made from herbal/botanical raw material. This is rapidly growing industry (7 – 12% per year) with more than millions of peoples using these natural products. According to recent analysis from Euro monitor, international global sales of health and wellness products are on track to reach a record of about \$1 trillion by 2017, fuelled by functional/fortified products designed to offer specific health benefits. The nutraceuticals industry in India is anticipated to grow around 20 per cent over the period to reach USD 6.1 billion by 2019 – 2020.

The Food Safety and Standard Authority has issued regulations with respect to Licensing and registration of food business, manufacturing, packing and labeling, food product standard etc. The Food Authority may enlist specific nutraceuticals as approved from time to time after undertaking proper scientific evaluation. Labelling of Nutraceuticals shall comply with the packaging and labelling requirements as laid down under Food Safety and Standards (Packaging and Labelling) Regulations, 2011. The Food Safety and Standard act will encourage manufacturers for product Research and Development; develop reliable protocols and carryout clinical studies. Foreign Direct Investment Act will also provide new opportunities for international firms to manufacture and sale nutraceutical products in India.

For better understanding of the updated requirements for Imports, Exports and Registration of drugs with CDSCO¹ and Dietary Supplements/Nutraceuticals with FSSAI in detail and to ensure the regulatory compliance in India, this project work is initiated.

Nutraceuticals are the products that offer health as well as medical benefits including the prevention and treatment of disease. The word nutraceuticals is a combination of two words – nutrition and pharmaceuticals. Nutraceuticals means a naturally occurring chemical compound having a physiological benefit or provide protection against chronic disease, isolated and purified from food or non-food source and may be prepared and marketed in the food format of granules, powder, tablet, capsule, liquid or gel and may be packed in sachet, ampoule, bottle etc. and to be taken as measured unit quantities. The nutraceutical industry is a dynamic, evolving industry that offers exciting opportunities to merge scientific discovery with growing consumer interest in health-enhancing foods. Nutraceuticals will continue to have great appeal because they are convenient for today's lifestyle. The greatest challenge still remains in the public policy and regulatory areas, which will encourage research and development of products that provide health benefits and permit truthful, non-misleading communications of these products while protecting public health and maintaining public confidence.

The Indian nutraceuticals market which has grown from \$ one billion in 2008 to \$1.8 billion in 2013, has crossed \$ two billion in 2014 and is expected to top \$ four billion by 2018. There has been an increasing awareness among the rising affluent middle class about health and wellness. Nearly 400 million people in India belong to the middle class and have disposable income which has made them capable of buying nutraceuticals and dietary supplements. It is an inevitable fact that affluence is one of the causes of lifestyle diseases, which nutraceuticals and dietary supplements often address. These factors will support the double-digit growth of the industry in the coming few years. The Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled 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. Ministry of Health & Family Welfare, Government of India is the Administrative Ministry for the implementation of FSSAI. The Chairperson and Chief Executive

Officer of Food Safety and Standards Authority of India (FSSAI) have already been appointed by Government of India. The Food Safety Standards Authority India (FSSAI) is the approving authority which grants the approval for the registration of the food products and food business for the sale of the products in the country. It also promotes the general awareness of the food safety standards in the country.

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

The market for Global Dietary supplements is segmented by form, by type, by application, and by end-user. Segmentation by form includes tablet, capsule, powder, liquid, and sweet foods. Segmentation for global dietary supplements by type includes vitamins, minerals, amino acids, botanicals, and others. Furthermore, dietary supplements market is also categorized on the basis of application into personal care, pharmaceuticals, and sports nutrition. Personal care market includes sub-segments - weight loss, general wellbeing, bone & joint, immunity, and digestive health⁴; by pharmaceuticals market includes sub-segments - heart health, allergies, and eye health. Additionally, the market has been divided on the basis of end-users into children, youth, adults, and geriatric. Nutraceuticals could complement drugs and can reduce over-dependence on medicines for treatment. There is considerable scope for value-addition of agri-by products. The biodiversity and traditional knowledge could make India a world leader in nutraceutical market, said Dr. BR Lokesh, chief scientist, Nutraceuticals, Central Food Technological Research Institute (CFTRI), Mysore. According to experts, nutraceuticals & functional foods would help mitigate malnutrition in India. Although, there is a huge potential for the growth of the sector, yet its development is slow. The country has a long way to go to en-cash much of its bio-agri wealth.

Dietary supplements are the largest category accounting for 64 per cent of the nutraceuticals market, driven primarily by the pharmaceutical sector in the form of vitamin and mineral supplements⁵. Functional foods will be the quickest growing category until 2015 followed by dietary supplements. However, dietary supplements, specifically herbal and dietetic supplements, will form the greatest opportunity areas for nutraceutical manufacturers, driven by growing demand from an evolving consumer base, stated the report. Most of the leading pharmaceuticals companies have ventured into nutrition and nutraceuticals space and have a growing portfolio of such products which targets various therapeutic segments. This trend is increasingly on the rise

and will continue to grow to a large extent in turn adding to the growth of the nutraceuticals industry. With the growing popularity of these supplemented foods, many multinationals are investing in the nutraceuticals market in India. These include Monsanto, American Home Products, DuPont, BioCorrex, Abbott Laboratories, GlaxoSmithKline Consumer Healthcare, Johnson & Johnson, Nestle, Novartis, Yakult-Danone India, Herbalife etc. These players are a major resource for nutraceuticals and related dietary supplements. Besides, India has many local players such as Dabur India, Cadila Healthcare, British Biologicals, Himalaya Global Holdings, Amway, Sami Labs, Sami Direct, Parry Nutraceuticals, Wockhardt etc.

The global demand for nutraceutical ingredients⁵ is forecast to rise 7.2 per cent annually to \$30 billion in 2017 according to report by Report linker. The best growth prospects will exist in substances with clinically supported health benefits and broad applications in foods, beverages, dietary supplements and adult and pediatric nutritional preparations. Included in this group are soy proteins; oat bran, psyllium, and soy fibers; Bifidobacterium and Lactobacillus probiotics; omega fatty acids; cranberry and garlic extracts; calcium, magnesium and zinc minerals and vitamins A and C.

Countries such as Brazil, China, India, Mexico and Turkey will be among the fastest growing consumers and producers of nutraceutical ingredients worldwide. Increasing economic prosperity will enable these countries to expand and diversify their food and beverage, processing, and pharmaceutical industries. In 2017, China, alone, will absorb more than 16 per cent of the value of global nutraceutical ingredient demand and will account for over 18 per cent of the value of related world shipments. Because of maturing markets, the supply and demand of nutraceutical ingredients in the United States, Western Europe, and other developed economies will increase more slowly than the average worldwide pace. Nonetheless, food, beverage and pharmaceutical companies in these economies will continue to pursue opportunities in conventional and speciality nutritional products and natural medicines. As a result, they will remain key customers for nutraceutical ingredients.

Nutrients, including proteins, fibres and various specialized functional additives, will remain the top-selling group of nutraceutical ingredients worldwide. Proteins will post the fastest demand gains as food and beverage makers throughout the world will introduce new high value-added nutritional preparations. Functional additives and fibre nutrients will also fare well in the global

marketplace. Demand for these ingredients will gain upward momentum from increasing clinical evidence of health benefits and expanding applications in speciality foods and beverages. Naturally derived substances, consisting of herbal and botanical extracts and animal- and marine-based derivatives, will see the fastest growth among the three major groups of nutraceutical ingredients. Among these substances, omega fatty acids derived from fish oils and other marine sources will lead gains, reflecting clinically proven cardiovascular benefits and expanding use in dietary supplements and nutritional therapies.

The rising popularity of preventive medicine will impact favourably on global demand for numerous other natural extracts and derivatives, including cranberry, garlic, ginkgo biloba, ginseng; and glucosamine and chondroitin. Well established applications in food and beverage fortification; infant, adult, and paediatric nutritionals; and dietary supplements will continue to be a large global market for mineral and vitamin ingredients. Within this group, essential minerals such as calcium, along with vitamin A and vitamin C substances, will post the fastest gains in world demand. According to a recent survey, there are more than 8,000 registered and non-registered nutraceuticals, herbs and related companies in India but most of them are small and medium enterprises. The increasing need for additional nutrition and food security concerns in India has resulted in government to introduce schemes for vitamin fortification.

Overall, the Indian nutraceutical market is emerging with strong growth potential. With increasing health awareness, and the shift towards preventative health care and increased regulatory clarity, India's future in nutraceuticals industry looks promising, for both manufacturers and consumers. However, there is a strong need of developing customized products, affordable pricing and distribution strategy.

FSSAI strengthens regulatory system for health supplements as it is poised to grow to USD 10 Billion by 2025

In December 2016, FSSAI had notified the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for special medical purpose, Functional food and novel food) Regulations, 2016. These regulations cover eight categories of foods and carry detailed requirements about their composition, claims, labels etc. These foods are health supplements, nutraceuticals, foods for special dietary use, food for special medical purpose,

speciality food containing plants or botanicals, foods containing probiotics, prebiotics and the novel foods. The regulations allow the manufacturing and selling of the above category of foods in the form of tablets, capsules and syrups and must fulfil quality requirements and standards as specified in the Indian Pharmacopoeia. As per these regulations, the formulation of articles of food shall be based on the principles of sound medicine or nutrition and supported by validated scientific data, wherever required.

A mere combination of vitamins and minerals formulated into tablets, capsules or syrup is not food unless vitamins and minerals are added to an article of food based on a food format. These foods are not permitted to contain hormones, steroids or psychotropic ingredients. These foods may use approved colours and additives as permitted in Schedule VF of these regulations, natural, nature identical or synthetic flavours as permitted in the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

Regulation of Nutraceuticals in India

According to Indian definition of nutraceuticals it must have the listed ingredients and must have the general given properties. Nutraceuticals do not include traditional foods. Nutraceuticals which contain some important component having therapeutic activity or formulated to satisfy dietary requirement. These are notified in such a way that all the required ingredients in the food stuffs must differ from the rules of Indian standards presented as such, from the ordinary food stuffs if though there exist any kind of food stuff then it must contain one or more than one of the following composition or ingredients which include the parts which are obtained in type of liquid extract, dry powder or extract in the way of ethyl alcohol and hydro alcoholic that may be in the form of combination or single added from the plants and namely botanicals. Enzymes which not be more than the limits. Vitamins, minerals, proteins and amino acid or their components of metals should not exceed more than the limits which has been mentioned in the recommended daily allowance (RDA) for the Indian rules and regulation. The substances which have been obtained from animal origin or any of the substance which are added as the dietary supplements in the diet which in result increase the intake of diet in the form of food. The Food Safety Standards Authority India (FSSAI) is the approving authority which grants the approval for the registration of the food products and food business for the sale of the products in the country. It also promotes the general awareness of the food safety standards in the country. Food safety

standard and standards act is laid down in 2006 in order to form the statutory body which regulates the manufacture, storage, distribution, sale and import, to ensure the availability of the food and food products within the country. Nutraceutical are grouped under the umbrella of foods by the FSS act 2006, rules and regulations 2011. The Food Safety and Standard Authority has issued regulations⁶ with respect to Licensing and registration of food business, manufacturing, packing and labeling, food product standard etc. The FSSA has 12 chapters with 101 sections and two schedules. The FSSA incorporates the salient provisions of the prevention of Food Adulteration Act 1954 with the aim to establish a single reference point for all matters relating to food safety and standards.⁷ The FSSA establishes the Food Safety and Standards Authority of India (FSSAI) as an apex regulatory authority, consisting of a Chairperson and 22 members. In their endeavour to carry out the provisions of the FSSA, the FSSAI shall be assisted by a Central Advisory Committee (CAC), Scientific Panels (SPs), and a Scientific Committee (SC); each with specific responsibilities.⁷ The Food Authority may enlist specific nutraceuticals as approved from time to time after undertaking proper scientific evaluation. Labelling of Nutraceuticals shall comply with the packaging and labelling requirements as laid down under Food Safety and Standards (Packaging and Labelling) Regulations, 2011⁶. The Food Safety and Standard act will encourage manufacturers for product Research and Development; develop reliable protocols and carryout clinical studies. Foreign Direct Investment Act will also provide new opportunities for international firms to manufacture and sale nutraceutical products in India.

For better understanding of the updated requirements for Imports, Exports and Registration of Dietary Supplements/Nutraceuticals with FSSAI in detail and to ensure the regulatory compliance in India, this project work is initiated.

Role of nutraceutical agents in cardiovascular diseases:

Nutraceuticals like carnitine, N-acetylcysteine, creatine, glutathione, selenium, resveratrol, beta-sitosterol and flavonoids are used in cardiovascular diseases. L-carnitine has beneficial effect on cardiac function and it has postulated to be cardioprotective due to its antioxidant effects.

Documents Requirement for FSSAI Food License

The FSSAI required documents for Food License depends on the kind of registration – simple Registration Form A or Food License Form B which depends on annual turnover. For tiny FBO only registration with food authority is required.

Annual Turnover	Registration / License
Below 12 Lakhs	Registration FORM A
12 – 20 Lakhs	State License FORM B
Above 20 Lakhs	Central License FORM B

Basic Registration is required for small Food Business Operators (FBO) having annual turnover less than 12 Lakhs.

Documents required with Form A

- Passport size photograph of Food Business Operator
- Document for Identity proof like ration card, voter ID card, Pan card, Driving License, Passport, Aadhar card, Senior citizen card, Department issued ID
- Supporting documents (if any): NOC by Municipality/Panchayat, Health NOC

State License is required for FBO having annual turnover of 12 – 20 Lakhs

Documents required with Form B (State License)⁸

- Form B must be appropriately completed and signed (in duplicate) by the proprietor or partner of the authorized signatory.
- It is mandatory for manufacturing and processing units to provide a blueprint plan of the processing units which shows the dimensions in meters or squares and operation wise area allocation along with name, list of equipment and machinery with their number, installed capacity and horse power used.

- It is mandatory for companies to furnish the list of Partners/Proprietor/Executive Members of society with complete address and contact details.
- Address proof and photo ID issued by Government authority
- In case of manufacturers, list of food category desired to be manufactured.
- Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, collection of samples, packing and dispatch. (for manufacturers / processors) Analysis report (Chemical and Biotechnological) of water to be used as ingredient in food from a recognized/public health laboratory to confirm the potability (mandatory only for manufacturing and processing units only).
- Proof of possession of premises (Sale deed/ Rent agreement/Electricity bill etc.) (optional)
- Partnership Deed/Affidavit of Proprietorship/Memorandum & Articles of Association towards the constitution of the firm. (optional) – For MoA – Three pages need to be uploaded (First page – Certification of incorporation, Second page – Authorization of food business activity and Third page – list of directors with addresses)
- Copy of certificate obtained under Co-Op Act – 1861/Multi State Co-Op Act – 2002 in case of Co-operatives. (Wherever applicable)
- NOC & Copy of License from manufacturer (mandatory for re-labellers and re-packers only)
- Food Safety Management System plan or certificate (if any)
- Source of milk or procurement plan for milk including location of milk collection centre's etc. in case of Milk and Milk Products processing units.(wherever applicable)
- Source of raw material for meat and meat processing plants. (wherever applicable)
- Pesticide residues report of water in case of units manufacturing packaged drinking water, packaged Mineral water and/or carbonated water from a recognised/ public health laboratory
- Recall plan wherever applicable, with details on whom the product is distributed. (optional)
- NOCs from Municipality or local body. (optional)

- Form IX: Nomination of Persons by a Company along with the Board Resolution.
- Certificate provided by Ministry of Tourism (HRACC) (Applicable for Hotels only)
- For Transporters-Supporting documentary proof for Turnover or self-declaration of number of vehicles
- Upload Production unit photograph
- Declaration form

Central License is required for FBO having an annual turnover of above 20 Lakhs

Documents required with Form B (Central License)

- Blueprint/layout plan of the processing unit showing the dimensions in metres/square metres and operation-wise area allocation (mandatory for manufacturing and processing units only).
- List of Directors with full address and contact details (mandatory for companies only)
- Name and List of Equipment and Machinery along with their number, installed capacity and horse power used (mandatory for manufacturing and processing units only).
- Photo ID and address proof issued by Government authority of Proprietor/Partner/Director(s)/Authorized Signatory. (optional).
- List of food category desired to be manufactured. (In case of manufacturers).
- Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, collection of samples, packing & dispatch. (Mandatory for manufacturing and processors).
- Analysis report (Chemical & Bacteriological) of water to be used as ingredient in food from a recognized/ public health laboratory to confirm the portability (mandatory only for manufacturing and processing units only).
- Proof of possession of premises. (Sale deed/ Rent agreement/ Electricity bill, etc.) (optional).

- Partnership Deed/Affidavit/Memorandum & Articles of Association towards the constitution of the firm. (Optional).
- Copy of certificate obtained under Co-Op Act – 1861/Multi State Co-Op Act – 2002 in case of Co-Operatives. (Wherever applicable).
- NOC from manufacturer (mandatory for Re-labellers and Re-packers)
- Food Safety Management System plan or certificate (if any).
- Source of milk or procurement plan for milk including location of milk collection centre's etc. in case of Milk and Milk Products processing units. (Wherever applicable). Source of raw material for meat and meat processing plants. (Wherever applicable). Pesticide residues report of water in case of units manufacturing packaged drinking water, packaged Mineral water and/or carbonated water from a recognized/ public health laboratory.
- Recall plan wherever applicable, with details on whom the product is distributed. (Optional). NOCs from Municipality or local body. (optional).
- Supporting document proof for turnover, NOC/PA document issued by FSSAI, IE Code document issued by DGFT
- Form IX Nomination of persons by a company along with the board resolution
- Declaration form

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

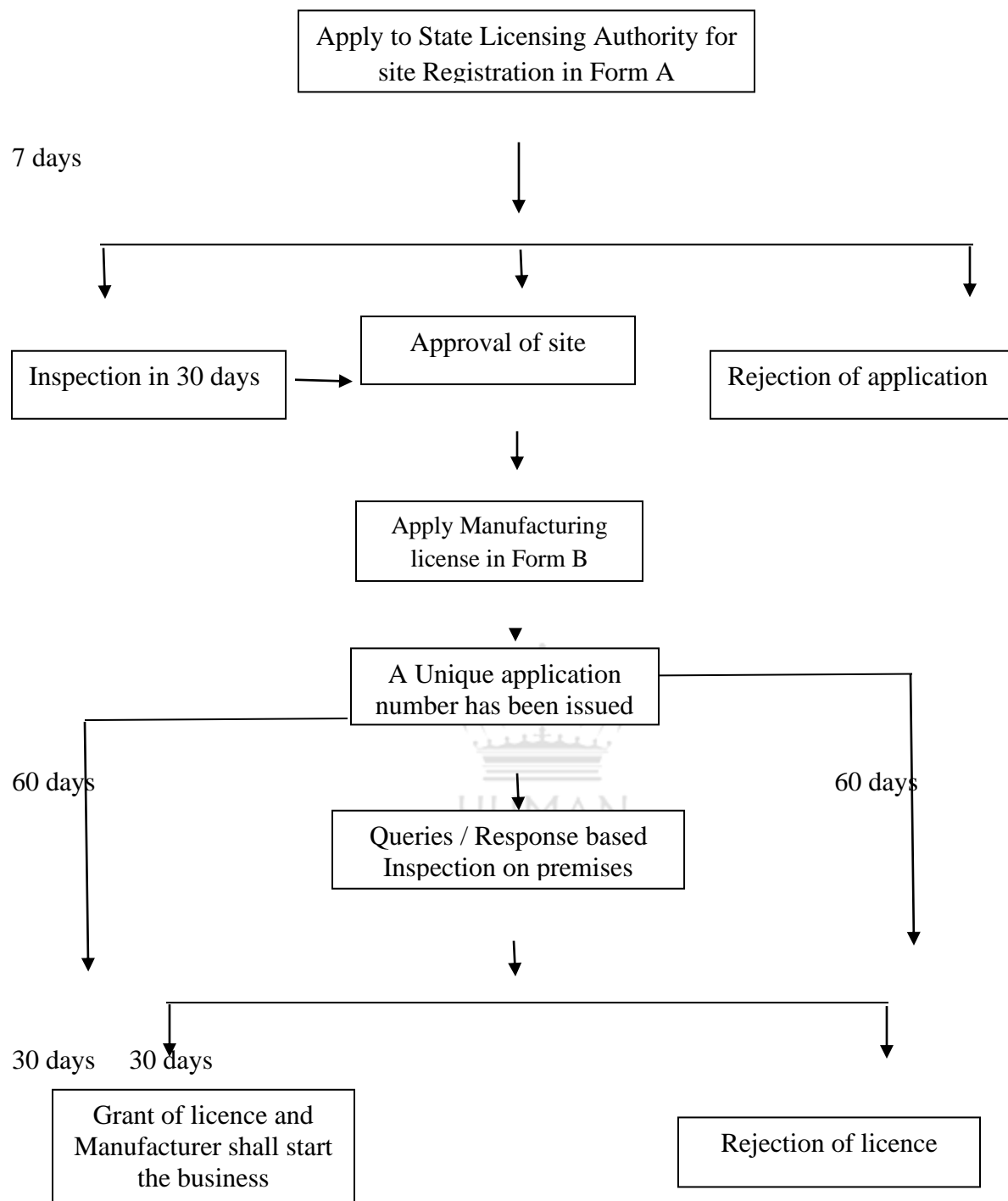


Fig. No. 3 FSSAI Licensing process

Food Import Clearance Process

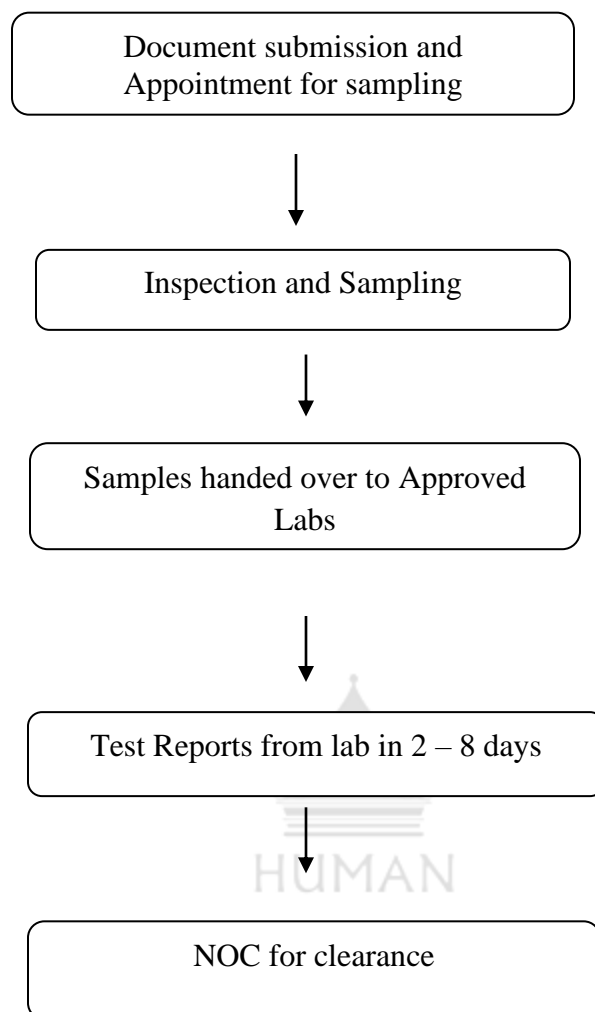


Fig.4 Food import clearance process

Web based Food Import Clearance System

- It facilitates CHA's / Importers to:
 - To Register online
 - Apply for NOC without visiting any FSSAI Office and make payments for testing
 - Track status of their application
- It facilitates FSSAI Authorized Officers / Inspectors to:

- Process applications for NOC
- Ensure timely sampling and inspection.
- Generate No Objection Certificate (NOC)
- It facilitates Labs to:
 - Update test results in the system
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 - Communicate with other labs
- It facilitates FSSAI HQ to:
 - To monitor the overall operations of the ports. Analyze the risk associated with importing countries.
 - Generate MIS reports.



Clearance of Imported Food by the Food Authority⁹

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

- (a) the Authorised Officer shall scrutinise the Form and may seek clarification if required
- (b) upon satisfactory scrutiny, the applicant shall pay the fees as specified by the Food Authority for scrutiny of documents, visual inspection and drawing of sample
- (c) where a single bill of entry is made up of articles of food consignment consisting of multiple categories of articles of food, inspection fee shall be paid for each category of articles of food
- (d) the Food Authority shall specify and review the inspection fee from time to time
- (e) on receipt of the fees, the Authorised Officer shall intimate the details of date and time of inspection to the Food Importer to facilitate the presence of the Food Importer or his Customs House Agent/Authorised representative at the time and place of inspection.

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

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

The report of the visual inspection shall be submitted in FORM – 1.

Food Import Clearance Process (FICS) of FSSAI

The Food Import Clearance System (FICS) is an online system which is seamlessly integrated with the Customs ICEGate (i.e., Indian Customs Electronic Commerce/Electronic Data interchange (EC/EDI) Gateway) through SWIFT (i.e. Single Window Interface for facilitating Trade) to allow a single window interface that provides an opportunity to the importers to file an application for easy clearance of food consignments.

- As, it is a web enabled system hence, can be accessed 24*7 by the importers.
- The applicable fees like lab testing fees can be deposited online.
- The appointment for joint Visual Inspection of the consignments also takes place through the same online system.
- The samples are also online referred to the laboratories through FICS.
- It also facilitates auto intimation of No Objection Certificate/Non-Conformance Report to the importers & the customs on real time basis.
- It also acts as a repository of all information related to food import data.

- It enables quick & easy generation of reports in different forms/format.

Food Imports¹⁰⁻¹⁵

Food products are imported from countries such as UK, Canada, USA, Australia, Russia, Germany, Indonesia, France and New Zealand. Thus, to ensure compliance to standards for imported food products, a robust and streamlined import clearance system is required.

For ease of doing business, FSSAI has integrated its Food Import Clearance System (FICS) with ICEGATE system of Customs under Single Window Clearance Interface to Facilitate Trade (SWIFT) at Delhi, Mumbai, Kolkata, Chennai, Kochi and Tuticorin covering 21 locations. To maintain parity of testing and import clearance at all the ports where FSSAI is not present, officials of custom department have been notified as Authorized Officers on 136 locations.

FSSAI import samples are sent to the labs which are NABL accredited. To streamline the functioning of labs for reducing the time taken in testing. 131 NABL accredited labs have been notified for testing of imported samples. Apart from this, 16 referral labs are also notified for re-testing of import samples. Customs in consultation with FSSAI has introduced Risk Management System (RMS) under which the testing and analysis of imported food is limited and reduced.

Licensing of Food Importers

1. No person shall import any article of food without an import license from the central licensing authority in accordance with the provisions of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.
2. The food importer shall register himself with the Directorate General of Foreign Trade and possess valid Import-Export Code.

Health claims and label claims:

It is very much required to know the regulatory frames of nutraceuticals which is different from other countries. All the health as well as label claims should be notified and followed very carefully.

- India has its specific packaging as well as labeling requirements

- Packaging also need to show up their components of the consignment along with the same need of the sample product to get it packed according to Indian specification.
- Content which has to be included in the claim.
- Structure claim
- Functional claim

Compliance with standards for packaging and labeling:-

(1) No food importer shall import articles of food that is not transported, or stored in optimal storage conditions of temperature and hygiene, packaged and labelled as per the regulations applicable to that particular article of food.

(2) Any consignment of food or multiple foods or food falling under different categories packed in a single container or carton or pallet or skid, shall be packed in such a manner that the Authorized Officer has easy access to all of them for inspection and sampling.

(3) If there is no proper stuffing list in respect of article of food, the Authorized Officer shall direct the customs officer to issue an order for de-stuffing the container and facilitate the de-stuffing, in order to facilitate inspection and sampling.

(4) In case of imported packaged food consignments, the following special dispensation on labelling shall be allowed for the rectifiable labelling deficiencies at the custom bound warehouse by affixing a single non detachable sticker or by any other non detachable method next to the principle display panel namely:-

- (a) Name and address of the importer
- (b) Food Safety and Standards Authority of India's Logo and license number
- (c) Non-Veg or Veg Logo

(5) Category or sub category along with generic name, nature and composition for proprietary food. In respect of the rectifiable labelling deficiencies referred to in sub-regulation (4), the Authorised officer may pass an order directing the Food Importer or his authorised agent to carry

out the permissible labelling rectifications, within a specified time in the customs area without altering or masking the original label information in any manner.

(6) On rectification by the Food Importer, the Authorised Officer shall carry out a re-inspection of the articles of food and if satisfied, draw the sample, subject to all other conditions being fulfilled by the Food Importer.

(7) In case the Food Importer fails to rectify the permissible defects referred to in sub-regulation (4) within the specified time, the Authorized Officer may pass an order refusing clearance of such imported articles of food and issue a nonconformance report.

(8) If the Authorised Officer is satisfied that the Food Importer has complied with the provisions of these regulations, the Authorised Officer or his representatives shall draw two parts of food sample from the imported articles of food in the customs area in the presence of Food Importer or his Customs House Agent for testing the samples.

(9) If the food analyst seeks additional information on ingredients or on any other parameters after receipt of the food sample, the Authorised Officer shall direct the Food Importer to provide such information duly supported by documentary evidence.

(10) The Authorised Officer shall reject the consignment not complying with the provisions of Labelling and Packaging Regulations, 2011 at the visual inspection and no sample shall be drawn from the consignment.

REFERENCES

1. Central Drugs Standard Control Organization (CDSCO) Import & Registration Division Guidance Document on Common Submission Format for Import and Registration of bulk drugs and finished formulations in India (2011) <http://www.cdsc0.nic.in/writereaddata/Guidance%20documents.pdf>
2. Senthil V et al. (2015): Regulatory process for import and export of drugs in India. IJPSR, Vol. 6 (12) : 4989 – 4999
3. Ganesh GNK et. al Nutraceuticals – A Regulatory review. International Journal of Drug Regulatory Affairs 2015, 3 (2). 22 – 29
4. Make in India Pharmaceuticals and Biotechnology sector (2018) www.makeinindia.com/sector/pharmaceuticals
5. Dietary supplements Market 2016: Industry analysis, Market segments, Key company's profiles forecast to 2027 <https://marketersmedia.com/dietary-supplements-market-2016-industry-analysis-market-segments-key-companys-profiles-forecast-to-2027/142881>
6. India in Business, Investment and Technology Promotion Division, Pharmaceuticals (2016)
7. Brand Equity Foundation [IBEF], Indian Pharmaceutical Industry (2016) <https://www.ibef.org/industry/pharmaceutical-india.aspx> Accessed on 20.12.2018

8. Prerna K. Ratnaparkhi et. al (2015): Nutraceuticals – Its current scenario and challenges in dietary supplements on World Journal of pharmacy and pharmaceutical sciences World Journal of Pharmacy and Pharmaceutical Sciences 4 (7). 460 - 474
9. Jain P, Rathod M, Jain V, Vijayendraswamy S. Current Regulatory Requirements for registration of Nutraceuticals in India and USA. International Journal of Drug Regulatory Affairs 6(2):22-9
10. McKinsey & Company, India Pharma 2020 Propelling access and acceptance, realising true potential, Pharmaceutical and Medical Products Practice (2016).
11. Nandedo Shinde et. al Nutraceuticals: A review on current status. Research Journal of Pharmacy and Technology 7 (1): January 2014. 110 - 113
12. Shridhar Met. al., The newer dimensions of nutraceuticals in the prospective of its validation – A review., ejpmr, 2016, 3(4), 152 - 162
13. Food Safety and Standards Authority of India, Regulations, Notification on The Gazette of India (2016) Food or Health supplements, nutraceuticals, foods for special dietary uses, foods for special medicinal purpose, functional foods and novel foods. https://www.fssai.gov.in/dam/jcr:6f183856-e806-4ff9-87ca-a4c257e69e49/Nutraceuticals_Regulations.pdf
14. Food Safety and Standards (Import) Regulations, 2017.
15. BDP's Customs Tariff with new import policy 2016 – 17.

