REVIEW

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REGULATORY GUIDELINES OF NUTRACEUTICALS IN INDIA AND EUROPEAN COUNTRIES

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ABSTRACT

Nutraceuticals are food supplementary substance and used to prevent diseases. Extensive research has been focused on nutraceuticals due to potential beneficial effects and therapeutic activities. A regulatory guideline is important to ensure the safety of public health. Each country is having different regulatory guidelines for nutraceuticals. This article mainly is focused to review the regulatory guidelines of nutraceuticals in India and European countries.

Keywords: Regulatory guidelines, Nutraceuticals, India, Europe

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INTRODUCTION: The term "Nutraceuticals" is the combination of these two words "Nutrition" and "pharmaceutical" coined in 1989 by Stephen DeFelice, MD, founder and chairman of the Foundation for Innovation in Medicine (FIM), Cranford, NJ. According to DeFelice, Nutraceutical can be defined as, "a food (or part of a food) that provides medical or health benefits, including the prevention and/or treatment of a disease.The phrase is applied to products that range from isolated nutrients, dietary supplements and herbal products, specific diets and processed foods such as cereals, soups, and beverages.[1]

Classification of Nutraceuticals[2]

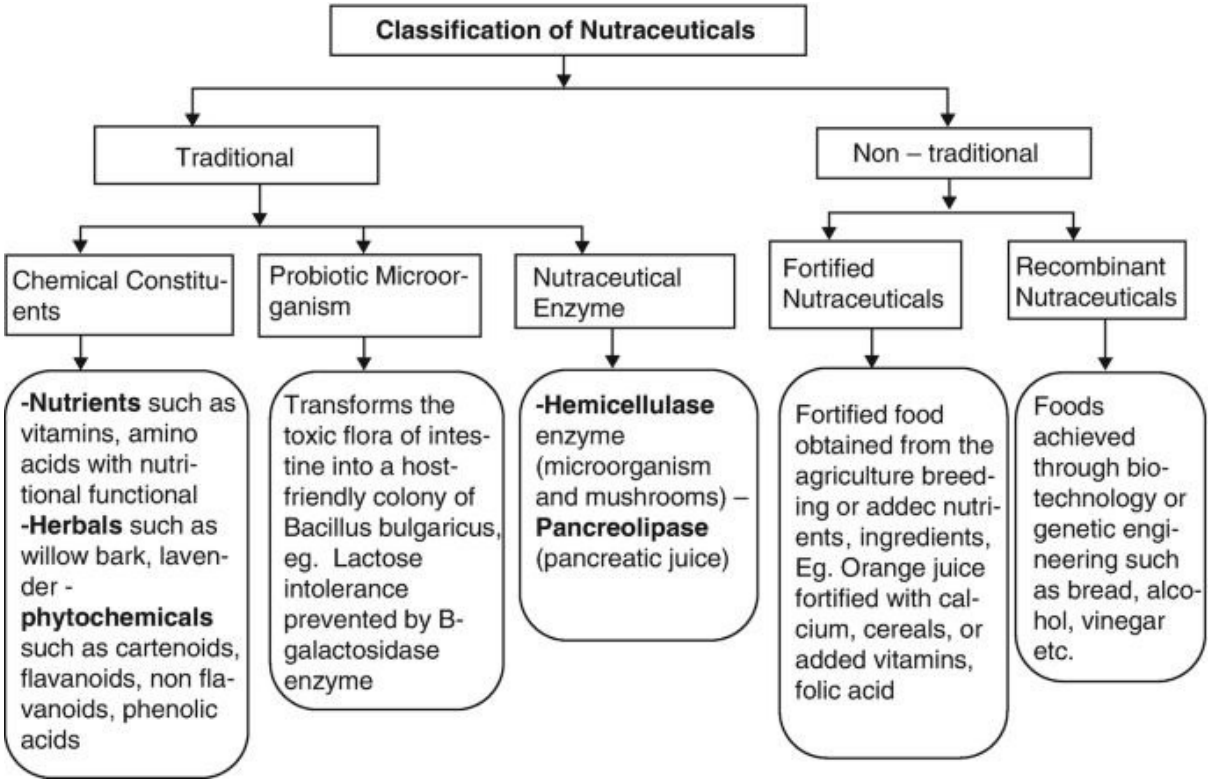

Figure 1: Classification of Nutraceuticals

Importance of Nutraceuticals Regulatory Guidelines

Increased numbers of patients with chronic conditions use nutraceuticals or food-based therapeutics. However, to date, there is no global consensus on the regulatory processes for nutraceuticals. With the increased use, issues of quality and safety have also arisen. This review summarises the current regulations held for nutraceuticals in the India and Europe jurisdictions using regulatory authority sites and databases. The efficacy and safety concerns, product development, gaps in regulation and challenges in ensuring product authenticity are also summarised. The data highlight the complexity that the globalisation of nutraceuticals brings with respect to challenges in regulation and associated claims regarding efficacy and safety. The development of an effective system with integrity is needed to increase vertical collaboration between consumers, healthcare practitioners, and government agencies and the development of international risk assessment criteria and botanical compendia. This will help in greater transparency and improved trust in the process and products. Emerging technologies could play a role in improving systems engineering by information sharing and leveraging the strengths of different countries. In conclusion, nutraceuticals have been poorly regulated leading to spurious claims based on little or no real evidence. This makes it difficult to separate meaningful results from poor data. More stringent regulation and an effective system of integrity are required to ensure efficacy and safety and enable the adequate

monitoring and increase consumer and healthcare professionals' confidence.[3]

The Nutraceuticals are the emerging sector in the Pharma Industry. As people are more and more concerned about their health and diseases caused by the malnutrition, the growth of the Nutraceuticals worldwide are inevitable. Despite of the growth and the need of the Nutraceuticals by global market there is no apparent regulatory definitions and pathways or procedures for the approval process of Nutraceuticals. The article deals with the regulatory perspective of Nutraceuticals.[4]Nutraceutical is a food or fortified meals product that supposedly offer medicinal or health benefits such as the prevention and remedy of disorder. Nutraceuticals have appeared as a requisite for consumers in developed as well as developing countries with diseases due to changing lifestyles. As nutraceuticals blur the border between food, medicine and health supplements, it is difficult, with the aid of legal definition, to differentiate between nutrients, meals components, drug and pharmaceuticals. Globally, regulatory authorities are converging on the product safety and quality as such products are destined for human intake. When food product reaches from one country to another, it becomes important to maintain safety and quality standards in compliance with the different regulatory guideline set by the respective government; which can be a real driver for the growth of the industry.[4]

REGULATORY GUIDELINES OF NUTRACEUTICALS IN INDIA

Nutraceuticals are not currently entitled by Indian law to any specific legal status. The Nutraceuticals Regulations of the Government of India include the Food Safety and Standards Act (FSSA), which was enacted in 2006 and is still to be applied. This comprises eight laws enforced by the Food Safety Commissioner According to FSSA, "food for special dietary use" is specially manufactured or designed to meet specific dietary requirements that exist due to a specific physical or physiological condition or specific diseases and disorders. Nutraceuticals are referred to in India as "Foods for Special Dietary Use." Food Safety and Standards Authority of India (FSSAI) describes nutraceuticals as "foods for specific dietary uses or functional foods or nutraceuticals or supplements for nutrition." Food Safety and Standards Act in India consolidates various acts and orders that existed in various ministries and departments to deal with food. FSSAI was established in related issues like to set science-based standards for food products and to regulate their manufacture, processing, distribution, sale and import in order to ensure the availability of safe and healthy food for human consumption. It therefore also refers to products 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 FSSA, 2006. [5]

LAWS GOVERNING - NUTRACEUTICALS

Nutraceutical have different names according to the country. The name even differs from region to region from Nutraceutical to dietary supplements and there are some countries which include Nutraceutical under the food umbrella. In general a dietary supplement is a substance which is administered orally that is made up of a dietary ingredient which is meant to be the add-on for the diet. Number of definitions and terms are used worldwide to denote Nutraceutical they are like Dietary supplement in USA, Canada calls it Natural Health Product, Australia uses the term Complementary medicines, European Union denotes it by the word Food Supplements, and in India it is known as Foods for Special dietary use.[6]

Food safety standard and standards act(FSSA): 2006

This act is laid down in 2006 in order to form the statutory body FSSA 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. Section 22(1) of FSSA, defines "foods for special dietary uses or functional foods or Nutraceutical or health supplements" as:

a) foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific

diseases and disorders and which 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, namely:
(i). 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.
(ii). 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);
iii. Substances from animal origin;
iv. A dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;
b)
(i) a product that is labeled as a "Food for special dietary uses or functional foods or Nutraceuticals or health supplements or similar such foods" which is not represented for use as a conventional food and whereby such products may be formulated in the form of powders, granules, tablets, capsules, liquids, jelly and other dosage forms but not parenterals, and are meant for oral administration;
(ii) 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 there under;
(iii) 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 the regulations made under FSSA;
(iv) does not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 and rules made there under and substances listed in Schedules E and E(I) of the Drugs and Cosmetics Rules, 1945.[7]

REGULATORY REQUIREMENT IN INDIA [8]

Product Evaluation
Analysis of every active Ingredient and Additive
Various steps in product evaluation include

• Developing extracts of documents
• Sample collection (in the presence of witnesses)
• Sample dispatch to the concerned authority
(different processes for bulk package and single package)
• Food analysis
1. If analysis is not complete within the stipulated period of time, further action
plan by the designated officer,
2. Proceedings for adjudication (holding investigation, appeal, hearing, etc.)

LICENSES

In order to obtain product licensed in India, a number of licenses (nearly 4-5) may be required, including:
• Import licensing
• Manufacturing licensing
• Marketing licensing and
• Other regulatory-required state and national clearances/ licenses to be taken care of before launching such products in India. Health and Tag Claims "Health claims" includes any description that says, indicates or implies the existence of a relationship between a food or a portion of that food and health. It includes:
• India specific requirements for labeling and packaging
• Packaging of consignment composition and the same approach to marketing
• Criteria for test content and registration declaration.

REGISTRATION PROCESS IN INDIA [9]

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

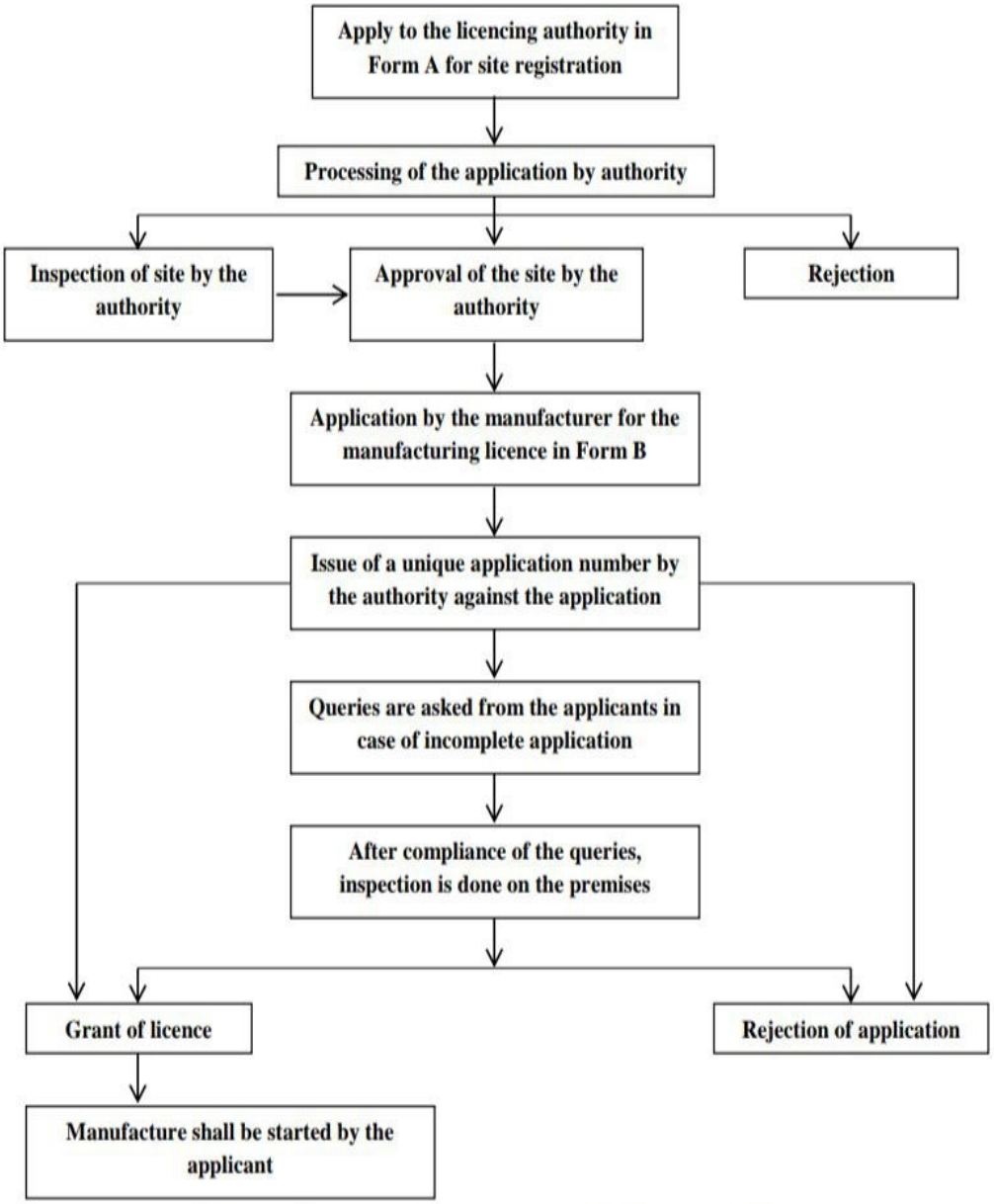

Figure 2: Nutracueticals registration process in India

INDIAN NUTRACEUTICALS MARKET

The two billion dollar Indian Nutraceutical market is subdivided into two main categories;
Functional foods and beverages and Dietary Supplements.

(i) Functional Foods and beverages

This category covers almost 60% of the total market. According to WHO the fortified food is referred to the addition of micro-nutrients to the processed food. This includes all the sports drinks, fortified drinks, fortified juices, fortified foods and Energy drinks.

(ii) Dietary supplements

This category covers up the remaining 40% of the Indian Nutraceutical market. This class includes Vitamins and Minerals supplement, herbal supplement, protein supplement and Chyawanprash also included in this category.[10]

REGULATORY GUIDELINES OF NUTRACEUTICALS IN EUROPEAN COUNTRIES (GERMAN, FRANCE, BELGIUM, ITALY)

Nutraceuticals include a wide range of substances that can be used as medicinal products, feed material, or feed additives. This makes a substantial difference in the regulatory aspect of the marketing authorization in the European Union (EU) because

for obtaining the appropriate marketing authorization, different procedures have to be followed. Since specific regulations do not apply to nutraceuticals, when they are used as feed additives for animal nutrition, they shall comply with Regulation No 1831/2003 on additives for use in animal nutrition. While nutraceuticals are administered as feed ingredients, they must comply with Commission Regulation (EU) No 68/2013. If nutraceuticals are administered with medical claims or if they exert a pharmacological effect, their use must comply with Directive 2001/82/EC. The EU legislation on this topic is very detailed and complex. Nevertheless, it allows the obtaining of marketing authorization with a wide safety margin, precautionary for animal health, human health, and the environment. The Scientific Committees and panels of the European Food Safety Authority (EFSA) are responsible for producing opinions that are used by the European Commission to adopt legislation related to animal nutrition. For veterinary medicinal products, the responsibility for marketing authorization is both granted by competent national authorities of the Member States or by the European Medicine Agency (EMA). This chapter describes legislation that is relevant to the marketing authorization of nutraceuticals for animals in the EU, elucidating the different categories of use, i.e., feed materials, feed additives, and veterinary medicinal products.[11]

Regulation of Food Supplements in European Countries

In Europe, food supplements are "foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological function, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities."Safety and Efficacy of Food Supplements are evaluated by the European Food Safety Authority (EFSA), an entity set up in January 2002 as an independent source of scientific advice that produces opinions which then are used by the European Commission to adopt legislation.Most relevant for companies in the food supplements sector, EFSA has also been tasked by the European Commission to evaluate proposals for the addition of vitamins and minerals to the Food Supplements Directive and to evaluate nutrition and health claims. EFSA has worked with the European Commission on assessing how to establish maximum limits for vitamins and minerals in food supplements and fortified foods, and provided opinions on substances other than vitamins and minerals. EFSA works in close collaboration with national authorities and in open consultation with its stakeholders.Natural Immunogenics is actively working on the data compilation requested by the EFSA, to assess the toxicological profile of Silver Hydrosol. Guidance documents from EFSA were released in July 2018, and NIC has targeted early 2020 to present the irrefutable evidence of silver hydrosol safety. It is important to note that some of the assays require months of evaluations and several hundreds of thousands of dollars. In the meanwhile, silver hydrosol remains available in the EU as a product for external use.[12]

EUROPEAN NUTRACEUTICALS MARKET GROWTH

The Europe nutrition and supplements market size was valued at USD 61.8 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 5.8% from 2022 to 2030. Europe's population has become more aware of health and fitness and has been increasingly adopting nutritional supplementation for achieving their dietary goals. The demand for natural and organic products has grown, and so has the demand for plant-based products and functional foods owing to the rapidly increasing geriatric population across the sub-continent. People are increasingly incorporating nutraceutical foods and beverages involving prebiotics, omega 3 etc into their diet to minimize the risk of diseases like cardiovascular diseases, diabetes, and other chronic diseases, which is positively impacting the growth of the European market.[13]

RESULTS AND DISCUSSION

Regulatory guidelines of nutraceuticals in India and European Countries was studied and comparative study was done.

Table 1: Comparative Study of Regulatory guidelines of Nutraceuticals in India and European Countries

COUNTRY	INDIA	EUROPE
Definition	FSSAI define food for special dietary use.	Nutraceutical regulated as food supplement.
Rules/Regulations for licensing and registration	Food safety standard authority India.	European food safety authority, Law of member state.
Regulation came into force in year	2008	2002
Responsible regulatory authorities for registration of nutraceuticals	FSSAI	Directive 2002/20/EC, Parliament Member States, Commission's Health and Consumer Protection Directorative.
Fee for registration	Rs100	Not defined
Authorities for approval of claim	FSSA	-member state -commission's Health and consumer protection directorate -EFSA
Health claim	-Nutrient function claim -Different nutrition characteristic claim -Reduction of risk claim.	Nutrition and fitness claim will handiest be allowed on food labels if they are covered in one of the EU tremendous lists.
Regulatory requirement for Registration	-Product Evaluation -Licensing -Health and Label claim.	-Novel food -Organic food -Food stuffs with nutrition.
Responsibility	-FSSAI of India is solely responsible for regulating the approval, promotions and labelling standards for health supplements and nutraceuticals	-Regulated by the EFSA, an independent agency responsible for scientific advice, risk assessment and for developing procedures for emergencies to ensure safety
Product Characterisation	-Food that provide medical or health benefits including the prevention and treatment of disease. -	-Food ingredient or medicinal substance depending on the effect on the body. -Comprise a board range of products that can be used for feed materials,feed additives or medicinal purpose.
Nutraceutical products	-Vitamin E capsule -Vitamin D -Green Tea -Selenium -Lycopene	-Vitamin Gummies -Protein Bars -Energy Bars -Cod liver oil -Lutein

The Nutraceuticals Regulations of the Government of India include the Food Safety and Standards Act (FSSA), which was enacted in 2006 and is still to be applied. This comprises eight laws enforced by the Food Safety Commissioner According to FSSA, "food for special dietary use" is specially manufactured or designed to meet specific dietary requirements that exist due to a specific physical or physiological condition or specific diseases and disorders. India has well defined regulatory guidelines and registration process for all nutraceuticals under government authorisation.

In European Union (EU) food law, a regulatory framework and registration for "functional foods" or "nutraceuticals" does not exist. The rules are numerous and depend on the nature of the foodstuff. According to EU regulations, claims regarding the beneficial effects of nutraceuticals can only be "health claims" and not "medicinal claims".

CONCLUSION

This study concluded that comparative study on regulatory requirements of nutraceutical products can help to know the regulatory authorities for registration of nutraceuticals and to focus marketing of new nurtaceutical products in India and Europe countries.

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