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REGULATORY REQUIREMENT AND STRUCTURAL FRAMEWORK FOR NUTRACEUTICALS AND FUNCTIONAL FOODS IN EUROPEAN UNION

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ABSTRACT

Nutraceuticals contains a range of substances that was originally coined in 1989 by Stephen DE Felice, founder and chairman of the Foundation for Innovation in Medicine from the words 'nutrition' (eating habits and how they impact your health, efficiently and rapidly deliver your material) and 'pharmaceutical' (associated to the manufacture of pharmaceuticals and treatments). The definitions of functional foods, nutraceuticals, and bioactive substances are made explicit in this review article. Dietary Supplement and Health Education Act marked the birth of the nutraceutical concept in the United States. It appears that it is impossible for all EU member states to consistently enforce the same standards for all pharmaceutical products are made clear. Nutraceuticals, food/functional ingredients, and bioactive substances are not as a whole controlled at the European level, as was previously stated. The EU's initial practical application dates back to 1951, it took more than 20 years before the first legislations rules with a focus on food were introduced. Dietary/food

supplements are governed by the European Commission's Food Supplements Directive 2002/46/EC. According to the Directive, supplements must be shown to be both amount and quality safe as well as available for body use. They are subject to the same regulations as food supplements, with a particular emphasis on vitamins and minerals. The procedure for EU food safety and authorization is described below with the appropriate citations. In the middle of the 1980s, Japan is where the phrase "functional foods" first appeared to describe processed foods with nutritional value as well as components that support particular physiological processes.

Keywords: European Union, Nutraceuticals, Functional Foods, Food Supplements

1.INTRODUCTION:

Nutraceuticals contains a range of substances that was originally coined in 1989 by Stephen DE Felice, founder and chairman of the Foundation for Innovation in Medicine the words 'nutrition' (eating habits and how they impact your health, efficiently and rapidly deliver your material) and 'pharmaceutical' (associated to the manufacture of pharmaceuticals and treatments) [1]. Hippocrates, considered the father of medicine, said "Let food be the medicine and medicine be the food," therefore the idea that meals can have therapeutic effects is not new [2]. Although food has long been used as medicine, dating back to the Indians and Hippocrates, and nutraceuticals have a centuries-long history. The studies used by the European Commission to suggest rules for nutraceuticals and botanicals are produced by the scientific committees and panels of the EUROPEAN FOOD SAFETY AUTHORITY (EFSA) [3]. Since the early 1990s, there has been a geometric increase

in the commercial distribution of nutraceuticals, and it is predicted that the market and industry will reach \$800 billion in 2023. The EU functions under the tenets of an unified internal market, complete harmonisation, and reciprocal recognition [4]. For Risk Management and Communication EFSA is important. Food or food constituents that have specific physiological benefits are known as the "Nutraceuticals" [5]. They frequently exist in a legal between the two categories of food and drug since they are difficult to classify as either. Nutraceuticals do not yet have a defined definition that is specific to them, unlike other food-derived categories such as feed additives, medicinal herbs, pre and pro-biotics, functional food ingredients, and fortified foods. The term "Nutraceutical," despite growing in popularity, still carries some ambiguity because it has regularly been misused or used dishonestly to describe a variety of products, including food and food products,

nutritional supplements, processed food, food ingredient, enhanced food, and medicative herbs/botanicals, among others. Nutraceuticals are now being acknowledged on a global scale as having the ability to improve health when included frequently in a varied diet and at appropriate doses). If nutraceuticals are used as feed components, they must abide by Commission Regulations (EU) No. 68/2013. (EU 2013) [6]. General terms,

there may be a shortage of scientific data to back up many of the current health claims made about the security, effectiveness, and effects on clinical or physiologic states of food supplements, pro- and pre-biotics, herbal supplements, and functional foods [7]. Botanical nutraceuticals face difficulties in the EU with regard to quality, safety, claims, and the resolving of grey areas [3].

Table 1: General difference between Fortified foods and Ayurvedic Nutraceuticals

TERM	DEFINITION	REFERENCE
Nutraceutical	<p>Anything that is a food or a food ingredient that has medicinal or health benefits, such as the ability to treat or prevent disease. These items might include everything from isolated nutrients, dietary supplements, and particular diets to designer meals made through genetic engineering, herbal products, and processed foods including cereals, soups, and drinks.</p> <p>It's vital to emphasise that this term covers all types of food and food components, from chicken soups consumed to ease common cold pain to dietary supplements like folic acid needed to prevent spina bifida.</p> <p>A bio-engineered designer veggie food, one that is high in antioxidant components, and a food that contains stimulants.</p>	[8]
Functional foods	<p>Many steps are involved in the creation of functional foods from the first concept to its implementation in the market. The goal of the current review is to describe the procedures used at each of these stages, starting with the conversion of an important idea into a workable prototype that can be sold. Such prototypes then need to undergo animal and human proof-of-concept testing to evaluate their efficacy and safety.</p> <p>The publication of efficacy and safety data boosts the credibility of functional food products and also prepares the road for regulatory approval and the development of health claims.</p> <p>Acceptance of health claims by consumers and their availability increases market presence for functional food companies, which in turn spurs efforts to create new products.</p>	[9]
Bioactive Compound	<p>The ingredients in foods or dietary supplements known as "Bioactive food components" are those that affect one's health without necessarily meeting one's basic nutritional needs.</p> <p>A sort of chemical that is present in trace amounts in plants and some foods, such as fruits, veggies, nuts, oils. Bioactive chemicals can improve health through their physical effects.</p> <p>They are being studied in an effort to fend off diseases like cancer, heart disease, and others.</p>	[10]

FORTIFIED FOODS	AYURVEDIC NUTRACEUTICALS
<ul style="list-style-type: none"> Sliced Bread- Fortified Folic Acid 	<ul style="list-style-type: none"> Brahma Rasayana (for protection from mental stress)
<ul style="list-style-type: none"> Orange Juice- Fortified with Calcium and Vitamin D 	<ul style="list-style-type: none"> Phala Ghrita (for reproductive health)
<ul style="list-style-type: none"> Rice - Fortified with Iron 	<ul style="list-style-type: none"> Arjuna Ksheerpaka (for cardioprotection)
<ul style="list-style-type: none"> Almond milk- Fortified with Calcium, Vitamin A and Vitamin D 	<ul style="list-style-type: none"> Chyavanprash (to promote general well-being and prevent respiratory diseases)

2. EUROPEAN UNION IDEA OF NUTRACEUTICALS:

The initial form of the nutraceutical idea and products was significantly influenced by the (DSHEA, 1994), which was invented in the U.S. in 1994 and has since allowed for actions necessary and distorted the distinctions between foods and meds existing in other parts of the world. A dietary supplement is allowed by the DSHEA to contain "an herb or other botanical" as well as "a concentration, metabolite, constituent, extract, or combination of any substance from the other categories." AESGP, the European Association of the Self-Medication Industry, conducted a research on 1998 conducted on request of the European Commission, and the results showed that numerous EU member states appeared to have difficulties uniformly enforcing uniform norms across the board for all pharmaceutical goods. According to a paper titled "Herbal Medicinal Products in the European Union," none of the 15 member states consistently applied the herb provisions of the Medicines Directive 65/65/EEC (AESGP, 1998) [11].

The fundamental legislative actions of basic European law are directives and regulations. To understand how European legislation influences the systems of law of the EU member states, consider the different legal effects that rules and directives may have. Regulations frequently include very explicit provisions. They are self-executing inside each of the member states, therefore they take effect right away without the need for further execution of acts. Because they are not immediately applicable inside the member states, directives must be implemented by the specific addressee member states in the event of minor exceptional situations.

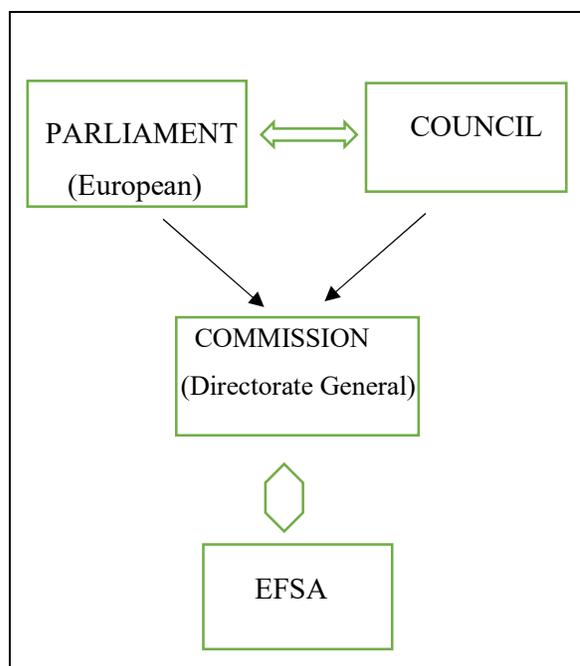


Figure 1: EU Law Procedure

3. EUROPEAN REGULATORY FRAMEWORK:

- The EFSA and the basis for food safety are also established by the European Union 's general Food Legislation (Regulation (EC) No. 178/2002), which oversees all facets of food legislation at the European level [12].
- This guideline also embodies the "Precautionary principle," the cornerstone of judgement in nutrition circumstances when uncertainties exist.
- For individuals who want to review the application of this idea, the study by van der Roest *et al.* (2003) is advised.
- Nutraceuticals, food/functional ingredients, or bioactive substances are not as a whole controlled at the European level, as was previously stated.
- Each type of bioactive chemical that is suitable for inclusion in food may be subject to one (or more) regulations [10].
- If the EU's initial practical application dates back to 1951, it took more than 20 years before the first legislations rules with a focus on food were introduced.
- The only recognised nutrients listed in Directive 2002/46/EC are vitamins and minerals.

- Dietary/food additives are ruled by the European Commission's Dietary Supplements Directive 2002/46/EC.
- According to Directive, dietary additives must show to be both of the amount and quality safe as well as available for body use.
- The Food supply Chain and Animal Health Care Standing Committee, which was established by Regulation (EC) No 178/2002, established a so-called "positive list" of vitamins and minerals that may be used in the production of food supplements in order to implement the directive in 2002 (Annexes I and II of the Directive) [10], [13][14].
- In the EU, dietary supplements are subject to the same regulations as foods, with a particular emphasis on the vitamins and minerals they contain [15].

4. EU FOOD SAFETY:

- I. The EFSA was created in 2002, and Parma, Italy, serves as its administrative centre. It consists of a management committee, an executive director and personnel, a technical committee, an advisory council, and other committees for different food safety-related topics. Risk management strategy in place are the two key EFSA duties. Despite receiving money from the EU budget, it operates independently to maintain openness and transparency.
- II. The quick alert system is used to notify the network of Member States, the Commission, and EFSA of any risk to human health. Any action that Member States take in relation to a specific product or any risk management advice they receive from operators must be reported to the Commission. This includes any denial of food or feed by the authorities of a Member State or an EU border crossing [3].
- III. Claims made under Article 14 of the EU Regulation about improving child development or health and reducing disease risk.
- IV. Normative parameters for nutritional profiles [16].

5. EUROPEAN AUTHORISATION PROCEDURES IN NUTRACEUTICALS:

Under the European Novel Foods Regulation (EC) No. 258/97 of the EU Parliament and of the Council of January 27, 1997 governing new ingredients and foods, nutraceuticals and nutraceutical products may be subject to the same risk analysis process as that applied to novel foods. Before being sold, certain foods and ingredients must pass a safety evaluation conducted by the Community. But when Member States express concern over issues

related to food safety, the Community's risk analysis system is activated. Initially, Regulation (EC) No. 258/1997 covered foods and food products made from, the absence of genetically engineered organisms as defined by Directive 90/220/EEC, as well as food products made from these organisms. However, the recent arguments made by the Standing Committee over what constitutes "substantial usage" may indicate that we are not moving toward a more straightforward and straightforward method, but rather toward a more expansive use of the authorisation procedure. Instead of a Novel Food Regulation, it appears that we will end up with a New Use Regulation [17].

6. EUROPEAN UNION FOOD LAW:

The procedures that permit the marketing of new substances in "functional food", "nutraceuticals" are covered by rules of EU food legislation. Food contact materials are likewise subject to European union food law.

The majority of laws that made up the European union food law are regulations, such as Regulation (EC) 1333/2008 on food additives and Regulation (EC) 1924/2006 on food labelling made on foods, which do not need to be implemented as national law in Member States.[18]

The procedures that permit the marketing of innovative substances in "functional

food" and "nutraceuticals" are covered by rules of EU food legislation. Food contact materials are likewise subject to EU food law [19].

While retaining their own laws, members are required to enact the entirety of European law. EU legislation takes precedence over national laws when they contradict [20].

7. BOTANICALS:

All primarily entire, broken up, or chopped plants, parts of the plant, algae, fungus, and moss in their natural state, typically dried but occasionally fresh. Also considered to be herbal compounds are amount of harmful that have not experienced a specific treatment. The botanical name and the part of the plant that is used to manufacture a herbal substance are used to define exactly it in accordance with the binomial classification (genus, species, variety, and author).

8. FUNCTIONAL FOODS:

Although the current idea of functional meals began in Japan in the middle of the 1980s to describe prepared meals that contain substances which support certain furthermore, physiological processes to having nutritional value.it has been spreading throughout the world. Functional food definitions have so far been presented by a variety of governmental authorities, academic institutions, and business organisations [21].

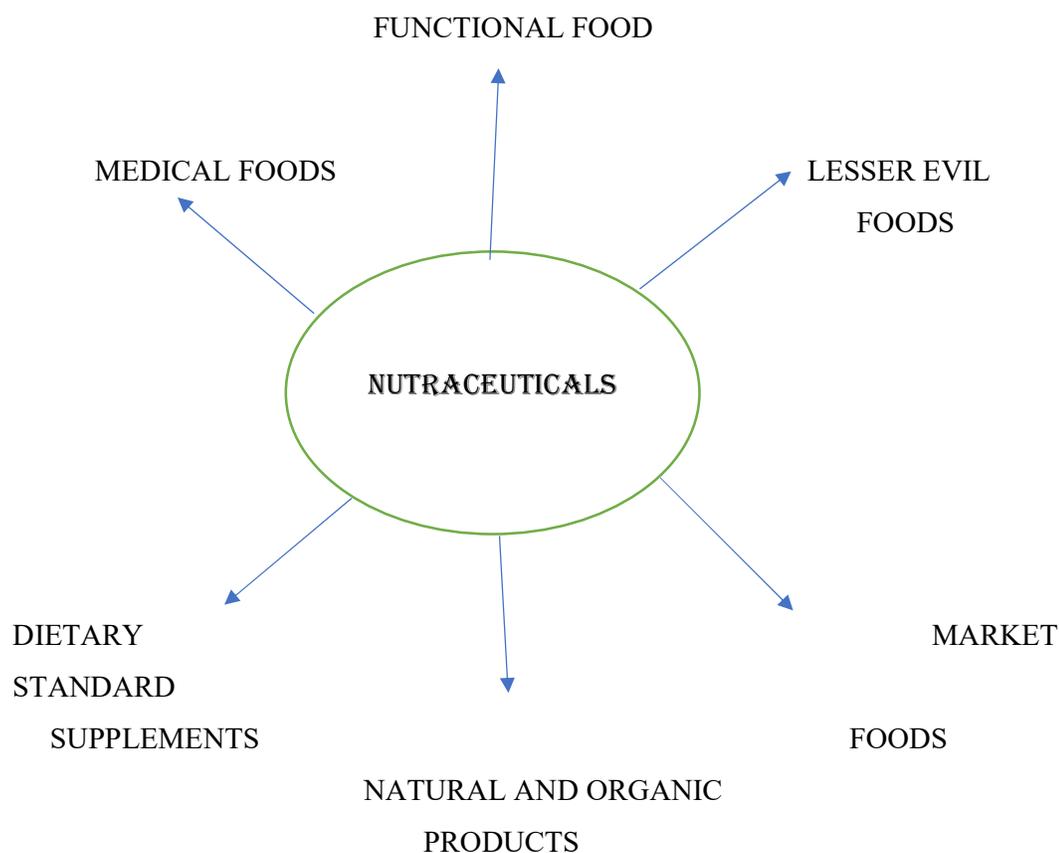


Figure 2: Types of Nutraceuticals

9. REGULATION ON FUNCTIONAL FOODS IN EU:

1. It is challenging to analyse the legal framework supporting the functional food industry or, more broadly, the category of nutraceuticals. In reality, there is currently no specialised body of law for these products in the European Union. However, it would have a relatively complex structure. The most important requirement is to clearly define these references.
2. Functional foods are goods that do not fit the definition of "food" as it is generally understood and, in countless ways, are extra closely related on fields of pharmaceuticals and/or cosmetics. As a result, their origin continues to be somewhat ambiguous.
3. Just consider how a beauty product might work to improve one's look or protect one's body's natural well-being while also keeping it in good condition. These advantages associated with foods high in

antioxidants are obviously similar to these functions.

4. Although they differ primarily in how they have been used and benefits they provide, comparable to the underlying active component [22].
5. As a result, the EU Members adhere to their own national legislations in the absence of uniform EU law. This, however, can result in significant disparities in how materials are viewed after crossing borders; occasionally, legislation places a product in one group in one nation, but categorised differently in other European nations, which poses significant trade challenges [23].

10. CLAIM MADE BY THE EUROPEAN COMMISSION AND THE EUROPEAN FOOD SAFETY AUTHORITY:

10.1. Nutrition Claim: Any assertion that a product has specific nutritional benefits because of the amount of energy (carb value) it provides, provides at a decreased or higher rate, or does not provide, as well as the amount of nutrients or other substances it includes, contains in a decreased or increased proportion, or does not contain such a percentage.

10.2. Health Claim: Any argument that there is a link during a certain dietary

category, a specific food, or perhaps its contents and health is referred to as a health claim.

10.3. Claim that disease risk has decreased: Any health claim which asserts, implies, or suggests that consuming a certain food group, food, or one of its components knowingly lowers a risk factor for developing a disease in humans [24].

11. CURRENT LAWS GOVERNING FOOD, NUTRITION AND HEALTH CLAIMS:

Every European Union Member State also has their individual law governing food health claims prior to the implementation of new EU regulations in 2006. A voluntary standard for food health claims was created by a number of nations, including the Netherlands and the UK. The first requirement was that the assertion must be supported by generally recognised scientific evidence. There's been increasing issue that the member states' divergent assertions might lead to misleading claims and trade barriers.[24]

12. FDA CLAIM VS EFSA CLAIM:

There are many reasons why the functional food sector is growing, among them. a deteriorating regulatory framework that permits health claims on foods, an ageing population with rising health concerns. The FDA's position on how to handle certain claims is still unclear. The largest challenge facing functional food items [25]. This can

be ascribed to the population's general absence of access to functional foods and food label health claims. Consumers only care that they can understand a food label's health claim completely. If the intention was to increase consumer knowledge of these products through health claims, then not just the EFSA but also the manufacturer bears some of the blame. So as to avoid confusion with such other general health foods, functional food products (FF) ought to be promoted with the goal of making them far more apparent and recognisable to ultimate customers. Manufacturers need to be able to develop a plan that appeals to consumers' interests and is both inviting and compliant with the law [25].

13. DISCUSSION:

Based on the foregoing discussion, it is deemed necessary to restructure the whole regulatory framework of functional foods in light of the role of nutraceuticals in order to recognise their various functions and definitions and, second, to evaluate their unique contributions to the preventative and curative of pathological conditions, while only endorsing their possible medical use in prevention and therapy when supported by reliable scientific and clinical evidence.

A sufficient safety profile proving the safety for human consumption must be provided for functional foods, nutraceutical ingredients, and those legally defined as

natural materials that may be used singly, in combined effect, or even added to food or beverage for a specific technological purpose or health benefits. The possibility of pharmacological toxicity or side effects prompts us to think of safer nutraceutical and functional food-based approaches to health management.

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CONFLICT OF INTEREST:

Authors declare no conflict of interest amongst themselves.

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