



**University of Echahid Hamma Lakhdar
Eloued**

Faculty of Natural and Life Sciences

**Dietary Supplements (Food supplements)
and natural ingredient- based functional
foods**

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2nd year Master: Biodiversity and plant physiology



Semester: 3th Semester

UE: Fundamental Teaching Unit 1

Subject 1: Dietary Supplements (Food supplements) and natural ingredient-based functional foods

Credits: 4

Rating: 2

Teaching objectives

The student must know the concepts and terminology of water and the different soils, study methods

and analyzes in correlation with the different ecosystems.

Content:

Introduction

1) Foods

- ✓ **Classification of foods according to their functions**
- ✓ **Nutrients in food**
- ✓ **NUTRITION**

Chapter I : Dietary Supplements or food supplements (definition, legislation, different categories of claims, labeling rules, content of files)

1) Regulations and legislation on food supplements

- ✓ **food supplements legislation in the US**
- ✓ **food supplements legislation in the UE**

2) Structure/ function claims requirements for functional foods and dietary supplements

✓ *Health Claims*

✓ *Nutrient Content Claims*

✓ **function claims**

2) Generally recognized as safe (GRAS) substances

3) General labelling requirements

Chapter II Marketing and distribution of Dietary Supplements or food supplements

1) Conditions required for marketing

Chapter III: Examples of natural nutraceutical ingredients: mixture of natural substances, plant extracts, purified active ingredients

1) Compositions of organic food supplement

2) Examples of natural nutraceutical ingredients

Chapter IV: Functional foods (definition, legislation, different categories of claims, labeling rules, content of files)

1) Definition of Functional foods

2) Grouping of Functional Foods

3) Example of functional food

4) Health Benefits of Functional Foods

5) Effect of Food Processing and Storage

Chapter II

Marketing and distribution of Dietary Supplements or food supplements

II- Introduction

The global dietary supplements market is expected to reach USD 340.62 billion by 2030, at a CAGR of 8.97% from 2022 to 2030. The rising consumer awareness would drive the dietary supplements market growth for general well-being and preventive healthcare. The increase in lifestyle diseases and other chronic conditions also drives the demand for dietary supplements. The increasing disposable income of individuals also aids market growth. The growing trend of personal nutrition will also propel the market's growth. Product innovations for applying dietary supplements in personal care, weight management, preventive healthcare, and general well-being will contribute to the development of the market.

II-1- Market Overview:

Dietary supplements are additional micronutrients consumed in addition to a regular diet. Dietary supplements fulfill the body's nutritional needs that are not completed by regular food intake. Dietary supplements are available in tablets,

capsules, liquids, gummies, or soft gels. These are natural, cost-effective, and safe ways of restoring the body's healthy functioning. Dietary supplements include vitamins, minerals, enzymes, probiotics, and more. They promote heart, lungs, skin, hair, gut, and bone health. With extensive research, regulated consumption of dietary supplements has proved promising in curing conditions like constipation, diarrhea, yeast infections, urinary tract diseases, gum disease, and inflammatory bowel disease, among many others. Continued research and development in dietary supplements will offer lucrative opportunities for the growth of the market in the future.

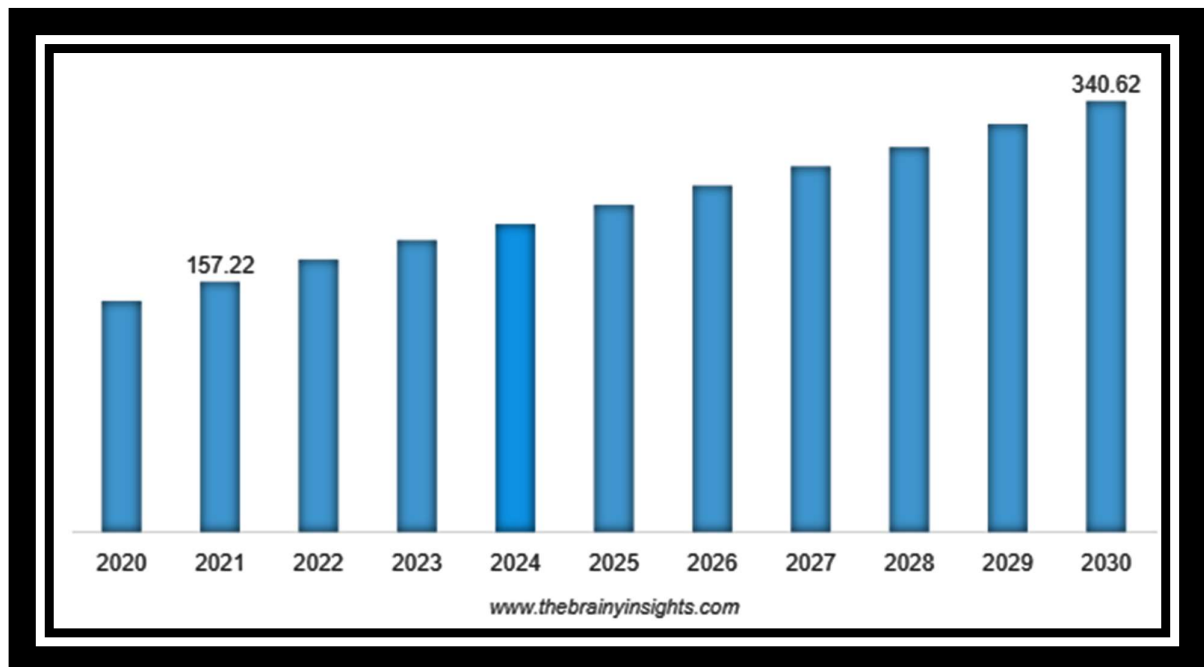


Figure 4: Global dietary Supplement Market Size (USD Billion)

II-1-1- Regional Segmentation Analysis:

The regions analyzed for the market include North America, Europe, South America, Asia Pacific, and the Middle East and Africa. North American region emerged as the largest market for the global dietary supplements market, with a 40.34% share of the market revenue in 2021.

North America currently dominates the dietary supplements market due to increasing lifestyle and chronic diseases/conditions, encouraging people towards preventive healthcare such as dietary supplements. The population's high disposable income is driving the region's dietary supplements market. The growing geriatric population is also propelling the intake of dietary supplements that are high in nutritional value and low in calorific content. The rising consumption of vitamins, minerals, and other dietary supplements by working individuals, athletes, fitness enthusiasts, and regular people are driving the market. The Asia Pacific is expected to grow the fastest during the forecast period, given the growing western influence on consuming dietary supplements in the region. The increasing disposable income drives personalized nutrition demand in markets like China, India, South Korea, and Vietnam. The thriving pharmaceutical sector and large consumer base are attracting major market players to the region. Market players are adopting innovative competitive

strategies to capture the market by increasing research and development and thereby contributing to the growth of the regional dietary supplements market.

A- Global Dietary Supplement Market Segmentation Analysis

The Global Dietary Supplement Market is segmented on the basis of Ingredient, Product, Application, Distribution Channel, and Geography.

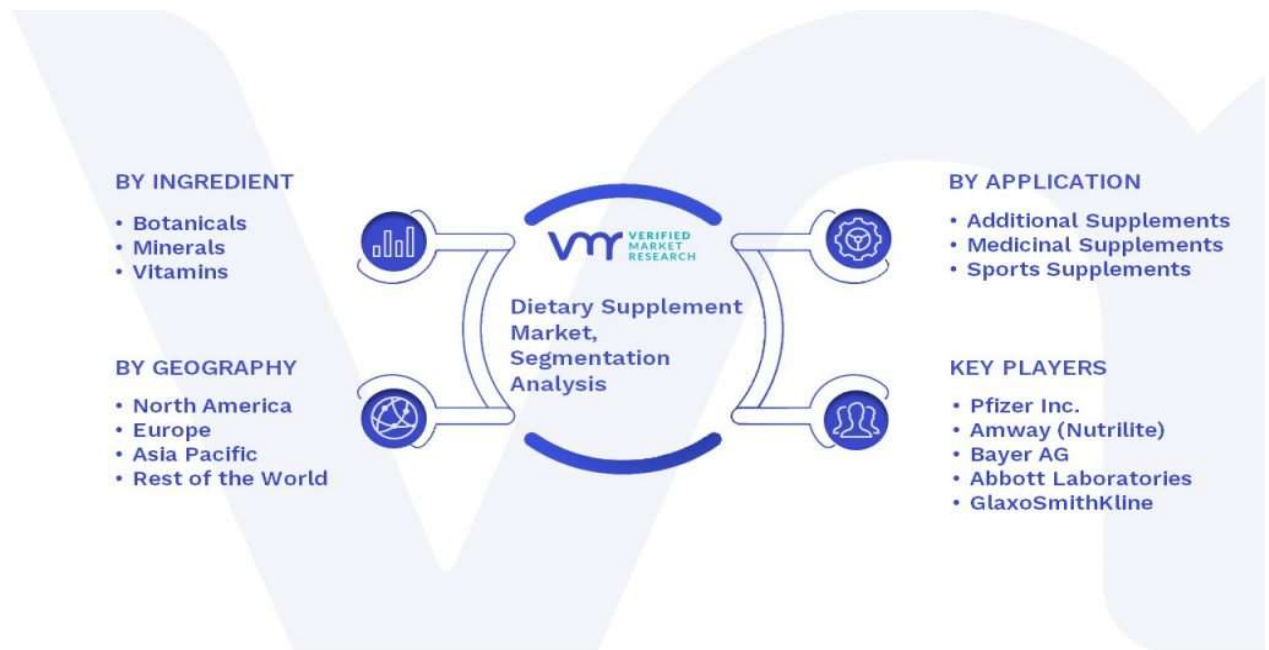


Figure 5: Global Dietary Supplement Market Segmentation

B - Dietary Supplement Market, By Ingredient

- Botanicals
- Minerals

Chapter II Marketing and distribution of Dietary Supplements or food supplements

- Vitamins
- Proteins & Amino Acids
- Enzymes
- Others

Based on Ingredient, the market is segmented into Botanicals, Minerals, Vitamins, Proteins & Amino Acids, Enzymes and Others. Vitamin's segment accounts for the largest share of the Dietary Supplement Market, and Vitamins dominated the market, accounting for 31.4 % in 2020, a growing market by working professionals and athletes for energy and weight control. The customers take multivitamins in tablets, powder, and liquid.

C- Dietary Supplement Market, By Product

- Tablets
- Capsules
- Powder
- Liquid
- Soft gels
- Others

Based on Product, the market is segmented into Tablets, Capsules, Powder, Liquid, Soft gels, and Others. Tablets the market and accounted for 34.2% share of the worldwide revenue in 2020. The growing community of multivitamin products in the type of tablets due to easy dosage cost-effective, higher shelf life, and higher service is expected to positively impact the growth of the tablets segment over the forecast period.

D-Dietary Supplement Market, By Application

- Additional Supplements
- Medicinal Supplements
- Sports Supplements

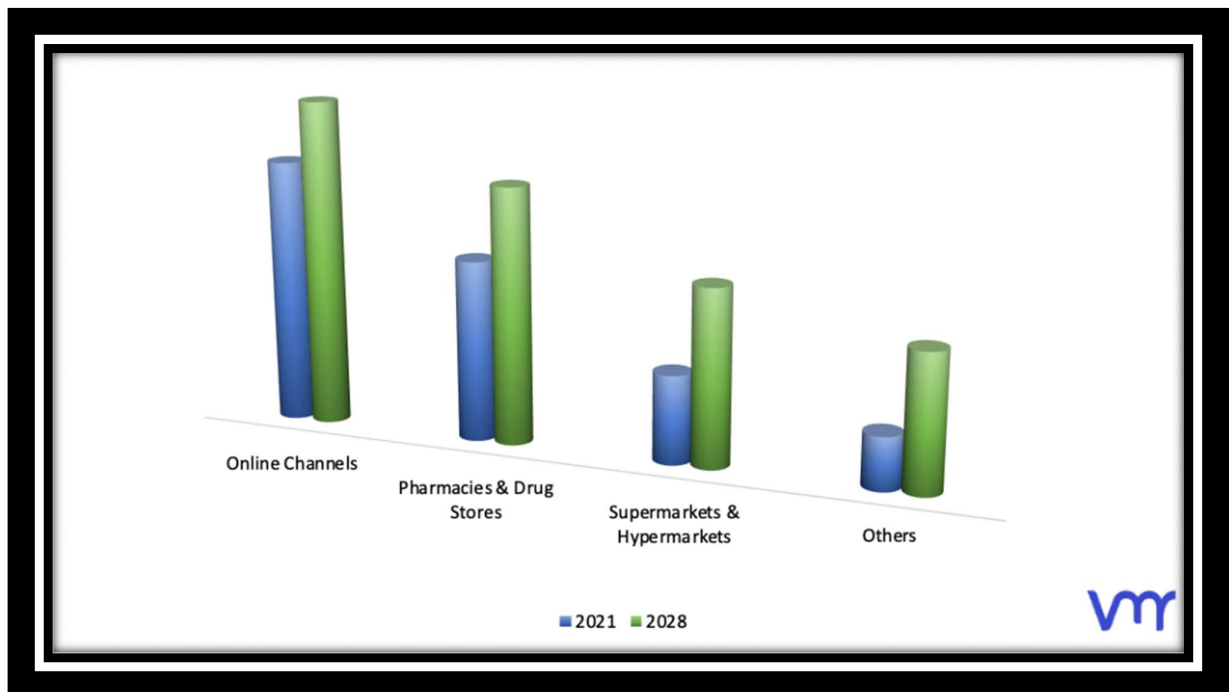


Figure 6: Global dietary supplement market by distribution channel

II-2- The market for dietary supplements: positioning, structure, industrial strategies

II-2-1-- Opinion of the Authority (positioning)

Unlike pharmaceuticals or ADAPs, the placement of dietary supplements on the market does not necessitate authorization from AFSSAPS or a declarative procedure to the prefecture. According to the decree of March 20, 2006 (JORF of March 25, 2006), the producer must:

1. The importer or manufacturer established in the territory of a Member State of the European Community or another State party to the agreement on the European Economic Area must make a declaration to the Directorate General for Competition, Consumer Affairs, and Fraud Control (DGCCRF).
2. This declaration must be accompanied by:
 - a) Identification of the manufacturer or importer;
 - b) A model of the labeling used for this product;
 - c) Documents and information attesting that the substance for nutritional or physiological purposes, the plant or plant preparation, or the product, are legally

manufactured or marketed in another Member State of the European Community or another State party to the agreement on the European Economic Area;

d) Presentation by the declarant of all data in their possession useful for assessing the substance for nutritional or physiological purposes, the plant or plant preparation, or the product.

3. An order from the ministers responsible for consumption, agriculture, and health specifies the procedures for transmitting this declaration.

4. Within a maximum period of two months after receiving the complete file of the declaration mentioned in point 1, the Directorate General for Competition, Consumer Affairs, and Fraud Control (DGCCRF) informs the declarant whether the product can be marketed and under what conditions.

- Response within the two-month period after receiving the complete dossier of the declaration constitutes authorization for market placement.

5. Refusal of marketing authorization is justified:

a) Either by the absence of documents and information mentioned in c) of point 2 of this article;

b) Or by scientific elements, notably issued by the French Agency for Food Safety, demonstrating that the product poses a risk to health.

6. The DGCCRF invites the declarant to present, if desired, their observations on this refusal of marketing authorization. The new ingredient is then integrated into the list of authorized substances within twelve months.

7. AFSSA provides a scientific opinion on these new substances; this opinion can demonstrate that the substances pose a risk to health. In this case, marketing authorization will not be granted.

8. When the marketing in the French market of substances for nutritional or physiological purposes, plants, or plant preparations has been authorized after the declaration mentioned in point 1, a refusal of registration in the forms mentioned in point 7 may, if applicable, be notified to the declarant when motivate.

9. The refusal to register substances for nutritional or physiological purposes, plants, or plant preparations leads to the cessation of marketing on the French market for products containing them.

- During this notification, authorities carry out several compliance checks, including composition, labeling, and advertising. If there is non-compliance with the legislation, the status of a dietary supplement is rejected, and marketing will not be authorized.

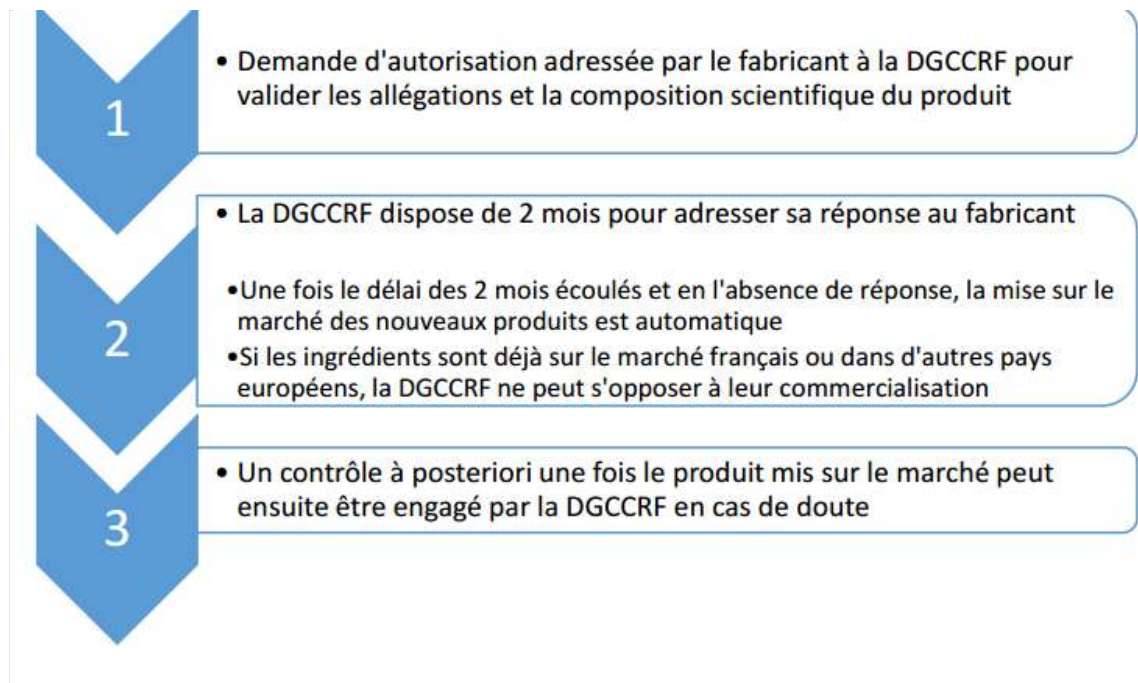


Figure 7: Authority's Opinion Procedure - Control and Market Placement of a Dietary Supplement before 2002

II-2-1-2- Required Conditions for Marketing:

According to the decree of March 20, 2006 (JORF of March 25, 2006), the producer must submit to the DGCCRF a labeling model before the first marketing. There are three cases:

a: Article 15 Procedure:

- The product complies with French regulations. This applies to substances already authorized: a simple declaration is required. Thus, the person responsible

for the initial market placement of the dietary supplement informs the DGCCRF of the initial market placement of the product by submitting a model of its labeling.

b. Article 16 Procedure:

- The product does not comply with French regulations but is legally manufactured in another EU Member State.

- The importer or manufacturer established in an EU Member State must make a declaration to the DGCCRF, which must be accompanied by:

- Identification of the manufacturer or importer.
 - A model of the labeling used for this product.
 - Documents and information attesting that the substance for nutritional or physiological purposes, the plant, the plant preparation, or the product are legally manufactured or marketed in another EU Member State.

- Presentation by the declarant of all data in their possession useful for assessing the substance, plant, or plant preparation, or the product.

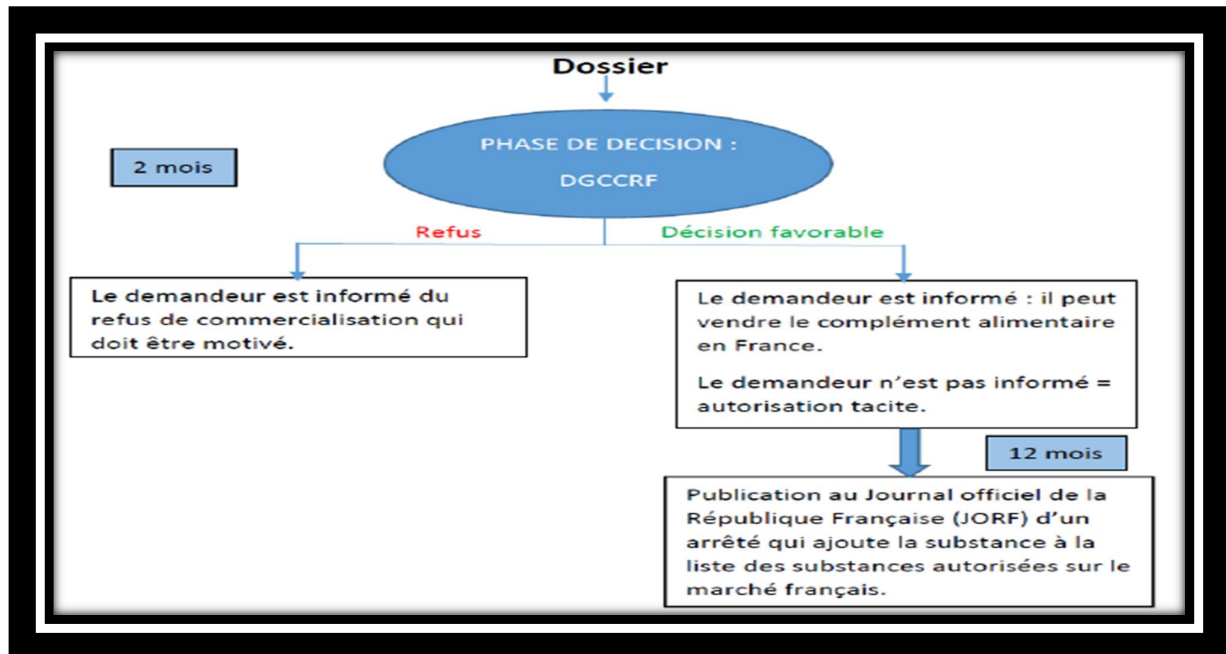


Figure 8: French Procedure for Market Authorization of a Dietary Supplement according to Article 16

c. Article 17 and 18 Procedure:

- The product is not present in the EU, or the request aims to modify or supplement the orders mentioned in articles 6 and 7 (articles relating to substances for nutritional or physiological purposes, plants, or plant preparations that can be used for the manufacture of dietary supplements).
- The complete dossier is sent to the DGCCRF, accompanied by the necessary dossier for instruction with a view to transmission to ANSES.

- The admissibility of the request is assessed, within a maximum period of 15 days, by the DGCCRF, which acknowledges receipt and transmits it to ANSES.
- ANSES issues, within 4 months, an opinion taking into account, as necessary, the elements provided by ANSM, when it concerns a request for authorization to

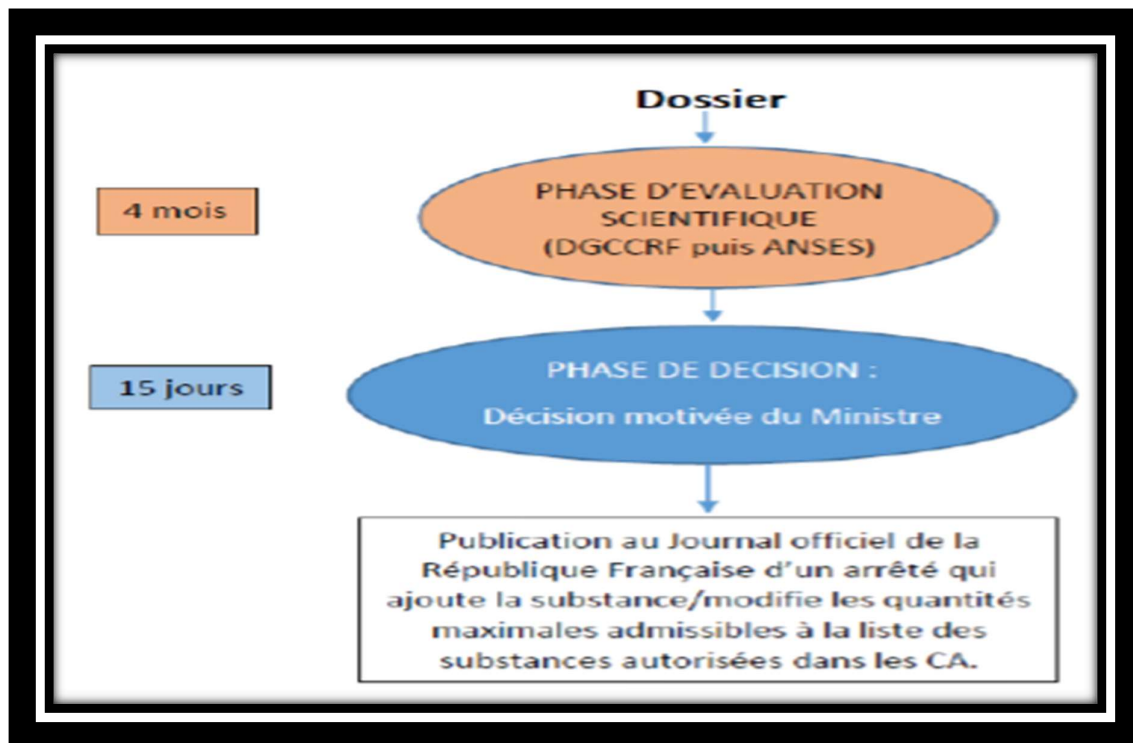


Figure 9: French Procedure for Market Authorization of a Dietary Supplement according to Articles 17 and 18

II-3- Distribution Channels (Structure, Industrial Strategies)

In France, the distribution of dietary supplements is quite complex. The significant number of distribution channels and types of sales points is one of the characteristics of the dietary supplement market. Each channel has its own specificities.

Sold over-the-counter and not subject to medical prescription, these products can be sold either in pharmacies or in large and medium-sized stores. However, the so-called "medical" channels (pharmacy and parapharmacy) are the most influential in this sector, as can be seen in the graph below:

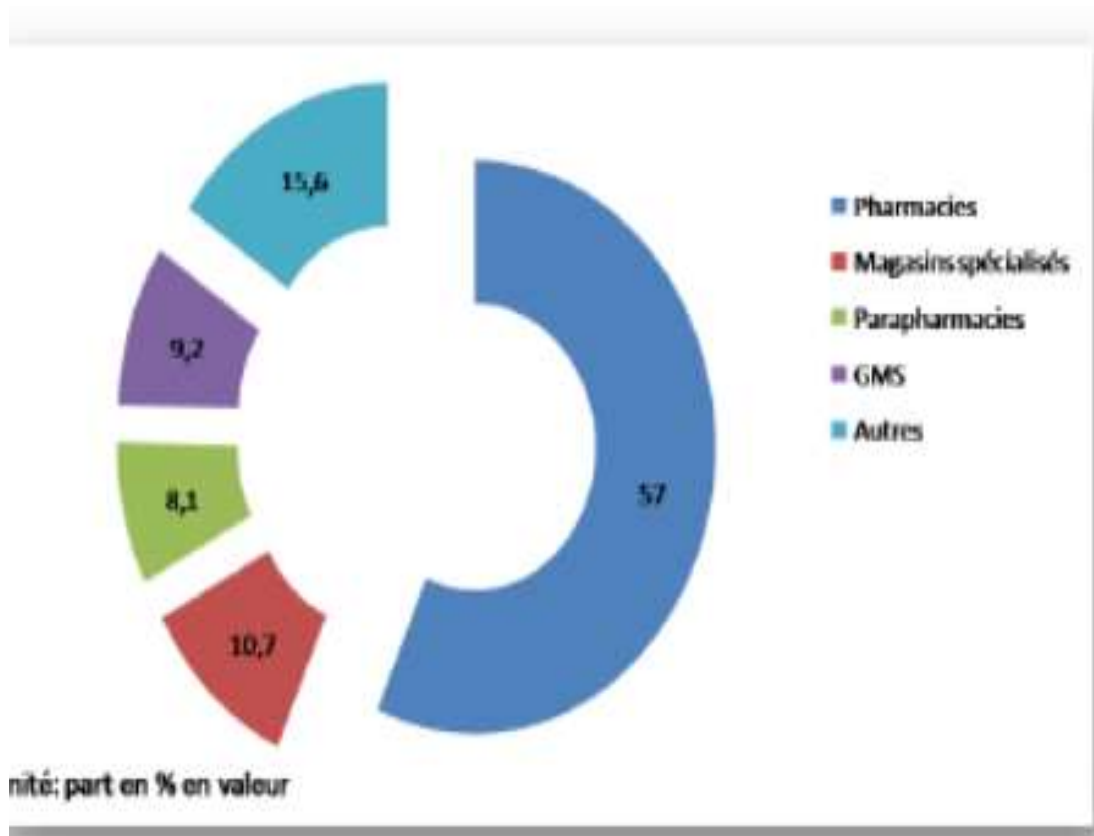


Figure 10: Distribution Channels

a) Pharmacies:

The monopoly on drug sales allows pharmacies to maintain a certain advantage in distributing health products, especially dietary supplements. Indeed, their credibility is strengthened by the sales advice provided by pharmacists to customers. This endorsement constitutes an important advantage, especially during regulatory harmonization periods. With more than 23,000 pharmacies listed in France, there is extensive coverage of the territory. However, compared

to other channels, pharmacies have low stocks and limited shelf space. The prices of products are generally higher, with an average margin rate of 40%.

b) Parapharmacy:

Parapharmacy is the most dynamic distribution channel for dietary supplements in the French market. The sale of dietary supplements in parapharmacies benefits from the advantages of pharmacies and large and medium-sized stores (GMS):

- Prices are lower than those practiced in pharmacies.
- Customers benefit from advice from pharmacists/beauticians/dieticians.
- Product offerings are extensive.
- Parapharmacies regularly offer promotional deals. Overall, it is estimated that there were 300 parapharmacies in France in 2009, spread between those present within food hypermarkets, chains like Parashop, or independent parapharmacies. However, the coverage of the territory by parapharmacies is more limited than that of pharmacies, and shelves are often overloaded.

c) Dietetic and Organic Stores:

These specialized stores are for "connoisseurs." They represent 10.7% of the market, with brands like Super Diet, Phytoceutic, or Diétaroma. This historical

channel has a specific offer and clientele but suffers from an aging image and a lack of clarity in terms of shelf placement.

d) Large and Medium-Sized Stores (GMS):

This channel, accounting for 9% of the market, offers a product range dominated by three leading brands: Juvamine, Floressance, Vitarmonyl. The poor performances of GMS recorded for many years can have several explanations:

- Dietary supplements present on GMS shelves are often less sophisticated, and new products do not receive as much communication as in other channels.

- Placing dietary supplements in two different locations, in the beauty aisle and/or the dietary aisle of commercial surfaces, does not facilitate the consumer's identification of the offer.

- The size of the shelf space dedicated to dietary supplements reportedly decreased by 32% in a year. The trend in this sector is towards restructuring and rationalization of offerings. It is also for these reasons that dietary supplement players in GMS have all positioned themselves

e) Direct Sales:

The direct sales approach encompasses internet sales, mail-order sales, and sales conducted at home. It's considered the most dynamic channel, accounting for 12% of sales, involving numerous small brands and websites.

II-1-3- Advertising Regulations

Advertising for Consumer Goods (CG) in France falls under the Consumer Code. It defines misleading commercial practices and mandates essential information in commercial communications regarding price, characteristics of the product or service, professional identity, delivery terms, payment methods, and the right of withdrawal, if applicable by law.

A- Regulatory Authorities:

Two agencies in France oversee CG advertising: ANSES evaluates scientific claims, while ARPP assesses the advertising format. ARPP aims for fair, truthful, and healthy advertising in the interest of consumers, the public, and advertising professionals. It provides guidelines for health claims in advertising, emphasizing clarity, truthfulness, objectivity, and fairness, with penalties for false advertising.

B- Market Insights:

The global dietary supplements market was estimated at 45 billion euros in 2006, with Europe contributing 30% of sales. France, among other European countries, holds a notable market share. French per capita consumption of dietary supplements in 2008 was lower compared to some other European nations.

C- Market Dynamics in France:

Chapter II Marketing and distribution of Dietary Supplements or food supplements

The French dietary supplement market experienced phases of growth, downturn, and resurgence between 2000 and 2015, attributed to market expansion, economic conditions, and regulatory changes affecting health claims.

Product Retraction and Recall: Product recalls or retractions may occur due to identified risks, suspected risks, or instances where quality standards are not met, prompting actions involving authorities and industry cooperation.

The text provides an extensive overview of various facets related to the distribution, regulation, and market landscape of consumer goods and dietary supplements in France and globally.

DS Global Market

The global DS market is growing exponentially in most countries. According to data from the National Health and Nutrition Examination Survey (NHNES), it has been gaining interest since the 1970s. The geographical distribution is highly variable and has been divided into six major regions. The USA, Europe, and Japan account for the largest share of the market, followed by Asia, Australia, and Oceania, all of which demonstrate the expansion of the market. In contrast, the

Middle East and Africa have seen a surge in DS sales, with South Africa remaining the most important market. In the Middle East, the demographics and socioeconomic status of consumers, particularly in Saudi Arabia, has led to the development of this market, which is estimated to reach SAR 875 million by 2021. Differences in these geographical distributions may be the result of several factors, such as socio-demographic and socio-cultural characteristics, consumer behavior, and ageing populations. Globally, the market size of DS increased from USD 82 billion to USD 149.50 billion in 2021 and this will supposedly

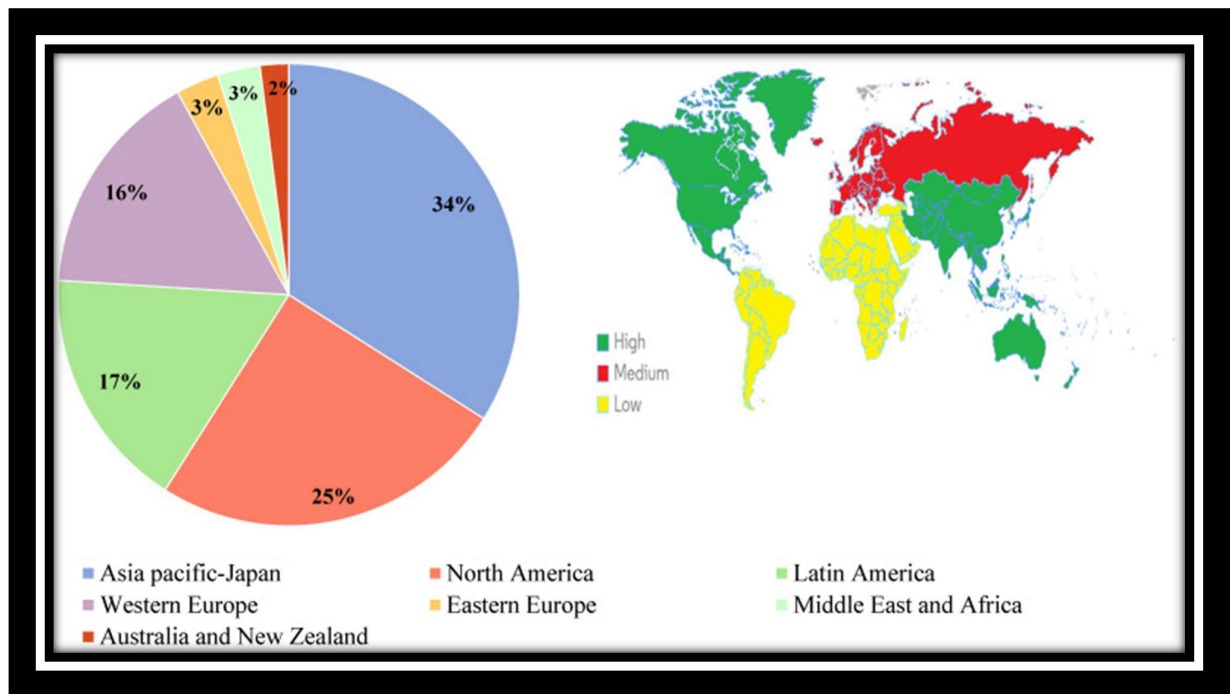


Figure 11: geographical distribution of dietary supplement market

Chapter II Marketing and distribution of Dietary Supplements or food supplements

Chapter I: Dietary Supplements or food supplements (definition, legislation, different categories of claims, labeling rules, content of files) the first lesson

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I- Introduction

Although the concept of a food additive has not yet been discussed, it is clear by the name that they are some form of substances used in foods. It is therefore important to look at how a food is defined, in order to better understand the ways in which food additives may be used. In the US, Congress defined ‘food’ as:

- 1) Articles used for food or drink for man or other animals,
- 2) Chewing gum, and
- 3) Articles used for components of any such article

The FDA clarified this by defining ‘food’ as human food, pet food, animal feed and substances migrating to food from food contact articles.

I-1- food additive Based on the above definition,

food additives are considered to be foods. A “food additive” in American legislation is specifically defined as: any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

- (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food;
- (2) or (2) a pesticide chemical;
- (3) or (3) a color additive; or

Chapter I: Dietary Supplements or food supplements (definition, legislation, different categories of claims, labeling rules, content of files) the first lesson

- (4) (4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. § 451 et seq.) or the Meat Inspection Act of March 4, 1907, as amended and extended (21 U.S.C. § 601 et seq.)
- (5) (5) a new animal drug; or
- (6) (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement

I-2- Nutraceuticals, Dietary Supplements and Functional Foods

Nutraceuticals, functional food ingredients and dietary supplements are important for health promotion and disease risk reduction. Although a myriad of bioactive are known to render the expected beneficial effects, the mechanisms involved are varied and may work individually or collectively in providing the effects.

Functional foods are defined as products that resemble traditional foods but possess demonstrated physiological benefits. However, **nutraceuticals and Dietary Supplements** are commodities derived from foods, but are used in the medicinal form of pills, capsules or liquids and again render demonstrated physiological benefits

Chapter I: Dietary Supplements or food supplements (definition, legislation, different categories of claims, labeling rules, content of files) the first lesson

I-3- FOODS

II-3-1- FOOD What is food

Food is anything liquid, semi-solid or solid which contains nutrients and energy and when taken or eaten nourishes the body. Food contains important substances which provide energy to move, think, work, run our body systems, keep us healthy, help to boost our immune system and protect us from infections. When we eat or take food, our bodies absorb useful nutrients into the blood and they are transported to areas where they are needed or stored. The food we eat or take is used for growth, maintenance and body functions.

I-3-2- Classification of foods

according to their functions Foods may be classified according to their functions in the body:

a) *Energy-giving foods* (“GO” foods) Foods rich in carbohydrates and fats are called energy-giving foods or “GO” foods. They provide energy to the body and are essential for physical activity and basic functioning of the body. Foods like cereals, roots, tubers, starchy fruits and vegetables oils, milk, butter and ghee are good sources of energy.

Chapter I: Dietary Supplements or food supplements (definition, legislation, different categories of claims, labeling rules, content of files) the first lesson



Figure 1: Some of the locally available energy-giving foods

b) Body-building foods (“GROW” foods)

Foods rich in protein are called body-building foods or “GROW” foods. These foods help to maintain life and promote growth, repair worn out and damaged body tissues. “GROW” foods come from animal and plant sources. Milk, meat, eggs and fish are good sources of animal proteins while legumes and nuts are good sources of plant protein. Animal protein sources are considered to be of high quality compared to plant sources, apart from soybeans.

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Figure 2: Some of the locally available foods that are sources of protein

c) Protective (“GLOW” foods)

Foods rich in minerals and vitamins are known as protective or “GLOW” foods. They are essential for promoting body immunity and regulatory functions. Fruits and vegetables are the main sources of “GLOW” foods. Fortified foods, including iodized salt, are also good sources of “GLOW” foods.

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Figure 3: Examples of locally available vegetables and fruits which are rich sources of vitamins and minerals

I- 4- Nutrients in food

Nutrients are substances contained in food that nourish the body. They are required by the body to maintain general health and physiological functions, for example: provision of energy, building the body mass, keeping the body warm, boosting immunity and regulating the various body functions that help someone to live.

Major nutrients in human nutrition

Nutrients in food are divided into three major categories: macronutrients, micronutrients and water.

1) Macronutrients

These are required in large amounts:

- Carbohydrates
- Proteins

Chapter I: Dietary Supplements or food supplements (definition, legislation, different categories of claims, labeling rules, content of files) the first lesson

- Fats/oils

✓ Carbohydrates

These are the primary source of energy in most diets. They include starches, fibre and sugars. Sweet foods such as sugar, jam, cakes and sugary drinks are sources of carbohydrates but should be consumed minimally because they do not provide any other nutrients and may increase risk of overweight.

✓ Carbohydrate requirements

Individual carbohydrate requirements vary according to age, sex, physical activity level and physiological status. The recommended daily carbohydrate intake should provide about 45% to 65% of the total body energy/calorie requirements of 2000–3000 kilocalories (kcal). One gram of carbohydrates provides 4 kilocalories.

✓ Proteins

are body-building foods and are required for growth and development, maintenance and repair of tissues, production of metabolic and digestive enzymes, and formation of certain hormones and all cells and tissues

✓ Protein requirements

The recommended intake of protein each day is about 1 gram per kilogram of body weight. Example: if a person is 60 kilograms, he will require 60 grams of protein each day. This is equivalent to one egg or a piece of meat about the size of an egg. However, children, teenagers, and pregnant and lactating mothers require more protein as indicated below:

- Children: 30–50 g (half a palm of meat)
- Teenagers: 60–75 g (a palm of meat)
- Adults: 60–70 g (a palm of meat)
- Pregnant and lactating mothers: 90 g (one and a half palm of meat)

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✓ Fats and oils

Fats and oils also known as lipids are derived from both animal and plant sources. Fats are rich in energy, build body cells, support brain development of infants, help body processes, and facilitate the absorption and use of fat-soluble vitamins A, D, E, and K. The major component of lipids is glycerol and fatty acids. According to chemical properties, fatty acids can be divided into saturated and unsaturated fatty acids. Generally, lipids containing saturated fatty acids are solid at room temperature and include animal fats (butter, lard, tallow, ghee) and tropical oils (palm, coconut, palm kernel). Saturated fats increase the risk of heart disease.

✓ Dietary fibre

This is a form of complex carbohydrate that is part of the nondigestible portion of the food. Dietary fibre increases the body's sense of satisfaction thus preventing overeating. Diets high in fibre protect against constipation.

2) Micronutrients

These are required by the body in small amounts and include: vitamins and minerals.

a- Vitamins

Vitamins are organic compounds that perform specific metabolic functions in the body. There are two forms of vitamins:

✓ Fat-soluble vitamins

These are stored by the body and require dietary fat to be absorbed. They include vitamins A, D, E and K. Fat-soluble vitamins are necessary for development and maintenance of body tissues and their functions, for example: eyes (vitamin A), bones (vitamin D), muscles and blood clotting (vitamin K), protection of cells (vitamin E), synthesis of enzymes and absorption of essential nutrients. Dietary sources of fat-soluble vitamins include carrots, tomatoes, liver, offal, kidney, gizzard, heart, milk and milk products and leafy vegetables.

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✓ Water-soluble vitamins

These are not stored by the body and must be consumed regularly. They include vitamins C (ascorbic acid) and the B complex group. Their functions include releasing energy, supporting utilization of macronutrients and synthesizing red blood cells. Dietary sources of water-soluble vitamins include fruits, dark leafy vegetables, whole grains, meat, fish, poultry and fortified cereals. Citrus fruits are an especially good source of vitamin C. Vitamin C is crucial for improving iron bioavailability from plant food sources

b- Vitamins requirements

- Water-soluble vitamins are not stored in the body and must be consumed daily.
- Fat-soluble vitamins are stored in the liver and may not have to be taken daily, excessive intake of these vitamins is toxic.

c- Minerals

Minerals are required for the normal functioning of body processes, including growth, development, water balance and neurological processes.

✓ Minerals of public health importance

Iron

is an essential component of blood and helps transfer oxygen to various body tissues. Dietary sources include red meat, fish, poultry (easily absorbed), legumes, leafy green vegetables (less easily absorbed, but absorption increases if eaten with animal source iron or vitamin C).

Calcium

is a key component of bones and teeth and is needed for a strong skeleton and important in blood clotting. The major source of calcium in the world is milk and milk products. Other sources include fish eaten with bones (silver fish—mukene,

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haplochromis species—nkeje) and dark green vegetables (plant sources are not well absorbed).

Iodine

is important for thyroid function and for mental development of children. The most important dietary source is iodized salt.

Zinc

enhances and strengthens the immune system, helps wound healing, facilitates digestion and is an important component of skeletal muscle. Dietary sources include beef, seafood, liver, nuts, beans and whole grains.

Other minerals

involved in various body functions are chromium, copper, fluoride, magnesium, manganese, molybdenum, nickel, potassium, phosphorus, sodium and selenium

I-5- What are Food supplements

Food supplements a normal diet by providing concentrated sources of nutrients or other substances. These substances should have nutritional or physiological effects. Food supplements may for example contain vitamins and minerals or various types of plant extracts, amino acids, fatty acids or fibres. The form of supplements can vary as they can be taken as pills, capsules etc but also in liquid form, to be taken with for example a teaspoon or tablespoon. Some supplements, such as effervescent tablets or powders, may need to be dissolved in liquid before ingestion. Common to all supplements is that they should be taken in measured small unit quantities

I-5-1- Characteristics of DS

Dietary supplements are products containing concentrated sources of nutrients or other substances such as vitamins, minerals, botanicals, algae, fungi, bacteria, synthetic products, products of animal origin, amino acids, metabolites, etc., that are intended to supplement one's diet and have a nutritional or physiological effect, either alone or in combination with other substances. They are usually sold in dosage form, including capsules, pastilles, softgels, gelcaps, tablets, pills, sachets of powder, dropper bottles, or any other form in which these products can be ingested and taken in measured doses. In addition, their presentation, labeling, or advertising must not claim or imply that they have the ability to prevent, treat, or cure human disease, nor must the product be promoted for use as a conventional food or as the sole component of a meal or diet.

The lack of a global consensus on DS may be due to differences between countries in the regulatory definition and categorization of DS products. The permitted ingredients and the types of products covered by the term DS vary widely and are referred to by different names in different countries. Differences in terminology can result in a product being classified in a completely different way, leading to discrepancies in regulatory decisions that vary significantly from country to country.

Chapter I: Dietary Supplements or food supplements (definition, legislation, different categories of claims, labeling rules, content of files) the first lesson

According to the Council for Responsible Nutrition, which tracks the sales of DS, the specific supplements that were most consumed in 2021 were vitamin or mineral supplements (98%), specialty supplements (46%; including omega-3 fatty acids, probiotics, etc.), botanicals and herbs (44%), sports supplements (30%), and weight management supplements (19%).

Table 1 Terminology and definition of dietary supplements in different countries.

Country	Category Name	Definition
<i>China</i>	Health food (HF)	HF refers to foods that claim to have specific health functions or provide vitamins and minerals. It is specific to certain groups and modifies organic functions in humans, but is not intended to treat disease and does not cause acute, sub-acute, or chronic harm to the human body.
<i>USA</i>	Dietary supplements (DS)	DS are dietary supplements that contain one ingredient or multiple ingredients, such as vitamins, minerals, herbs or other botanicals, amino acids, and enzymes, to supplement one's total dietary intake. They are sold in forms such as tablets, capsules, softgels, gel capsules, powders, and liquids. Unlike medicines, dietary supplements are not intended to treat, diagnose, prevent, or cure disease.
<i>EU</i>	Food supplements (FS)	FS are concentrated sources of nutrients or other substances containing a wide range of ingredients, including vitamins, minerals, amino acids, essential fatty acids, fiber, and various plant and herbal extracts, that have a nutritional or physiological effect and are available in specific dosage forms (pills, tablets, capsules, liquids) to supplement one's normal diet.
<i>Canada</i>	Natural health products (NHP)	NHP is a category of naturally derived products such as vitamins, minerals, amino acids, probiotics, herbal and homeopathic medicines, and traditional medicines intended to improve human health

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I-5-2- Legislative and Regulatory issues:

DS manufacturers follow a number of guidelines to ensure the production of products with real value. Numerous regulatory bodies around the world develop strict, comprehensive rules and standards to ensure consumer effectiveness and safety. Regulatory organizations may also consider whether the products provide value to the consumer. Due to restrictions that vary from country to country, exporting DS is challenging, especially if the regulations are unclear or the products have not been updated to comply with the regulations of the importing country

table 2 Regulations/laws and regulatory requirements of dietary supplements in different countries (USA, EU and Algeria).

	USA	EU	Algeria
Regulatory agency	Food and Drug Administration (FDA)	The European Commission and the competent authorities EFSA (European Food Safety Authority), if centralized procedures apply	NA
Regulation and law	FD & C Act (Federal Food, Drug, and Cosmetic Act) DSHEA (Dietary Supplement Health and Education Act) NLEA (Nutrition Labeling and Education Act) CGMP (Current Good Manufacture Practice: manufacturing, packaging, labeling, or holding operations for DS)	2002/46/EC EC No 1924/2006	/
Compliance process	The manufacturers and distributors are responsible	Notification/registration	/

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		Notification/registration: DS containing a new ingredient		
Category	Foods	+	+	+
	Medicines	–	–	–
Manufacturer Registration		–	+ (Limited)	–
Presence of a positive list		–	+	NA
Good Manufacturing Practice (GMP)		+	+ (HACCP)	NA
Clinical trials of individual products		–	+ (New ingredients)	NA
Obligated to display the usage and dosage		+	+	NA
Serious adverse event reporting		+	+	NA
Labeling and packaging		+	+	NA
Shape description		+	+	NA
Advertising requirements		+	+	NA
Health claims		–	–	NA

A) Regulation in European Union (EU)

In Europe DS are regulated by the European Commission through several directives. The European Commission has established continent-wide regulations to protect consumers and provide them with safe food. However, the regulatory framework for DS in Europe follows general food legislation and their manufacturing processes are subjected to Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Point (HACCP) procedures. To ensure the integrity and safety of dietary supplements and the safety of consumers, the scientific Committee on Food (SCF), currently the European Food Safety Authority (EFSA), has established upper tolerable intakes (UTIs) of minerals and vitamins that can be ingested daily to support and maintain good health. A variety of nutritional components other than vitamins and minerals may be used in the manufacturing of food supplements once they have been approved by the regulatory body (EFSA). Under Directives 2002/46/EC and 2001/15/EC, these substances can be classified as amino acids, enzymes, prebiotics and probiotics, essential fatty acids, and botanical extracts. In addition, the aforementioned directives established uniform guidelines for the

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labeling of food supplements, and these guidelines outline the requirements for specifying the identity and composition of DS products.

While the nutritional value of certain ingredients may be outlined on a product's label, the amount of vitamins and minerals, followed by the maximum recommended daily intake, storage conditions, and the risk associated with excessive consumption of the product must be stated. Therefore, DS must not make therapeutic claims or refer to conventional diets. These features provide consumers with general information and protect them from fraudulent advertising.

The legislative texts under Directive 1925/2006/EC allow for the prohibition or exclusion of certain ingredients, other than vitamins and minerals, to be added to foods, including food supplements that may have undesirable effects on the consumers. A positive list of safe substances should be established to ensure the proper functioning of the internal food supplements market.

Meanwhile, under Directive 2015/2283/EC, specific legislative measures apply to novel foods that have not been used in the European Community before 15 May 1997. This directive has led to the establishment of an appropriate list of the novel ingredients that may be used in the production of DS to ensure their access to the EU market.

B) Regulation in Algeria

To date, there is no strict regulatory framework in Algeria that applies exclusively and specifically to DS. They are subject to the regulations governing the commercial activity of foodstuffs (consumer control and protection) and do not require authorization from the Ministry of Trade and the Ministry of Health for their production, importation, or marketing. DS are over-the-counter products that can be acquired without a medical prescription and, unlike drugs, do not require authorization prior to being made available on the market.

The Ministry of Trade takes action in the event of a warning from the appropriate authorities regarding product withdrawals or anomalies in the dietary supplement market. The risks of dietary supplement consumption are related to the presence of toxic, banned, and unauthorized substances in the supplement's ingredients. There have been numerous cases of fraudulent advertising with respect to DS in Algeria,

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and many dietary supplements have been withdrawn from the market. In addition, in 2022, the Ministry of Trade and Export Promotion announced a ban on 20 dietary supplements that had been tested in laboratories and found to contain chemical components used in the pharmaceutical industry rather than those declared in the products' composition; thus, these products were deemed potentially harmful to consumers' health. These supplements mainly contained drugs used to treat sexual impotence, and consuming them without consulting a specialist is not recommended. Since the health crisis, the market for DS has grown, meaning that a regulatory framework is urgently needed. These risks require increased regulation. Therefore, DS need a specific regulatory framework that gives them a real status to ensure consumer safety and combat false advertising and poor manufacturing practices.

I- 6- Dietary supplement claims

Dietary supplement claims are a consumer's primary source of information about the product and its function. With a growing number of consumers new to the dietary supplements category, it is more important than ever for manufacturers to ensure the credibility of their claims in order to establish consumer trust.

The DGCCRF or FDA defines three different categories of claims that dietary supplement manufacturers are permitted to use on their product's packaging: structure/function claims, nutrient content claims, and health claims. All claims must be truthful, substantiated with scientific evidence, and compliant with placement and type size requirements, however each category has its own specific set of regulations.

1) Health Claims

Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition.

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A "health claim" by definition has two essential components: (1) a substance (whether a food, food component, or dietary ingredient) and (2) a disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in maintaining good health are considered to be dietary guidance rather than health claims.

2) Nutrient Content Claims

The Nutrition Labeling and Education Act of 1990 (NLEA) permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) if they have been authorized by FDA or DGCCRF and are made in accordance with DGCCRF or FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement

- FDA or DGCCRF notification is not required prior to use.
- All nutrients that are referenced in the claim, including those without an established DV, must be listed in the Supplement Facts panel
- "High," "rich in," or "excellent source of" may only be used to describe a product that contains 20 percent or more of a nutrient's daily value
- "Good source," "contains," or "provides" may be used to describe a product that contains 10 to 19 percent of a nutrient's daily value

Examples of compliant/permissible nutrient content claims:

- A supplement that provides at least 20% DV of Vitamin C per serving may use the claim "Excellent source of vitamin C" or other related descriptors.
- A supplement that provides at least 10% DV of Calcium per serving may use the claim "Good source of calcium" or other related descriptors.

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- Contains 300 milligrams (mg) of phosphatidylserine per serving
- Simple percentage claim: “40% omega-3 fatty acids, 10 mg per capsule”
- Comparative percentage claim: “Twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg).”

3) Structure/Function Claims and Related Dietary Supplement Claims

are the most common, permissible claim used for dietary supplements. DSHEA established special requirements for structure/function claims, including claims that are related to general well-being and nutrient deficiencies. Structure function claims can be easily confused with disease claims, which refer to a specific disease or class of diseases. Using a disease claim or including a S/F claim implying disease management on a dietary supplement product would be considered misleading and out of compliance.

To help distinguish the difference between structure/function claims and disease claims, FDA provides 10 criteria in their [Small Entity Compliance Guide on Structure/Function Claims](#), including:

- Manufacturers must collect and maintain “[competent and reliable scientific evidence](#)” to substantiate the relationship of evidence to the claim
- FDA notification is required within 30 days of marketing the product
- The disclaimer, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease” must either be linked to each claim with a symbol (e.g., an asterisk) or placed adjacent to the claim without intervening material
- Product names may not suggest that the dietary supplement has an effect on a disease.
- The claim’s overall context must not imply that the product treats or prevents disease or can substitute or augment medical treatments or prescription drugs.

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Examples of compliant/missible structure/function claims when supported by evidence:

- “Supports urinary tract health”
- “Helps maintain cardiovascular function”
- “Helps to maintain cholesterol levels that are already within the normal range”
- “Promotes joint health”
- “Helps maintain a healthy blood sugar level as part of a healthy diet”
- “Supports a healthy weight loss plan”
- “Supports immune health”
- “Mood support”

Examples of non-compliant/impermissible structure/function claims:

- “For chronic indigestion”
- “Relieves chronic constipation”
- “Helps ease depression”
- “Prevents hangovers”
- “Helps maintain a healthy blood sugar level for people with diabetes”
- “Prevents cold and flu”
- “Relieves headache pain”
- “Appetite suppressant treatment for obesity”
- “Lowers cholesterol”
- “Reduces joint inflammation and pain”

I-7- labeling rules of food supplements

Food Supplements legislation Food supplements have their own labelling requirements, laid out in the Food Supplements (England) Regulations 2003 and equivalent regulations in Scotland, Wales and Northern Ireland¹ made These stipulate that:

No person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is "food supplement".

Without prejudice to the Food Labelling Regulations 1996, no person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless it is marked or labelled with the following particulars

- (a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;
- (b) the portion of the product recommended for daily consumption;
- (c) a warning not to exceed the stated recommended daily dose;
- (d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;
- (e) a statement to the effect that the product should be stored out of the reach of young children; and
- (f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

I-7-1 General labelling requirements

The provisions of the Food Labelling Regulations 1996 (as amended) govern food labelling in the UK (apart from Northern Ireland, which has similar parallel legislation). These regulations lay down detailed requirements for the labelling of most foods to carry:

- A name;
- A list of ingredients,
- The amount of certain ingredients used;
- A date mark;
- Any special storage conditions or conditions of use;
- The name and address of the manufacturer, packer or EC seller;
- Instructions for use;
- The place of origin of the food, if failure to give it might mislead.

These requirements apply to food products, which are ready for delivery to the "ultimate consumer" or to a catering establishment. The "ultimate consumer" is someone who buys otherwise than a) for resale, b) for the purposes of a catering establishment or c) for the purposes of a manufacturing business.

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I-7-2- Most common labelling mistakes

- Non-authorized health claims are used the use of health claims is regulated in the EU. It is permitted to use health claims which are scientifically substantiated and authorized by the European Commission. The health claims requirements apply not only to sales packages but also to the information in the online store, presentations, advertisements and other forms of information.
- Health claims are provided about the product, not for the ingredients of the product Claims should be made with regard to the ingredients in the product and not to the product.
- Prohibitive claims referring to treat, prevent or cure the diseases Claims referring to diseases may be made for medicinal products. In the case of food supplements, it is permitted to use health claims, which refer to reducing the risk of disease, and are authorized by relevant legislation.
- Group names of additives not included in the list of ingredients This concerns in particular products from third countries (e.g. the USA) where the indication of group names of additives is not mandatory. In this case, group names of additives must be included to the product's labelling in Estonian.
- The quantities of active ingredients are not indicated for the recommended daily intake If the recommended daily intake is more than one capsule/tablet, quantities per unit should also be reported. If the recommended daily intake is between 2 and 4 tablets, the quantities should be reported for minimum and maximum quantities.
- The names of the ingredients are inaccurate For example, the Latin names of plants or the plant parts used have not been specified.
- The list of ingredients includes information on quantities Only a list of ingredients shall be included in the list of ingredients. The quantities of the active ingredients (per daily intake) must be specified separately. If all of the above-mentioned information is provided together, it is no longer easily understandable for the consumer.

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- A nutrition claim is presented without the quantities of the substances If a nutrition claim is made (e.g. ‘high vitamin and mineral content’), it should also be indicated which vitamins/minerals the product contains and what amounts. In the case of food supplements, quantities per recommended daily intake must be provided.
- The statement ‘The food supplement does not replace a varied and balanced diet and a healthy lifestyle’ is used One sentence is intended to meet two different requirements: - It is mandatory for all food supplements to use a warning that the food supplement should not be used as a substitute for a varied diet and - when health claims are made on a product, it is mandatory to refer to the importance of a varied and balanced diet and a healthy lifestyle. It is recommended to use two different sentences: ‘The food supplement may not be used as an alternative for a varied diet!’ and ‘It is important to have a varied and balanced diet and practice a healthy lifestyle.

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IV- Definition of Functional foods

Functional foods are close to traditional foods (appearances, nutritional qualities) but they provide demonstrated physiological benefits or reduce the risk of chronic disease, due to a modification of their composition (bioactive composition). They have a functional value that a traditional food does not have.

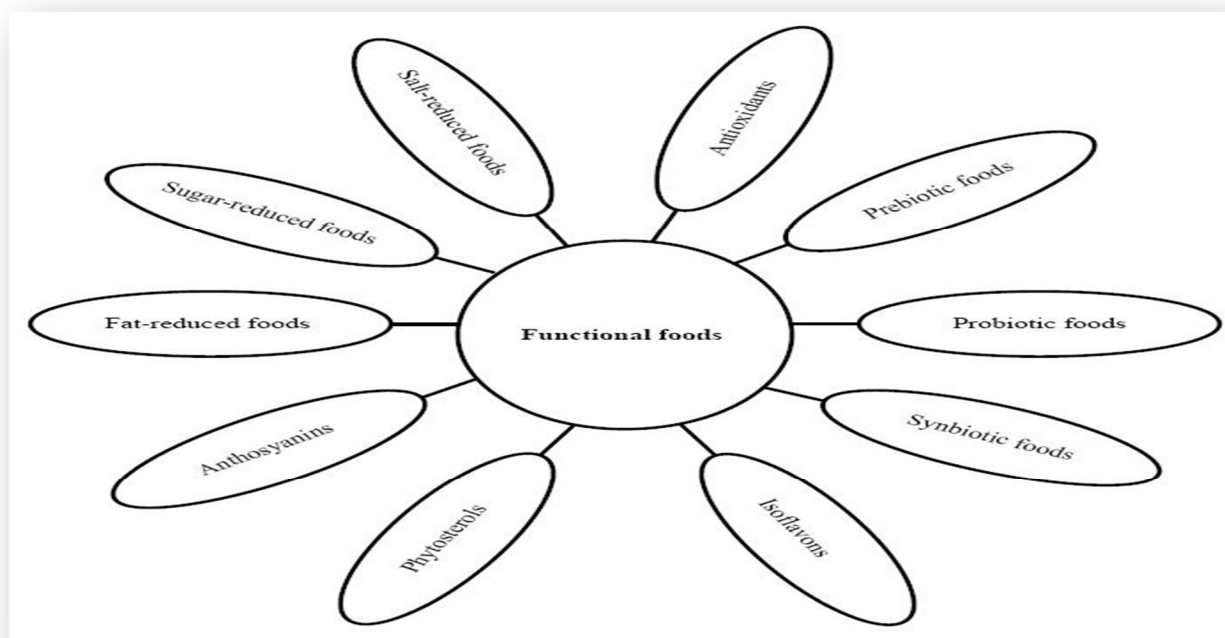
Examples: actimel, ω -3 margarine yogurt, classic margarine.

the functional foods are foods that have a potentially positive effect on health beyond basic nutrition. Proponents of functional foods say they promote optimal health and help reduce the risk of disease. A familiar example of a functional food is ‘Oatmeal’ because it contains soluble fiber that can help lower cholesterol levels. The Food and Drug Administration regulates the claims that manufacturers can make about functional food nutrient contents that effects on disease, health or body function.

Functional foods may include such items as cereals, breads, beverages that are fortified with vitamins, some herbs and nutraceuticals.

Functional foods can be considered to be those whole, fortified, enriched Functional Food or enhanced foods that provide health benefits when they are consumed with diet on a regular basis. All foods are functional, as they provide taste, aroma or nutritive value. The term functional food was introduced in Japan in the mid-1980s and refers to processed food containing ingredients that aid specific bodily functions in addition to being nutritious.

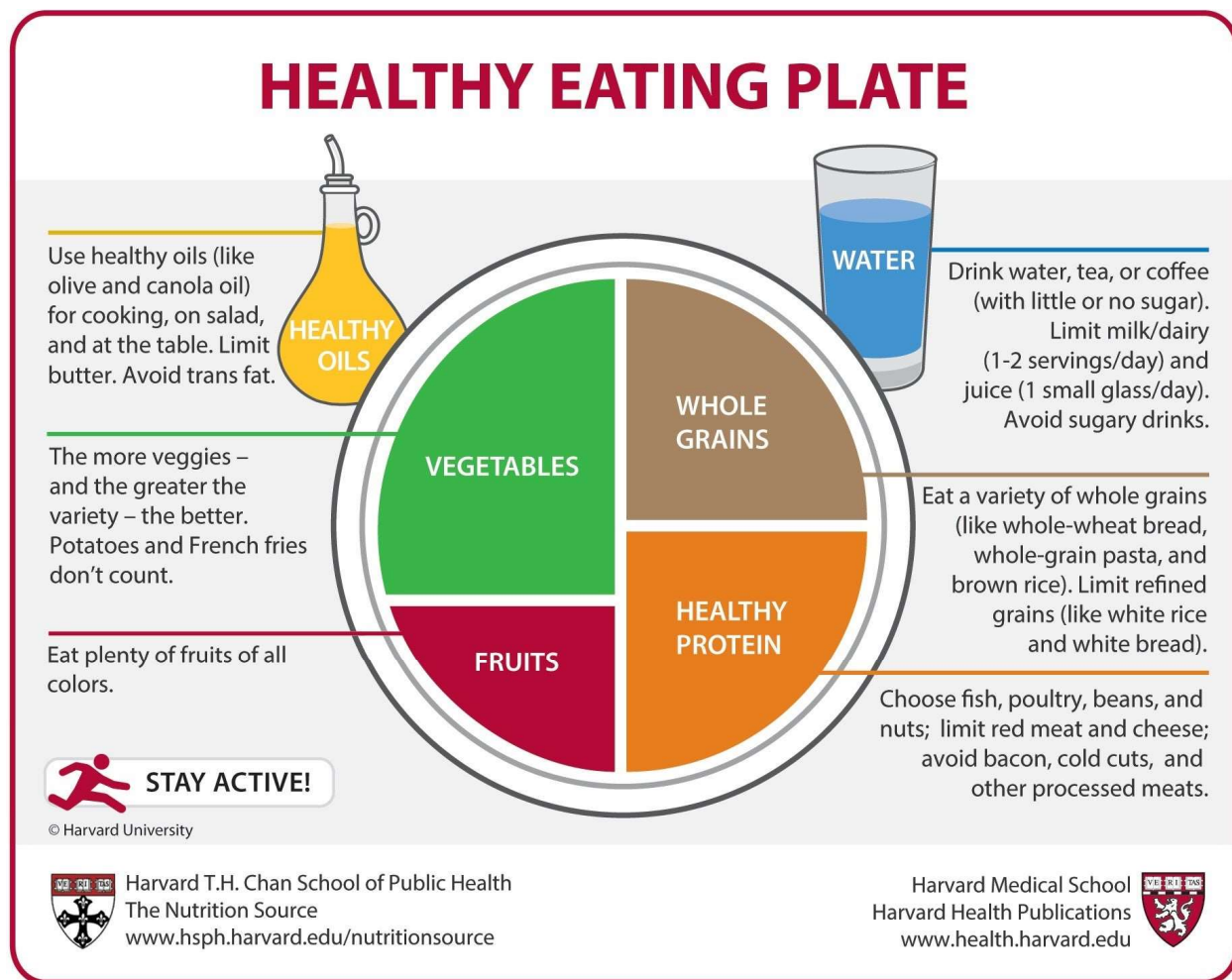
- The European Food Safety Authority (EFSA) defines functional foods as: “A food, which beneficially affects one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease. A functional food can be a natural food or a food to which a component has been added or removed by technological or biotechnological means, and it must demonstrate their effects in amounts that can normally be expected to be consumed in the diet



Features of Functional Foods

1- Benefits of Functional Foods

- A functional food may be a traditional food which we consume as part of our usual diets. It is shown to have physiological benefits and reduce that risk of chronic disease as it contains bioactive compounds.
- A functional food is a typical food that has specific nutrients added to it, like vitamins or minerals, fiber or probiotics or prebiotics. In general, this includes anything for a specific function purpose.
- Functional foods can be considered to be those whole, fortified, enriched or enhanced foods that provide health benefits beyond the provision of essential nutrients, for example vitamins and minerals, when they are consumed at efficacious levels as part of a varied diet on a regular basis. However, not all foods on the market today that are claimed to be functional foods



2- Types of Functional Foods

1. **Whole Food:** It includes Oats, Soya, Fish, Garlic, Flaxseeds and Nuts, Grapes, Fruits and Vegetable.

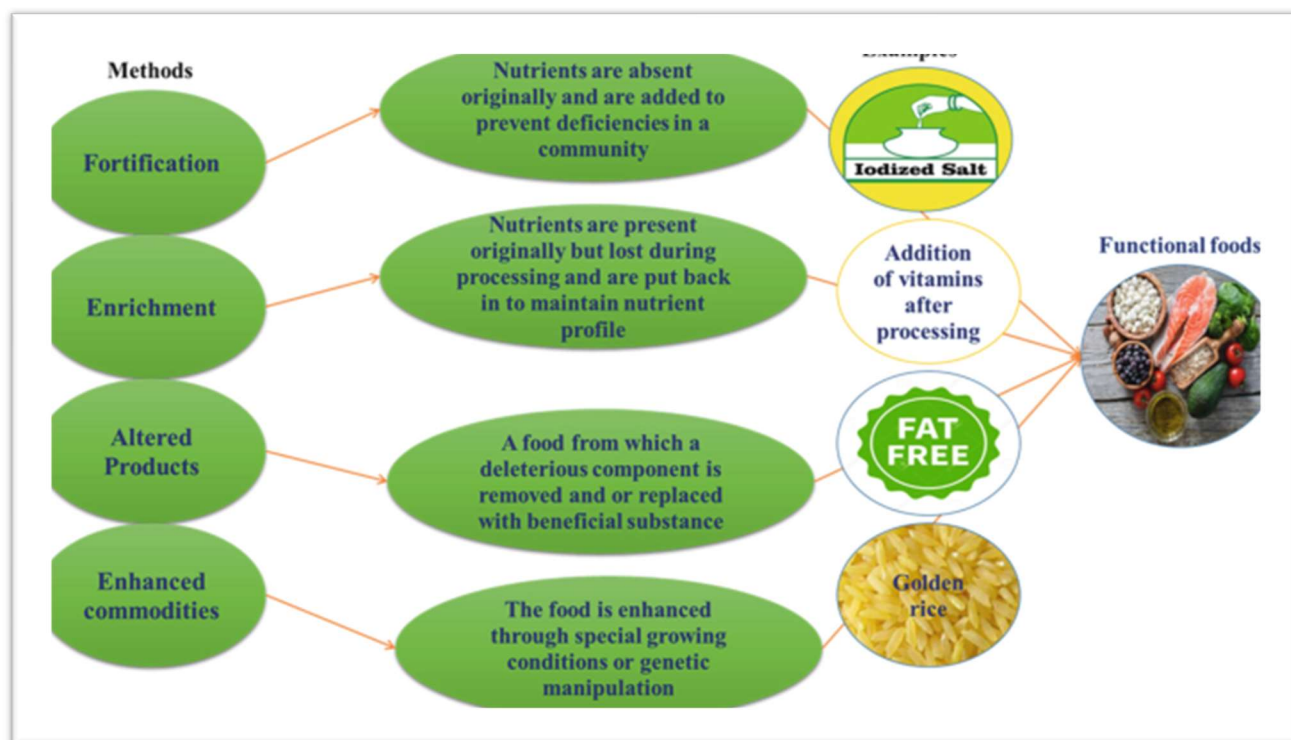
2. **Fortified Foods:** It includes the following;

- Fortified foods are natural foods fortified with other nutrients.
- Cereal and Cereals-Based products fortified with Folic Acid.
- Milk and Milk products are fortified with Vitamin B.

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- Fats and Oils are fortified with Vitamin D and E.

3. **Enhanced foods** are foods that have more of a functional component through traditional breeding, genetic engineering, etc., for example dairy product with probiotics.



The benefits derived by these foods are as follows:

- ✓ Reduce risk of Colon Cancer.
- ✓ Treatment of Respiratory Allergies.
- ✓ Control of Diarrhea and Dysentery Disorders.
- ✓ Decreases the Cholesterol level thus reducing the risk of heart disease.

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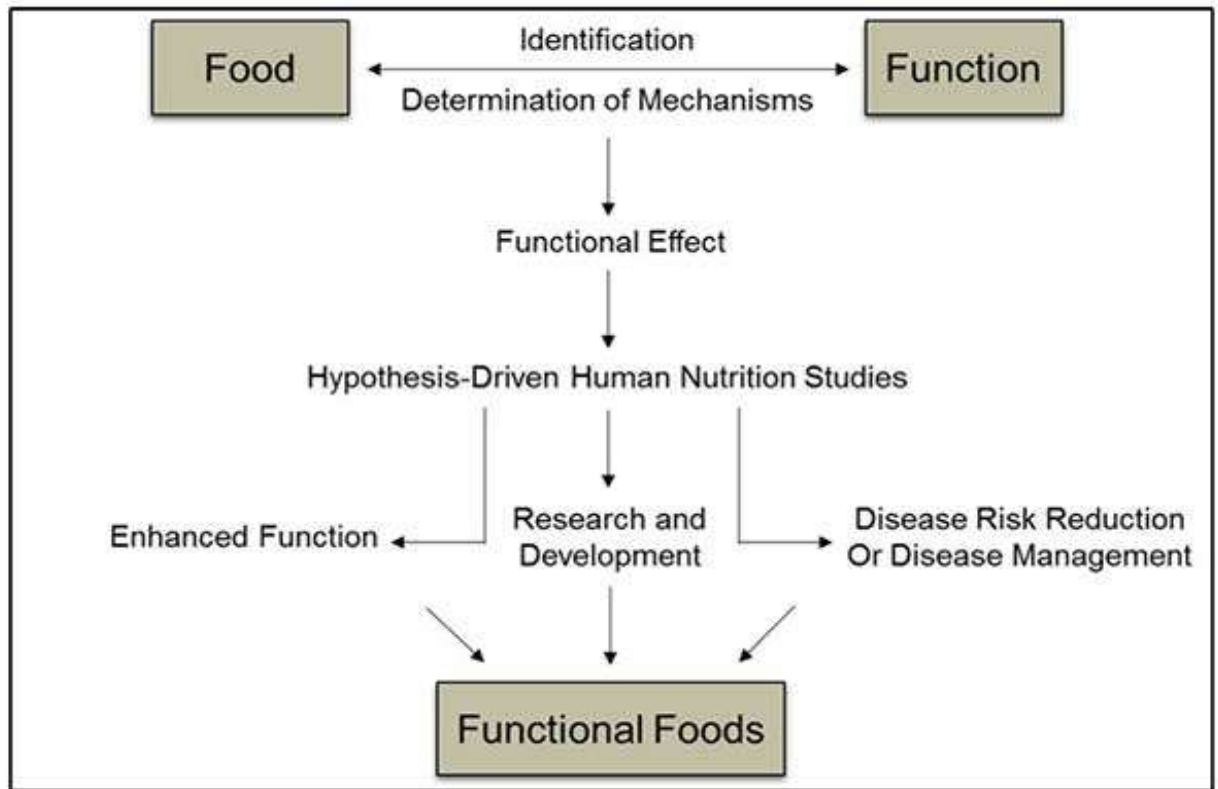


Figure 1. Scientific Basis for Establishing Functional Foods. Gibson GR, Williams CM. Woodhead publishing limited: 2000 Jan 1.

a. Grouping of Functional Foods

the functional foods are grouped as follows.

Basic Foods

Tomatoes having the natural level of the antioxidant Lycopene.

Processed food includes Oat Bran Cereal having the natural level of Beta Glucan.

Fortified Foods

- Tea, Beverages and Fruit Juices are fortified with Calcium.
- Milk is fortified with Vitamin D.
- Grains are fortified with Added Fibers.

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- Fats and Oils are fortified with Vitamin D and E.

Enhanced Foods

Enhanced foods have more of a functional component through traditional breeding, genetic, engineering, etc.

- Dairy products with probiotics.
- Eggs with Omega-3 isolated. Purified preparations of active food ingredients, such as herbal products.
- Curcumin from Turmeric. • Isoflavones from Soy. • Omega-3 from Fish Oils.

b. Example of functional food

• Prebiotics

Prebiotics are compounds in food that induce the growth or activity of beneficial microorganisms, such as Bacteria and Fungi. The most important example is in the gastrointestinal tract, where prebiotics can alter the composition of organism in the gut micro-biome.

Definition of Prebiotics:

According to International Scientific Association Probiotics and Prebiotics (ISAPP), 'the prebiotics are a substrate that is selectively used by a host microorganism to produce a health benefit'.

Dietary prebiotics are typically non-digestible fiber compounds that pass indigested through the upper part of the gastrointestinal tract and stimulate the growth or activity of advantageous bacteria that are colonial in the large bowel by acting as substrate for them.

Compounds that can be classified as prebiotics must also meet the following criteria:

- Non-digestible and resistant to breakdown by stomach acid and enzymes in the human gastrointestinal tract.

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- Selectively fermented by intestinal microorganisms.
- Selectively target and stimulate the growth and activity of beneficial bacteria.

Prebiotics are classified as the non-digestible food ingredients that probiotics can feed. They are used in the gut to increase populations of healthy bacteria and digestion and enhance the production of valuable vitamins. Good bacteria play a significant role in regulating your immune system, inhibiting the growth of pathogens and digesting food. Galacto-Oligo-Saccharides (GOS) are the most advanced form of prebiotics which belong to a group of particular nutrient fibers that feed and encourage the growth of good bacteria in the gut.

- **Probiotics:**

These are good bacteria that are either the same as or very similar to the bacteria that are already in your body, it helps to improve immune system also and promote the production of natural antibodies in the body.

Different Types of Probiotics

There are several different kinds of probiotics, and their health benefits are determined by the job that they do in the gut. There are the different types of probiotics and their health benefits

1) Lactobacillus

There are more than 50 species of Lactobacilli. They are naturally found in the digestive, urinary and genital systems. It is the most common probiotic and you will find in yoghurt and other fermented foods. Lactobacillus has been used for treating and preventing a wide variety of diseases and conditions. EX: diarrhoea, lactose intolerances, skin disorders, eczema and acne and prevention of respiratory infections

2) Bifidobacteria

There are approximately 30 species of Bifidobacteria. They make up most of the healthy bacteria in the colon. It is present in some dairy products. It may help ease

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the symptoms of Irritable Bowel Syndrome (IBS) and some other conditions. They can help on improving Blood Lipids and Glucose Tolerance

3) *Saccharomyces Boulardii*

Saccharomyces Boulardii is a yeast found in probiotics. It appears to help tight diarrhoea and other digestive problems.

4. Streptococcus Thermophilus

Functional Food Lactase enzyme is produced by Streptococcus Thermophilus probiotic making it effective, according to some reports, in prevention of Lactose Intolerance

.5) *Leuconostoc Leuconostoc*

has been used extensively in food processing throughout human history, and ingestion of foods containing live bacteria, dead bacteria and metabolites of these microorganisms has taken for a long time

a- Synbiotics

refer to dietary supplements combining probiotics and prebiotics in a form a synergism, hence Synbiotics.

When a product contains both probiotics and prebiotics it is termed as “synbiotics”. This word implies synergy acting together. Synbiotics therefore, were developed so that the prebiotic component helps the probiotic microorganism grow and overcome possible survival difficulties. The probiotics use the prebiotics as a food source, which allows the probiotics to survive for a longer period of time inside the GIT than would otherwise be possible. And this is based on evidences that show improvement of the probiotic bacteria’s survival when it passes the upper intestinal tract. H₂O₂, pH, organic acids, oxygen, moisture and stress are among several factors that have been shown to affect the viability of probiotics especially in dairy products like yogurts. Synergism also acts to provide more efficient implantation in the colon of live microbial dietary supplements as well as stimulating the growth of probiotics. A probiotic needs its food and a prebiotic fuel for its perfect survival in the GIT. But

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it is important that in order to have a beneficial effect on human health, prebiotic compounds should selectively stimulate the growth of probiotics and not stimulate other microorganisms. A combination of Lactobacillus or Bifidobacterium genus bacteria with FOS (fructooligosaccharides) is the most common example of a symbiotic.

Benefits of Symbiotic

1. Support Digestive Health Symbiotic pack a double punch when it comes to gut health by supplying a stream of both pre and probiotics to the body. Probiotics are form of beneficial bacteria that help promote proper digestion. In fact probiotics have shown improvement in several digestive ailments and are helpful in the treatment of uncreative colitis and Irritable Bowel Syndrome (IBS)
- . 2. Enhance Immune Functions Studies have shown that 70 per cent to 80 per cent of the body's immune cells are right in digestive tract. Symbiotic can help enhance immune function by increasing the amount of good bacteria in the gut while simultaneously decreasing inflammation. Studies have found that supplements with probiotic can improve immunity. In one study consuming milk with probiotics decreased the incidence and severity of respiratory infections by about 17 per cent among children
- . 3. Improve Mental Health Adding symbiotic to your diet may improve cognitive function and protect mental health by delivering a healthy dose of probiotics and prebiotics in each serving certain types of bacteria, such as Lactobacillus and Bifidobacterium enhance memory and improve symptom of Anxiety, Depression, Autism, Spectrum Disorder and Obsessive-Compulsive Disorder
- . 4. Boost Weight Loss Most interesting benefits of Symbiotic is their ability to boost weight loss and grant up fat burning. Probiotics may help block fat absorption to cut calories consumption. Prebiotics are found in high fibre which have been linked to a lower body weight and decreased body fat
- . 5. Promote Heart Health Heart problem is increasing day by day around the world. Symbiotic can help keep your heart healthy and strong by reducing several heart disease risk factors.

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Sources of Functional Foods

The different dietary sources of Functional foods with their bioactive compounds are given below:

Functional foods

Nuts, seeds, and oils

Fish

Legumes

Anthocyanins, catechins,

Grapes and red wines
myricetin,

Citrus fruits and vegetables

Tomatoes

Vegetable oils
tocotrienols

Bioactive compounds

-Vitamin E

- Omega-3 fatty

- Polyphenols ,

cyanidins, and flavonols,

- Vitamin C

- Lycopene

- Tocopherol,

Health Benefits of Functional Foods

Some functional components of foods have a major role in health enhancement. In fact, the big importance of these “bioactives” present in many foods, either naturally or added, has lead many scientists of different fields to conduct studies aimed for establishing the scientific basis that supports and validates the benefits of a particular food or component for the human health.

Soyabeans

Several classes of anticarcinogens have been identified in soyabeans, including protease inhibitors, phytosterols, saponins, phenolic acids, phytic acid and isoflavones. These, isoflavones (genistein and daidzein) are particularly noteworthy because soyabeans are the only significant dietary source of these compounds. Isoflavones are heterocyclic phenols structurally similar to the oestrogenic steroids.

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Because they are weak oestrogens, isoflavones may act as antioestrogens by competing with the naturally occurring endogenous oestrogens. This may explain why populations that consume significant amounts of soya have reduced risk of oestrogen dependent cancer. However, more epidemiological data and clinical intervention trials are needed to investigate the role of soya in reducing cancer risk.

Flaxseed

Flaxseed is one of the richest sources of mammalian lignan precursors. Because enterodiol and enterolactone are structurally similar to both naturally occurring and synthetic oestrogens, and have been shown to possess weakly oestrogenic and anti-oestrogenic activities, they may also play a role in the prevention of oestrogen-dependent cancers. In rodents, flaxseed has been shown to decrease tumours of the colon, mammary gland and lung. Phipps et al. (1993) demonstrated that the ingestion of 10 g of flaxseed per day elicited several hormonal changes associated with reduced breast cancer risk. However, as is the case with soya, epidemiological data are required to support the hypothesis that enterodiol and enterolactone have anticarcinogenic properties in man.

Tomatoes

Tomatoes have received much attention in recent years because of interest in lycopene, the primary carotenoid in this fruit, and its potential role in cancer risk reduction. In a prospective cohort study of more than 47 000 men, those who consumed tomato products ten or more times per week had less than onehalf the risk of developing advanced prostate cancer. Interestingly, lycopene is the most abundant carotenoid in the prostate gland. Other cancers whose risk has been inversely associated with serum or tissue levels of lycopene include breast, digestive tract, cervix, bladder and skin. Proposed mechanisms by which lycopene could influence cancer risk are related to its antioxidant function. Lycopene is the most efficient quencher of singlet oxygen in biological systems.

Garlic

Garlic (*Allium sativum*) is probably the herb most widely quoted in the literature for medicinal purposes. Allicin then decomposes spontaneously to form numerous sulfurcontaining compounds, some of which have been investigated for their

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chemopreventive activity. Garlic components have been shown to inhibit tumourigenesis in several experimental models. A review of twenty epidemiological studies suggested that allium vegetables, including onions, may confer a protective effect on cancers of the gastrointestinal tract.

Tea

Catechins are the predominant and most significant of all tea polyphenols. The four major green tea catechins are epigallocatechin-3-gallate, epigallocatechin, epicatechin-3-gallate and epicatechin. Much of the work on the health effects of tea has focused on its cancer chemopreventive effects. The consumption of five or more cups of green tea per day was shown to be associated with decreased recurrence of stage I and stage II breast cancer in Japanese woman.

Effect of Food Processing and Storage

There are many changes mainly chemical, physical, and nutritional occurred during food processing and storage. The several advantages occurred after food processing as follows:

- ♣ Increased shelf-life.
- ♣ Decreased hazards from microbial pathogen.
- ♣ Prevents qualitative and quantitative losses of nutrients.
- ♣ Prevents spoilage (microbial, enzymatic, etc.).
- ♣ Inactivation of anti-nutritional factors.
- ♣ Ensured round the year availability of seasonal foods.
- ♣ Facilitates production of easy to handle and transport food items.
- ♣ Saves time and labour.
- ♣ Makes food distribution easy.

Chapter IV: Functional foods (definition, legislation, different categories of claims, labeling rules, content of files)

♣ Makes foods more acceptable through the incorporation of variety, colour, texture and tastes.....etc. However, there are certain disadvantages of food processing and storage. The very few are discussed below:

♣ Damage of colour.

♣ Changes of flavour.

♣ Changes of functional properties of the food.

♣ Damage of texture of the foods.

♣ Development of toxic constituents.....etc. In case of cereals, husk or bran are often losses of dietary fibre, Vitamins etc. Antioxidants are destroyed as parboiled rice is more susceptible to lipid peroxidation. Refining process of fat & oil comprises of lecithin, free fatty acids removal. In processing fruits & vegetables are losses of carotenoids and other pigments into cooking as well as canning.

Chapter III

Examples of Natural Nutraceutical Ingredients: Plant Extracts

III-1- Examples of Natural Nutraceutical Ingredients: Plant Extracts

Nutraceuticals, also known as functional foods, are foods that have a beneficial effect on the body. Nutraceuticals can be found in all foods, regardless of their action, and can also be consumed in the form of dietary supplements.

A- Animal-Derived Nutraceuticals:

The most effective nutraceuticals derived from animals are fatty acids. They are abundant in fatty fish such as tuna, salmon, sardines, mackerel, or herring. These fatty acids are essential for the cell membrane, particularly those of the eye and brain. Probiotics are another type of nutraceuticals. These are microorganisms found in dairy products like yogurt, which promote good digestion.

B- Plant-Derived Nutraceuticals:

There are numerous nutraceuticals extracted from plants. Garlic can be used to lower blood pressure and thus ensure good cardiovascular health. Some nuts, as well as cocoa, help control cholesterol levels. Red wine, like grape juice, contains nutraceuticals that are also beneficial for the heart

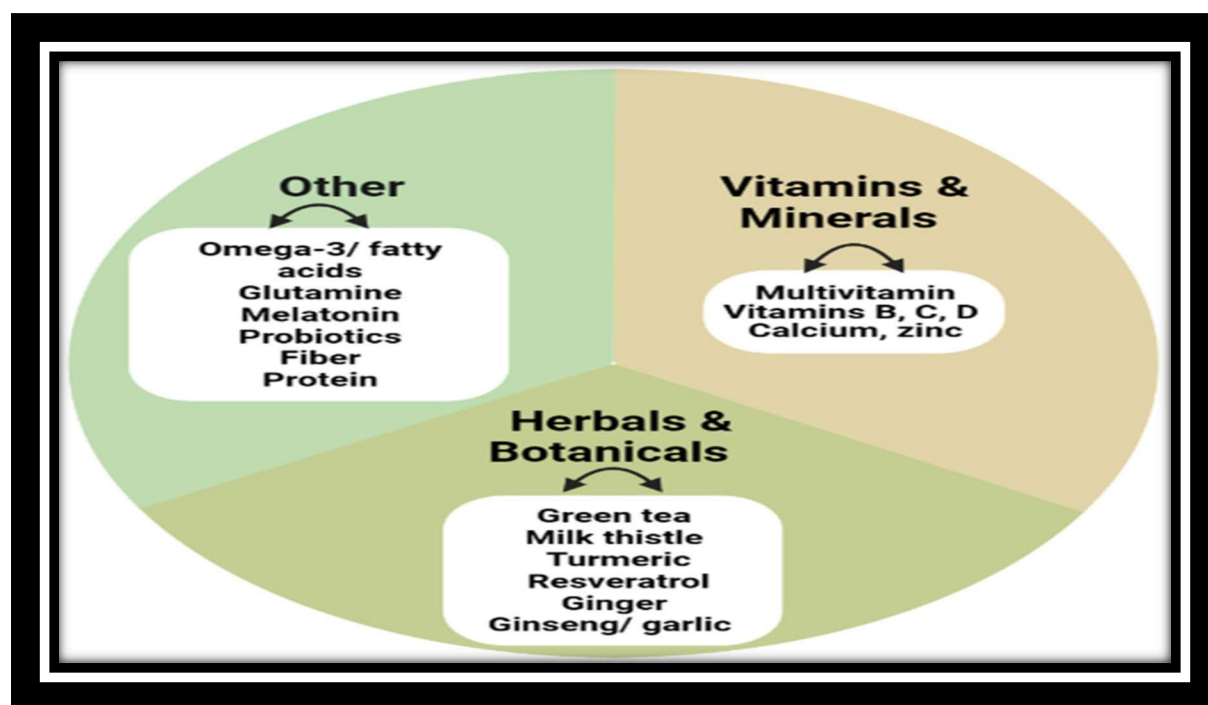


Figure 12: Natural Nutraceutical Ingredients

C- Consumer Interest in Dietary supplements and Uptake

Dietary supplements appear to be attractive to consumers who wish to maintain or restore a normal state of health and correct or prevent imbalances. According to the Council for Responsible Nutrition, the most-cited reasons for taking supplements are to improve immune health (36%) or “maintain” general health/well-being (44%). Despite a lack of evidence for their therapeutic efficacy, more than one third of adults in the US or Europe take a daily multivitamin/mineral supplement to prevent the development of chronic diseases. Although there is currently a plethora of supplements on the market, some of the most commonly used ones are summarized.

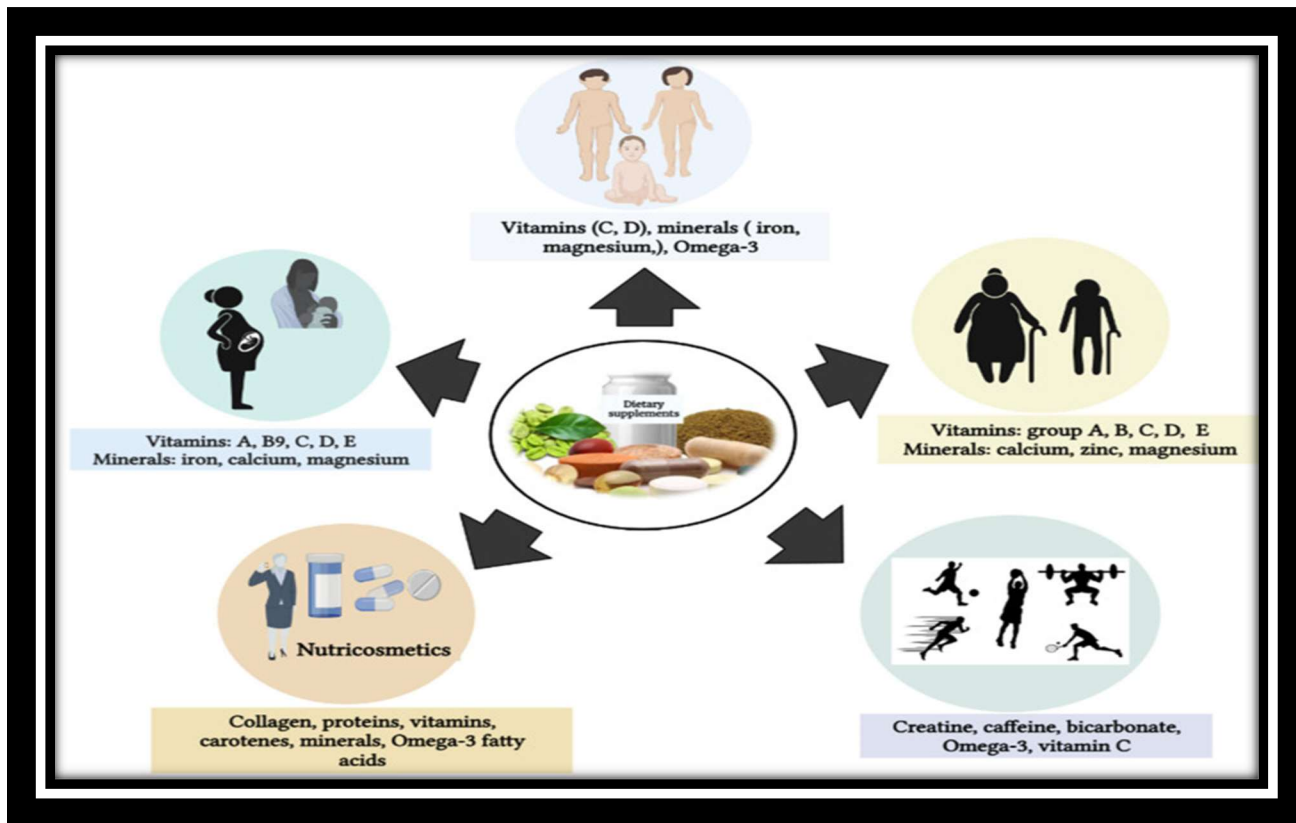


Figure 13 : Consumer Interest in Dietary supplements and Uptake

III-1-1 - Manufacturing Process of Dietary Supplements:

a- Manufacturing:

The selected ingredient is integrated into a mixture and presented in a galenic form: tablet, capsule, or infusion. This form will subsequently be packaged and identified by a lot number to ensure traceability. A declaration to the DGCCRF (Directorate-General for Competition, Consumer Affairs, and Fraud Control) will be mandatory before any market placement (Website, synadiet). The manufacturing traceability of a dietary supplement is illustrated step by step in the following figure.

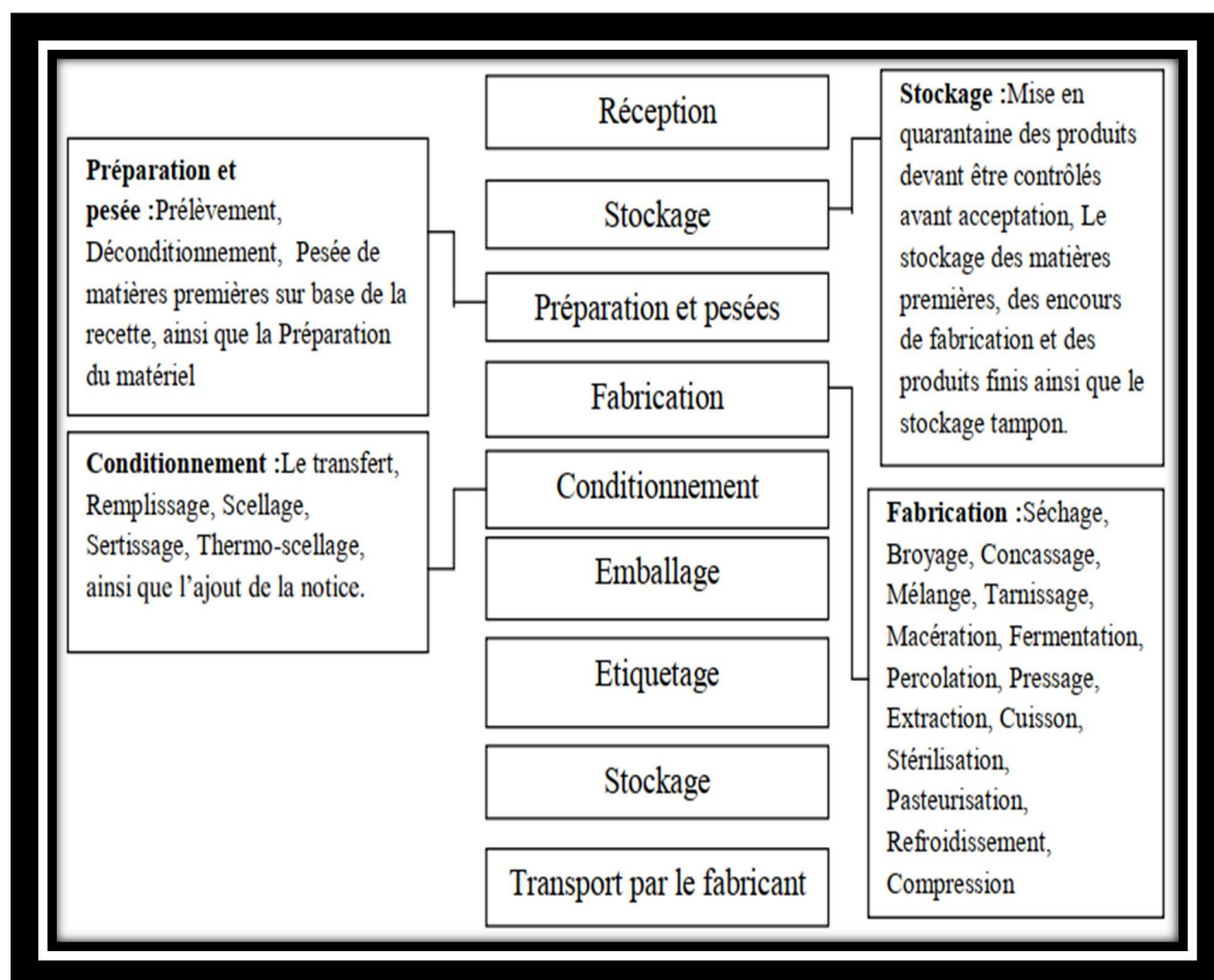


Figure 14: Manufacturing Process of Dietary Supplements

- Ingredients must be part of a positive list, i.e., authorized vitamins and minerals.
- Each element must adhere to a different maximum dosage depending on the target group (pregnant women, elderly individuals, etc.).
- Strict criteria are defined regarding the purity of the vitamins and minerals used. The development of a dietary supplement must consider quality and safety requirements from its conception. This step is fundamental as it determines the product's quality and sustainability.

b- HACCP Analysis:

The Hazard Analysis and Critical Control Points (HACCP) method, made compulsory by Regulation EC 853/2004 on food hygiene, involves a comprehensive analysis of hazards, their severity, and frequency of occurrence associated with each stage from product conception to delivery. This analysis leads to adopting appropriate and preventive control measures and defining critical control points to ensure product safety and quality. The goal of HACCP is to enable professionals to effectively manage hazards that may affect consumer health. It aids in establishing effective management and monitoring of hazards assessed as unacceptable in terms of their impact on consumer health. An HACCP study should be applied from the early stages of product development to minimize potential risks and even eliminate them.

c- Quality Control:

Quality control can be applied to both packaging materials: each packaging article must comply with the regulatory requirements of Regulation EC No. 1935/2004 and Decree No. 92-631 dated July 8, 1992, along with its specifications. The final packaging must bear necessary information and specific mentions in the required form and place. An authorized person must ensure that the packaging aligns with regulations.

III-1-2- Plants in Dietary Supplements:

As a reminder, 540 plants are authorized in France, with 73 subjects to specific restrictions. Comparing the Belgian and Romanian lists, 632 species appear common to both, 246 plants are specific to the Romanian list, and 36 to the Belgian list.

Plants authorized in the composition of dietary supplements are defined based on various criteria. They must possess nutritional or physiological effects that do not classify them as plants with therapeutic properties. Authorized plants can:

- Be part of the 148 plants whose free sale is authorized.
- Be traditionally used in the diet of at least one European Union country.
- Benefit from European authorization as a new food ingredient.

Order dated June 24, 2014, establishing the list of plants, other than fungi, authorized in dietary supplements and the conditions of their use.

a- Annex I: PLANTS WHOSE USE IS AUTHORIZED IN DIETARY SUPPLEMENTS.

Chapter III Examples of Natural Nutraceutical Ingredients: Plant Extracts

NOM scientifique	FAMILLE	NOM vernaculaire	PARTIES utilisées	SUBSTANCES à surveiller	RESTRICTIONS	
Abies alba Mill.	Pinaceae	Sapin pectiné, Sapin blanc, Sapin argenté	bourgeon, feuille (aiguille), écorce	dérivés terpéniques		
Abies balsamea (L.) Mill.	Pinaceae	Sapin baumier	feuille (aiguille), écorce	dérivés terpéniques		
Abies sibirica Ledeb.	Pinaceae	Sapin de Sibérie	feuille (aiguille)	dérivés terpéniques		
Acacia nilotica (L.) Delile	Leguminosae	Acacia du Nil	fruit, écorce, gomme			

Annex II: Information to be provided by operators in the food sector regarding the characterization of plant preparations:

1. Plant:

- Scientific name (botanical family, genus, species, variety with author's name, and, if applicable, chemotype).
- Vernacular names.
- Part used.
- Geographical origin (continent, country, region).
- Cultivation and harvesting conditions.

2. Plant raw material used for the preparation of the plant:

- Specifications in accordance with reference standards (pharmacopoeias, internal standards...) including identification tests and dosages of constituents responsible for physiological effects, possible markers, and, if applicable, constituents responsible for adverse effects (search for toxic substances: alkaloids...).

3. Preparation of plant and finished product:

- Standardization criteria (constituents responsible for physiological effects, relevant markers for plant identification, constituents presenting a toxicological risk). Specifications (quantitative levels per recommended daily portion and per 100 g, for constituents responsible for physiological effects and for markers).
- Physico-chemical properties of constituents of interest (stability).
- Purity criteria (microbiology, heavy metals, residual solvents, other contaminants).
- Justification of the formulation.
- Storage conditions.
- Post-market surveillance.

**Annex III: INFORMATION TO BE COMMUNICATED BY OPERATORS
IN THE FOOD SECTOR REGARDING THE SAFETY OF PLANT
PREPARATIONS:**

1. Exposure level:

- Estimated consumption of plant preparation, including quantity (maximum and average exposure), frequency, and duration.
- Potential consumption of plant preparation through other sources (other foods, medications).
- Modalities of use of the plant preparation.
- Known consumption data of the plant preparation.

2. Toxicological data:

- Constituents responsible for adverse effects (identification, dosage).
- Toxicology data from the bibliography (safety limits or tolerable doses in active substances or tracers, limits on potentially toxic secondary metabolites).
- Developments in the manufacturing process.
- Risk analysis demonstrating safety under the proposed conditions (target, recommended daily portion...).
- Information collected as part of global incident surveillance. This information also concerns neighboring species.
- Possible contraindications, especially for certain populations (pregnant women, breastfeeding women, infants, and young children...).
- Known molecular interactions (especially medicinal).

III-1-3- Definition of "Ambivalent" Plants:

Since the implementation of the "plant order," questions have arisen, particularly regarding so-called ambivalent plants. Indeed, many plants considered as food also have pharmacological properties justifying their use as medicinal plants. For example, traditional tea is used to combat fatigue. It is essential to note that food law does not prohibit the use of medicinal plants, and medical use does not exclude dietary use. In 2009, the European Court of Justice reiterated that one or more medicinal plants used in the composition of a product are not sufficient to consider the product as a medicine rather than a foodstuff.

III -2- Example of Manufacturing a Dietary Supplement from a Mixture of Natural Substances and Plant Extracts:

The use of plants in dietary supplements is based on traditional uses of powders, dry or aqueous extracts, or more modern extraction techniques allowing the isolation of substances from plants, e.g., lutein, lycopene... Among the most commonly used plants in the dietary supplements market:

Manufacturing Echinacea from Echinacea



Figure 15: Echinacea purpurea and the Echinacea dietary supplement

1- Plant description:

The genus *Echinacea* of the Asteraceae family, which comprises 11 taxa (9 species and 2 subspecies), includes plants approximately 1 meter in height with yellow, pink, and occasionally white flowers. The center of the flower is covered with prickly tips. Known for its content of echinacosides and echinacein, *Echinacea* was used to support the immune system during periods of extreme cold.

2- The ECHINACEA dietary supplement:

Contributes to the normal functioning of the immune system and helps increase the body's resistance during cold periods.

Composition of ECHINACEA:

- *Echinacea purpurea* (150 mg/tablet): (Dry extract of aerial parts) is beneficial in facing winter aggressions. It contributes to the proper functioning of the immune system and helps increase the body's resistance.
- *Echinacea angustifolia* (50 mg/tablet): (Dry extract of the root) provides valuable support to the immune system, often weakened during the winter season.
- Vitamin B6: Contributes notably to the normal functioning of the nervous system, normal metabolism of proteins and glycogen, and normal psychological functions.
- Vitamin C: Or ascorbic acid. It notably contributes to protecting cells against oxidative stress and reducing fatigue.
- Zinc: It notably contributes to protecting cells against oxidative stress and maintaining healthy skin, hair, and nails.

3- Directions for use:

Take 2 to 3 tablets per day, 20 days per month, for 2 to 3 months. Swallow with water.

Keep out of reach of young children. It is advisable to respect the recommended daily dose. Not a substitute for a varied, balanced diet, and a healthy lifestyle. Store in a cool, dry place.

Table 5: Recommended daily portion Per 1 tablet:

For 1 tablete	
d'echinacée (purpurea)	150 mg
d'echinacée (angustifolia)	50 mg
Vitamine C	40 mg
Vitamine B6	0,63 mg
Zinc	5 mg

- 150 mg of echinacea (purpurea)
- 50 mg of echinacea (angustifolia)
- 40 mg of vitamin C
- 0.63 mg of vitamin B6
- 5 mg of zinc

ANNEX I: Vitamins and Minerals Authorized for Use in the Manufacture of Dietary Supplements

Extract from DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

Vitamins

- Vitamin A (μg RE)
- Vitamin D (μg)
- Vitamin E (mg α -TE)
- Vitamin K (μg)
- Vitamin B1 (mg)
- Vitamin B2 (mg)
- Niacin (mg NE)
- Pantothenic Acid (mg)
- Vitamin B6 (mg)
- Folic Acid (μg)
- Vitamin B12 (μg)
- Biotin (μg)
- Vitamin C (mg)

Minerals

- Calcium (mg)

- Magnesium (mg)
- Iron (mg)
- Copper (µg)
- Iodine (µg)
- Zinc (mg)
- Manganese (mg)
- Sodium (mg)
- Potassium (mg)
- Selenium (µg)
- Chromium (µg)
- Molybdenum (µg)
- Fluoride (mg)
- Chloride (mg)
- Phosphorus (mg)

ANNEX IV: MAXIMUM DAILY DOSES

Order of 9 May 2006 on the nutrients that can be used in the manufacture of dietary supplements

Vitamins

- Vitamin A: 800 µg.
- Vitamin D: 5 µg.
- Vitamin E: 30 mg (mg α-TE).
- Vitamin K: 25 µg.
- Vitamin B1: 4.2 mg.

Chapter III Examples of Natural Nutraceutical Ingredients: Plant Extracts

- Vitamin B2: 4.8 mg.
- Niacin:
- Nicotinamide: 54 mg.
- Nicotinic acid: 8 mg (mg NE).
- Pantothenic Acid: 18 mg.
- Vitamin B6: 2 mg.
- Folic Acid: 200 µg.
- Vitamin B12: 3 µg.
- Biotin: 450 µg.
- Vitamin C: 180 mg.

Minerals

- Calcium: 800 mg.
- Magnesium: 300 mg.
- Iron: 14 mg.
- Copper: 2000 µg.
- Iodine: 150 µg.
- Zinc: 15 mg.
- Manganese: 3.5 mg.
- Sodium: quantum satis according to the quantity provided by the anions.
- Potassium: 80 mg.
- Selenium: 50 µg.
- Chromium: 25 µg.

Chapter III Examples of Natural Nutraceutical Ingredients: Plant Extracts

- Molybdenum: 150 µg.
- Fluoride: 0 mg.
- Chloride: quantum satis according to the quantity provided by the cations.