

CHAPTER - 1.1

History and Definition of Functional Foods and Nutraceuticals

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Introduction

The role and requirements of six significant nutrients, viz., carbohydrates, proteins, fats, vitamins, minerals and water present in foods are well known. Besides these nutrients, certain health-promoting essential nutritional factors are present in foods that have protective and preventive functions for our body. The health-promoting effect of foods beyond their nutritional value is gaining wide popularity. This expansive vision of nutrition has led to the concept of “functionality”.

The principal reasons for the growth of the functional food market are the ageing population, health trends and public education. Due to the increase in life expectancy, the number of elderly continues to rise in the total population. Obesity, heart disease, cancer, osteoporosis and arthritis continue to climb worldwide. The internet has opened the doors for a wealth of information. People have become more nutrition savvy than ever before. Their curiosity regarding health care information can be met by just a single click, giving them vast knowledge about the etiology, prevention, and treatment of various diseases. Similarly, consumers are becoming more alert to health claims and are eager to know advanced information about food products.

History of Functional Foods and Nutraceuticals

During the last 2000 years, from the time of Hippocrates (460–377 BC) to the beginning of modern medicine, there was little distinction between food and drugs. Hippocrates, the father of medicine, clearly recognised the essential relationship between food and health and emphasised that “...differences of diseases depend on nutriment”. The concept of “Medicine and food are isogonics” originated in ancient China and

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transported to Japan long ago. Similarly, the doctrine of Hippocrates, “Let food be thy medicine and medicine be thy food,” has had a rebirth.

In 1984, a research team headed by Professor Soichi Arai at the University of Tokyo initiated the first national project on functional foods. The “Systematic analysis and development of food functions” project was sponsored by Japan’s Ministry of Education, Science and Culture (MESC). The food value criteria were defined in three categories:

1. Primary functions identified as functions of nutrients.
2. Secondary function refers to sensation.
3. Tertiary function as body modulating function of non–nutrients

During 1988-1991, the second project was taken up by Arai *et al.* on ‘analysis of body modulating (Tertiary) functions of foods. The project’s thrust was on the tertiary functions of foods, i.e., body modulating function of non-nutrients. With the advancement of DNA microarray techniques, the last project was undertaken in 1992, which focused on “Analysis and molecular design of functional foods”. The sub-themes were body-regulating food factors, body defending food factors and developing a technological basis specific to designing functional foods at the molecular level.

In 1989, **Dr Stephen L. DeFelice, M.D** coined the term ‘*nutraceutical*’, which is a hybrid or contraction of *nutrition* and *pharmaceutical*. He established the Foundation for Innovation in Medicine in 1976 in New York, US.

In 1991, the Ministry of Health and Welfare, Japan, launched the world’s first policy, “Foods for Specified Health Uses” (FOSHU), for legally permitting the commercialization of some functional foods. Each of the FOSHU products claimed a certain degree of health benefit. The first FOSHU product approved in 1993 was ‘hypoallergenic rice’ developed after immunological studies. These scientific activities were reported in *Nature* news with the headline, “Japan explores the boundary between food and medicine,” which took everyone back to the old days saying, “Medicine and food are isogonics’.”

The research team scientifically investigated hundreds of fruits and vegetables for functional food components. The advancement in this latest science also involved the introduction of sophisticated methods, viz., assessment of the oxidative stress due to food factors using the “XYZ’ evaluation technique, compilation of data on the structure-function relationships of non-nutrients and evaluation of individual food factors at the molecular level using DNA microarray techniques.

The initiation of functional food science and implementing of the FOSHU policy in Japan had a substantial impact on many countries worldwide, particularly in Europe. In 1995, the UK Ministry of Agriculture, Fisheries, and Food defined (although temporarily) functional foods as those incorporating components that confer specific medical or physiological benefits other than nutritional effects. The *International Life Sciences Institute (ILSI) Europe* addressed the present status by claiming that they stand today at the threshold of a new frontier in nutritional science. They also stated that the concept

of food is changing from a past emphasis on eating to satiate hunger into a focus on the potential uses of food to reduce the risk of chronic illness.

Nutrigenomic research institutions formed consortia to merge their activities aiming at evidence-based functional food science through cooperation in developing systems biology. In North America, the National Institute of Health (NIH) provided financial support for an ongoing research project on the relationship between diet and genes and between diet and disease in collaboration with nine research centres and four external affiliated organisations.

Europe launched a six years project in January 2004 that commenced with the participation of 22 research institutions from ten different countries. The European Union allocated a budget of 17.3 million euros for this project. A research organisation was set up in Oceania specialising in gut health research, and New Zealand and Australia played a leading role.

These initiatives were replicated in Canada, China, South Korea, Singapore, and other countries to form a global network. These countries launched a clear strategy to exchange information and invest their research resources in domains where they can capitalise on their strengths.

The history of functional food will remain incomplete if the views of Dr Stephen DeFelice, described by Jeffrey K. Aronson (2017) in his article published in the British Journal of Clinical Pharmacology is not mentioned. Dr Stephen DeFelice originally invented the term ‘nutraceutical’ in 1989. During the 25th National Congress of the Italian Chemical Society-SCI, held at the University of Calabria in 2014, he delivered a lecture on ‘Nutrition stymied: the nutraceutical solution’ in which he confessed that nutraceuticals do not work and ‘the quest to demonstrate whether ... long-term supplementation [with nutraceuticals] can prevent serious diseases ... has come to an end.

He stated that ‘within the past decade, the past ten years, many studies have been published on dietary supplements and diets ... and most of them have proven that these things do not work. The results of clinical studies have shown that they do not work. Later Dr DeFelice explained that it might be because the cell does not need them’. If the cells are not deficient, it does not need them. The cells just do what they want to do. ... There’s a lack of efficacy. Why is there a lack of toxicity? And then he came up with his theory. It’s called the cell–nutraceutical acceptance–rejection theory’. Dr DeFelice did not explain his theory; he merely said, ‘it is self-explanatory.



Figure 1.1.1 Fruits as Functional Foods

Health Claims

The health claim for each functional food was defined by the three different phrases viz., nutrient function claims, other function claims, and reduction of disease risk claims. Japan was the first country to legalize health claims under Foods for Specified health uses (FOSHU) in 1991. There were ten categories of health claims under FOSHU, which are presented in Table 1.1.1.

Table 1.1.1 Categories of Health Claims under “Foods for Specified Health Uses” (FOSHU)

Categories	Health claims
Category 1	Modulation of gastrointestinal conditions
Category 2	Modulation of serum cholesterol level
Category 3	Modulation of serum cholesterol level and gastrointestinal conditions
Category 4	Modulation of blood pressure
Category 5	Acceleration of mineral absorption
Category 6	Acceleration of mineral absorption and modulation of gastrointestinal conditions
Category 7	Promotion of bone health
Category 8	Maintenance of healthy teeth
Category 9	Modulation of blood sugar level
Category 10	Modulation of serum triacylglycerol level and blood fat percentage

Since 1991, about 1271 products have been given a green signal under FOSHU. Recently about 400 foods have been approved under Japan’s 2015 “Foods with Function Claims” (FFC) regulation.

The structure/function claims in the United States were expressed in the Dietary Supplement Health Education Act (DSHEA) in 1994. European Union established a science-based approach for concepts in functional food science as “Functional Food Science in Europe” (FUFOSE) in 1996. Codex adopted the guidelines in which the nutrient function claim was included in 1997. In India, the nutraceutical regulation was implemented in 2010 under The Food Safety and Standard Authority of India (FSSAI) Act.

Important milestones in the history of Functional foods and Nutraceuticals are shown in Table 1.1.2.

Table 1.1.2 Important milestones in the history of Functional Foods and Nutraceuticals

Year	Event
1984	Dr Arai <i>et al.</i> launched a project on “Systematic analysis and development of food functions’ sponsored by Japan’s Ministry of Education, Science and Culture.
1988	Arai <i>et al.</i> took up a second project on ‘the analysis of body modulating (i.e., Tertiary) functions of foods’.
1989	Stephen L. DeFelice, M.D. Founder and Chairman of Foundation for Innovation in Medicine New York, US coined the term <i>nutraceutical</i> from <i>nutrition</i> and <i>pharmaceutical</i>
1991	The Ministry of Health and Welfare, Japan, launched the world’s first policy “Foods for Specified Health Uses” (FOSHU) for legally permitting the commercialization of some functional foods
1992	The third project by Arai <i>et al.</i> on “Analysis and molecular design of functional foods”.
1993	“Hypoallergenic rice” was the first FOSHU product approved, developed after the immunological studies.
1994	The structure/function claims were expressed in the Dietary Supplement Health Education Act (DSHEA) in the United States.
1996	Functional Food Science in Europe (FUFOSE) established a science-based approach for concepts in functional food science.
1997	Codex adopted the guidelines in which the nutrient function claim was included.
2010	In India, nutraceutical regulation was implemented under The Food Safety and Standard Authority of India (FSSAI) Act.
2014	Dr. Stephen L. DeFelice, M.D., confessed that nutraceuticals do not work, and ‘the quest to demonstrate whether ... long-term supplementation [with nutraceuticals] can prevent serious diseases ... has come to an end’

Definitions of Functional Foods and Nutraceuticals

Functional foods are found in many fruits, vegetables, grains, herbs and spices to provide a health benefit, lower the risk of certain diseases or affect a particular body process. Different terminologies are used for functional foods such as Nutraceuticals, designer foods, vita foods, pharma foods, medicinal foods, prescriptive foods, therapeutic foods, superfoods, foodaceuticals and medifoods.

There were no universally accepted definitions for nutraceuticals and functional foods till 2017, although commonality existed between the definitions offered by different health-oriented professional organizations. But finally, in 2017, the Functional

Food Centre (USA) defined functional foods by providing clarity and a more comprehensive understanding of their meaning.

The following health-oriented professional organizations have defined functional foods and nutraceuticals.

- The International Food Information Council (IFIC), USA
- The International Life Sciences Institute of North America (ILSI)
- Health Canada
- Nutrition Business Journal (US)
- The American Dietetic Association (ADA)
- The American Council on Science and Health
- The Institute of Medicine of the National Academy of Sciences (IOM)
- According to the International Food Information Council (IFIC), functional foods are “foods or dietary components that may provide a health benefit beyond basic nutrition.”
- The International Life Sciences Institute of North America (ILSI) has defined functional foods as “foods that by physiologically active food components provide health benefits beyond basic nutrition”.
- Health Canada defines functional foods as “similar in appearance to a conventional food, consumed as part of the usual diet, with demonstrated physiological benefits, and/or to reduce the risk of chronic disease beyond basic nutritional functions”.
- The Nutrition Business Journal classified functional food as “food fortified with added or concentrated ingredients to functional levels, which improves health or performance. Functional foods include enriched cereals, bread, sports drinks, bars, fortified snack foods, baby foods, prepared meals, and more”.
- The American Dietetic Association (ADA) states that functional foods, including “whole foods and fortified, enriched, or enhanced foods, have a potentially beneficial effect on health when consumed as part of a varied diet and on a regular basis, at effective levels,”
- The American Council on Science and Health states that functional foods are “whole, fortified, enriched, or enhanced foods that provide health benefits beyond the provision of essential nutrients when consumed at efficacious levels as part of a varied diet on a regular basis.”
- The National Academy of Medicine (NAM), formerly called the Institute of Medicine (IoM), states that functional foods are “those in which the concentrations of one or more ingredients have been manipulated or modified to enhance their contribution to a healthful diet”.
- European Commission Concerted Action on Functional Food Science in Europe considers foods to be functional if they have a beneficial effect on one or more functions of the body and are still in the form of food, not a dietary supplement.

- In Japan, the FOSHU organization states that functional foods are “processed foods containing ingredients that aid specific body functions in addition to being nutritious”.
- The Functional Food Center/Functional Food Institute (FFC), Dallas, USA (2017) defines “functional foods” as: “Natural or processed foods that contain biologically active compounds; which, in defined, effective, and non-toxic amounts, provide a clinically proven and documented health benefit utilizing specific biomarkers for the prevention, management, or treatment of chronic disease or its symptoms.”

Nutraceuticals

The above definitions given by the Health-oriented professional organizations were for functional foods. The Foundation for Innovation in Medicine, the Nutrition Business Journal and the Health Canada defined nutraceuticals as follows:

- The term *nutraceutical* is a hybrid or contraction of *nutrition* and *pharmaceutical*. It was coined in 1989 by **Stephen L. DeFelice, M.D.**, who established the Foundation for Innovation in Medicine in 1976 in New York, the US, an educational foundation established to encourage discoveries in medicine.
- Dr Stephen DeFelice (1992) defined nutraceutical as any substance that may be considered a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements, and diets to genetically engineered “designer” foods, herbal products and processed products such as cereals, soups and beverages.”
- On the other hand, Health Canada states that nutraceuticals are a product that is “prepared from foods but sold in the form of pills or powders (potions), or other medicinal forms not usually associated with foods. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease.
- The Nutrition Business Journal states that it uses the term nutraceutical for anything that is consumed primarily or particularly for health reasons. Based on that definition, a functional food would be a kind of nutraceutical.
- In India, nutraceuticals are food components made from herbal or botanical raw materials, which are used for preventing or treating different types of acute and chronic maladies.



Stephen L. DeFelice, M.D.
The founder and chairman of
the Foundation for Innovation
in Medicine



Figure 1.1.2 Herbs as Functional Foods

The regulatory bodies of Japan, Europe and America regarding the concept of functional foods are as follows.

According to the **Japanese Ministry of Health and Welfare, Foods for Specified Health Uses (FOSHU)** are:

- Foods that are expected to have a specific health effect due to relevant constituents, foods from which allergens have been removed, and foods where the effect of such addition or removal has been scientifically evaluated, and permission has been granted to make claims regarding the specific beneficial effects on health expected from their consumption.
- Foods identified as FOSHU are required to prove that the final food product, but not isolated individual component(s), is likely to exert health or physiological effect when consumed as part of an ordinary diet.
- Moreover, FOSHU products should be in the form of ordinary foods (i.e., not pills or capsules).

Functional food: a European consensus by Functional Food Science in Europe (FUFOSE): The unique features of functional foods are:

- being a conventional or everyday food
- to be consumed as part of the normal/usual diet
- composed of naturally occurring (as opposed to synthetic) components, perhaps in unnatural concentration or present in foods that would not normally supply them
- having a positive effect on target function(s) beyond nutritive value/basic nutrition
- may enhance well-being and health and/or reduce the risk of disease or provide health benefits to improve the quality of life, including physical, psychological and behavioural performances
- have authorised and scientifically based claims.

Dietary Supplement Health Education Act (DSHEA) United States (1994) formally defined "dietary supplement" "using several criteria.

- A dietary supplement is a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, a herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients.
- is intended for ingestion in pill, capsule, tablet, or liquid form.
- is not represented for use as a conventional food or as the sole item of a meal or diet.
- is labelled as a "dietary supplement"
- includes products such as an approved new drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license (unless the Secretary of Health and Human Services waives this provision).

Conclusion

Functional foods are generally linked to health promotion. The physiological effects of functional food or bioactive compounds may vary. Still, their categories of action include physical performance, cognitive, behavioural, and psychological function, organ or system function, and combating chronic disease.

The term 'functional food' was born in Japan, and the Japanese were the first to observe that food could have a role beyond nutrient supply. Japan was the first country to legislate these products as 'Foods of Specified Health Use'. Europe and the American countries later incorporated the concept of food's added value.

The Functional Food Center (FFC), Functional Food Institute, USA (2017) defines "functional foods" as: "natural or processed foods that contain biologically active compounds; which, in defined, effective, and non-toxic amounts, provide a clinically proven and documented health benefit utilizing specific biomarkers for the prevention, management, or treatment of chronic disease or its symptoms."

Nutraceuticals are defined as chemical components of food, when ingested in appreciable amounts, demonstrate attributes such as good bioavailability and bio-efficacy and exert positive effects on health characterized by disease prevention and alleviation.

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