

THE FUNCTIONAL FOODS: DEVELOPMENT AND OPPORTUNITIES

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Abstract: The development of food science in near future depends on advance in functional food science, the concept of which was proposed first in Japan nearly in the 1980s. The Japanese government developed a regulatory agency to oversee the approval of functional foods in 1991. The name of this agency is called Foods for Specified Health Use (FOSHU). Functional foods are increasingly popular in the United States. Furthermore, functional foods are reported as one of the fastest growing segments of the food economy in United States. Research on food and nutrition plays an important role in the Framework Program of Development and Research in the European Commission, established in the seventh Framework Program for Funding and in conducted Europeans projects: PASSCLAIM, FUFUSE, etc.

INTRODUCTION

The way of approaching food has suffered a lot of modifications lately. One has changed the subsistence economy, where food was a problem of survival, with the abundance economy, where the excess food causes a lot of so-called “diseases of civilization”: heart disease, obesity, diabetes, and some types of cancer. Our society tries to find an optimum diet which should try to promote the consumption of foods with benefic effects on health. This is the context where the concept of “functional food” appeared. (Secretin, M., 2001).

a) FUNCTIONAL FOOD IN JAPAN

The history of functional food is not very old. In the 1980s, Japanese society, being aware of the aging process, has become more and more concerned with the prevention of the lifestyle related diseases, through daily dietary. This gave a strong impetus to food science and to the politicians in the food sector. (Arai, S., 2001).

The first national project with the theme „functional food”, entitled Systematic Analysis and Development of Food Function was started in 1984 and it was sponsored by Ministry of Education, Science and Culture (MESC). This project establishes three functions of food:

- the regular function, of feeding the body;
- the sensory function, related to the effects of taste and smell on the sense organs;
- the body modulating function of non-nutrients (a newly-defined function), which is directly or indirectly connected with the disease prevention.

Practically speaking, the third function established the basis of functional food, which can be defined as food that can intervene effectively in reducing the risk of lifestyle related diseases. The first project (1984 – 1987) was followed by a second one, entitled „Analysis of Body-modulating functions of Foods”. The last project from the series MESC „functional food” was realized in 1992. This one focused on „Analysis and Molecular Design of Functional Foods”, having the following sub themes:

- body regulation factors of aliments;
- body protection factors of aliments;
- development of a specific technological basis in designing functional foods at the molecular level.

The Ministry of Health and Welfare established in 1991 the world’s first policy that allows the legally commercialization of functional foods using the expression Food for Specified Health Use (FOSHU). According to the new legislation, food may be declared FOSHU if each expected effect specified that it could contribute to maintain health is based on certain data concerning the relationship between food (the components of food) and health.

If an applicant wants that his product to be approved as FOSHU, he must provide a sample of the product and the necessary documentation. The Ministry of Health and Welfare’s criteria for approval are:

- food is expected to contribute to the improvement of diet and to maintain / improve health;
- health benefits of food or its components must have a clear basis of nutritional care;
- the amount of daily food and its components consumption must be determined on appropriate medical and nutrition knowledge;
- the food and its components must be safe for consumption and they must be established by experiments;
- food components must be clearly defined in terms of physico-chemical properties and they must be analytically determined (both quantitative and qualitative);
- there should not be significant loss of nutritional components of food in comparison with normal values that are present in similar food;

- food must be in the form of ordinary consumption into a daily diet rather than consumed only occasionally; it must be in the form of ordinary food (not in another one, such as capsules or pills). In other words, the food and its constituents should not be used solely as medicines.

After inspection, the food that is recognized in this manner gets the permission to have printed on its label the official approval and the special benefit for health. (Arai, S., 2001).

Policy is centered on the approval of health claims for each FOSHU product. According to the health benefit, foods can belong to the following categories:

- foods that promote the growth of bacteria which are beneficial to the intestinal micro flora and help to maintain intestinal health medium;
- foods suitable for people with increased cholesterol levels;
- foods for minerals supplement with high absorption capacity (calcium and iron);
- foods that are beneficial for hypertensive people;
- beneficial foods for people with a high concentration of glucose in blood;
- beneficial foods for people with a high concentration of triglycerides in blood.

The first FOSHU product was approved in 1993 and that was the hypoallergenic rice, and, by 2001, there have been approved 192 FOSHU products.

Most food industries have given attention to the concept of functional food introduced by the research projects of the MESC, started in 1984. In the first five years after the introduction of FOSHU products (1991 – 1996), not many of them have shown interest because the permitted claims were limited to a small number of indirect and unattractive experiments, as compared to the large volume of scientific data required. Some permutations have gradually been realized and in recent years more functional products with popular brands have entered the market very well.

On this background a Committee of functional foods has been organized in Japan, at the International Life Sciences Institute, in 1996. Its members are divided into four groups: criteria for establishing the scientific data, rules for health claims, sales situation, and research.

From the events that have marked the history of functional food in Japan, Soichi Arai selected some studies on:

- Antioxidant factors. The oxidative stress can cause the free radicals reactions that produce the damage of the membranes, enzymes and DNA. Diseases of aging, such as cancer, arteriosclerosis and diabetes are also related to oxidative stress. Starting from the idea that endogenous antioxidants from plants play an important role in defense against oxidative stress, Japanese researches obtained important results by researching the sesame lignans, the phenols and β -quinones.
- Cancer preventing factors, taken from fruit and vegetables, with special attention to plants on the families Rutaceae, Cruciferae, Umbelliferae, Zingiberaceae, which are also used for other than their nutritional values (e.g., odor, flavor characteristic and traditional medicinal proprieties). These plants contain anti-tumour promoters at high rates.
- Derived peptides from food proteins. A large number of bioactive peptides have been separated from milk proteins (casein and lactoferrin), but also from other protein sources (gluten, ovoalbumin, fish proteins, soy proteins), and the effects on health are well known (anticholesterol, antiinfectious, immunostimulative, antihypertensive effects etc.)
- Modulators of the immune system – (the probiotics and the prebiotics). The probiotics are viable microorganisms that have beneficial effects in the host's health by improving the indigenous microflora. They stimulate the immune defense of the host. The prebiotics are indigestible food ingredients that influence the host beneficial by stimulating a selective growth and / or the activity of certain species or a limited number of bacteria from the colon.
- Hypoallergenic products from wheat;
- Hypoallergenic products from soy;
- „XYZ” evaluation system. Noting the reactive oxygen with [X], the hydrogen donor with [Y], the presence of a certain substance [Z] with the role of mediator is necessary so that the photons should be emitted.
 - The phenomenon of photon emission in the visible domain was observed when studying the saponins from the soybeans.

The photon emission in the „XYZ” system was imagined to appear through the translation of the electron or the reduction of the hydrogen between X Y and Z because the proprieties of Y are both to „clean” the radicals and to donate electrons, just like the phenolic compounds. The result is the photon mission that „sweeps” the free radicals. Experimental evidence based on XYZ system suggests that this phenomenon is fundamental for our life and also the environment.

- Building a database of safe doses of biologically active compounds. The incidents of various diseases related to lifestyle, such as cancer, BCV, diabetes, are strongly influenced by the eating habits. The polyphenols of tea and the phytoestrogens are good examples of biologically active compounds able to prevent some diseases. The consumption in excess of these substances may have toxic effects. To establish the safe dose (that avoids the toxic effects) one must know the absorption rate, the biological effect and mechanism, the rate of metabolism and the rate of elimination. Health effects of these food factors can be estimated by calculation, using tables with the composition of the suitable aliments.
- There are a lot of MAFF research programs on food and the most important conclusions are:
 - the consumption of citrus fruits is associated with a decreasing risk of cancer;
 - polyunsaturated fatty acids from the series ω - 3 and ω - 6 increase hepatic oxidation of fatty acids and decrease their synthesis;
 - the sesamine, a lignan in sesame, is the potential inductor of the hepatic oxidation and fatty acids.

These events and activities have attracted the attention of the Western world, especially after the article entitled „Japan explores the boundary between food and medicine” appeared in 1993. In this article the term „functional food” appeared for the first time in English. (Arai, S., 2002).

b) FUNCTIONAL FOOD IN USA

Functional foods have entered quite quickly in the US, the problem being the concern both to the scientists and the ordinary people. There is no doubt that health and nutrition are in close connection. An appropriate diet is considered the first factor in worsening the genetic potential, in reducing the physical and cognitive performance, and increasing the risk of certain diseases. The introduction of the functional food on the American market and in the Americans' lives is based on studies about the health of the population and their availability to accept a change in their diet.

The strategies to optimize nutrition by using functional food or food supplements are very popular and considered to be suitable for increasing the quality of life. The importance of these strategies is accentuated by the recognition of the fact that approximately one third of cancers are related to eating habits. Actually, more than half of the US deaths are related to an inadequate nutrition. Many Americans believe that changing diets and using food supplements are the most important ways to decrease the health costs and improving the health. The functional foods were defined in different ways. The International Life Sciences Institute (ILSI) from the North America defined them as food with physiological capacities of the active components in food to bring health benefits besides the basic function of feeding. Approximately 60% of the resident adults in the US are confident in the health foods, no matter their age or sex. While young people choose foods to increase their physical or mental performances, older people select foods to decrease the risk of disease or to improve the qualities of their lives. (Milner, J., 2002).

The American researchers have focused on the study of the bioactive components. Preclinical and clinical epidemiological studies bring evidence on the dynamic relationships between nutrients (defined as any substance from the diet that is causing physiological effects) and health.

In the US special attention has been given to claims that accompany the products with a functional role. In the US legislation there are three categories of claims:

1. Health claims. Health claims describe a relationship between the active substances in food and the disease or the condition that affects health. There are three sets of laws by which Food and Drug Administration (FDA) is exercising the authority with respect to the use of health claims.

- Health claims authorized by the Nutrition Labeling and Education Act (NLEA) – they are included in the NLEA law from 1990, the law of the dietary supplements from 1992 and Dietary Supplement Health and Education Act (DSHEA) from 1994. Under these laws FDA (Food and Drug Administration) may approve health claims for foods and food supplements based on evidence from scientific literature, using the standard for determining what the relationships are established between nutrient and disease.
- Health claims based on statements of the authorities – according to FDAHA issued in 1997. The health claims can be approved for a certain type of food under an authorized declaration of the scientific stuff from the US Government or the National Academy of Sciences.
- Qualified health claims – according to the law on consumer health information for the initiative for a better nutrition, in 2003 – it allows FDA to recognize the qualified health claims when there is an obvious relationship between a food / ingredient of food or the food supplement and the decrease of the risk for a disease or the maintaining of health. FDA prepared a guide on the procedures to obtain the qualified health claims.

2. Claims on nutrients content. NLEA allows the use of the claims that characterize the level of the nutrients in food in accordance with the rules of the FDA approval.

3. Structure / Function claims – by DSHEA in 1994 there are established some specific rules for claims on labels of food supplements. The structure / function claim describes the role of the nutrient or the food ingredient which positively affects the structure or function of the body.

There were 15 approved health claims in 2001. Here are some of these claims:

- calcium and osteoporosis;
- sodium and hypertension;
- saturated fat foods and cholesterol and cardiovascular disease;
- stanols and heart disease;
- fruits and vegetables and cancer.

To better clarify the claims of health problems, the ILSI North American Technical Committee on Food Components for Health Promotion developed in 1997 a „Strategy to develop the public health and to accept the secure foods which bring significant benefits for health”. Some of the ways achieve these goals are: creating a foundation for functional food science; promoting people’s trust; the development of the consumer’s preferences for functional food; the optimization of the rules and creating marketing strategies for the development of the functional foods.

A large number of studies had as a theme the genetic and epigenetic action of nutrients that caused phenotypic changes. The studies on nutritional genome offer the opportunity to identify how the components of food influence the growth and increase the health level and to clarify the specific mechanisms of action. It is known that the homeostasis is regulated by the fine balance between the multiplication, controlled growth, differentiation and apoptosis (the process of programmed cell death). The destruction of this balance can determine deep phenotypic changes starting from a reduction in growth to the transformation of the cell from a normal cell into a cancer cell (neoplastic cell). The disorders in the apoptosis process are frequently accompanied by the appearance of the pathogenesis, with a wide range of events including heart disease, neurodegenerative diseases, cancer, etc.

There have been identified some factors which influence the cellular homeostasis: vitamin A, vitamin D, the lignans, etc. A special attention was given to the sterols, the selenium, the folic acid, the polyphenols, and the inulin. (Milner, J., 2002).

A special attention was given to the development of the guides of the nutrition for the population.

c) FUNCTIONAL FOOD IN EUROPE

Europe had a wide variety of regulations on the approval of the products, the type of nutritional information indicated to appear on the packaging, and the type of functional claims and healthcare which are permitted in connection with the products. (http://www.fao.org/agn/agns/files/Functional_Foods_Report_Nov2007.pdf).

In functional food domain, a large number of European agencies are operating:

- European Commission – (<http://ec.europa.eu>). European Commission entirely supports and represents the interests of Europe. It is independent of the national governments. It proposes the plans of the new European laws which are presented in the European Parliament and the Council. It leads the implementation of the politics and it uses the EU funds. The Commission monitors the compliance of the European treats and laws. It can act against those who violate the law, appealing to the Court of Justice if necessary.
- EFSA (European Food Safety Authority) – it is an European agency based on UE budget, which operates separately from the European Committee, the European Parliament and the EU member states. EFSA (European Food Safety Authority) brings scientific evidence and scientific and technical support in all areas that affect food safety. It is an independent source of information in all areas of this field and it ensures that the public is well informed.
- EUFIC (The European Food Information Council) – it is a non profit organization which obtains scientific information related to food safety, quality and health, nutrition, for media, professionals from health and nutrition, educators and opinion leaders.
- ILSI (International Life Science Institute) – it is a world non profit organization which tries to improve the life of the public using the scientific discoveries. Its purpose is to promote the understanding of scientific issues related to nutrition, food safety, toxicology and risk assessment and it unites scientists from academia, government and industry.

The Framework Directive (the Directive 90/496/CEE) defined the nutritional labeling, in 1990, as „any representation or slogan that says, suggests or implies that a particular foodstuff has special nutritional properties due to high or low energetic content or nutrients in high or low proportion. (<http://ccvista.taix.be/Fulcrum/CCVista/RO/31990L0496-RO.doc>).

In July 2003, the European Commission proposed a harmonization regulation (COM/2003/0424) on nutritional and health claims on aliments, including the food supplements.

The Regulation on nutrition and health food claims was adopted in December 2006 by the European Council and the European Parliament. The following definitions were proposed in this Regulation:

- *Claim* – any message or presentation that is not bound by Community or national legislation, including pictures, graphs, or symbolic representations, in any form, which express or suggest or imply that a certain food has particular characteristics.
- *Nutritional claims* – any claim that expresses, suggests or implies that a certain food has particular beneficial nutritional characteristics due to:
 - a) the caloric value: (1) provided caloric value, (2) provided in a lower or higher caloric value, (3) it does not have a caloric value OR
 - b) the nutrients or other substances that (1) they contain, (2) they contain in a higher or lower proportion and (3) they do not contain.
- *Health claims* – any claim that expresses, implies or suggests that there is a relationship between a certain food or a component of the food and health.
- *Claims to reduce the risk of disease* – any health claim that expresses, implies or suggests that through the consuming of a category of food, a food or a constituent of a food the risk factors in certain diseases development are reduced.

The medical claims for food (for example claims that express, imply or suggest that the product has healing, prevention or curing properties) are prohibited by the European and National labeling rules. In order to wear a medical claim, a product must be classified as medicine in accordance with the definition from the order 2001/83/EC of the European Parliament and the European Council, from 6th of November 2001, on the Community Code relating to medical products for human use.

EFSA is implied in the implementation of the new Regulation and it published a guide to help the companies which want to submit health claims to be authorized (EFSA, 2007). The evaluation of the health claims made by EFSA is the first step in the process of authorization. Only those claims that are scientifically sustained will be allowed to be used. The final approval of the health claims is the responsibility of the European Commission and of the EU member states, and it is based on a scientific evaluation, expressed by the opinion of the EFSA Jury. It is the first time when the harmonized approach for the authorization of the health claims has been established by the EU state members.

The European Agencies have conducted and are conducting a large number of projects in the field of functional food. From these one can mention:

1. FUFOSÉ – it is an action program on „The functional food science in Europe”, coordinated by ILSI Europe, with the following objectives:

- assessment of current state of knowledge in the field;
- the analysis of data from the perspective of the „functional effect”;
- to reach a consensus on change for the food and their components.

The conclusions of the working group coordinated by ILSI Europe include:

- a definition of functional foods – „a food can be considered functional if it is demonstrated in a satisfactory way that it beneficially influences one or more target functions of the body, besides the basic nutritional effect – either it improves health or it reduces the risk of disease”.
- a strategy of development the functional food, base on:
 - identification and understanding the mechanisms of interaction between the components of the foods and the functions of the body;
 - the validation of the components effects using appropriate methods (being preferred the use of specific biomarkers);
 - studies on human beings (when appropriate) which demonstrate the beneficial effects on health.

2. PASSCLAIM – Process for the assessment of Scientific Support for Claims on Food) – It intends to provide the industry, academia, consulting groups, and legislators methods to assess the scientific basis of health claims (Verschuren, P., 2002).

The objectives of this project are to develop the rules for functional foods, to use the high standards and extensive processes to evaluate the scientific basis for the claims.

One can mention between the results of the project the following:

- consumers’ confidence in claims has increased;
- important documents for fixing the claims have been obtained (Salminen, S., 2005).

Research on food and nutrition play an important role in the Framework Program of Development and Research in the European Commission. In the seventh Framework Program for Funding, three important directions have been established (<http://www.functionalfoodnet.eu/asp/default.asp?p=75>):

- the combat of obesity – through the development of tasty and healthy food (and clinical documentation) to prevent obesity, by using both classic and modern concepts promoted by science;
- improving heat stability of probiotics;
- food products and chronic inflammation.

The optimizing nutrition is a major challenge of the XXI century and the functional foods play a very important role.

The developing of new products and related health claims should remain a main concern of the science. This is the successful condition of which both human health and food industry will benefit.

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