

FUNCTIONAL FOODS AND HEALTH CLAIMS IN THE CONTEXT OF EUROPEAN LEGISLATION

Simac Viorel

National R&D Institute for Food Bioresources – IBA – Bucharest, Romania

Simac Viorel, simacv@yahoo.com

Abstract: functional foods and dietary supplements have undergone recent years austere rules at European level regarding health claims. Countries began to adopt these laws at national level, which will affect food producers. We will present the causes of issue of these regulations, their main characteristics, compliance with these conditions and how to obtain approvals for the use of new health claims.

Key words: functional foods, health claims, legislation, pharmaceutical industry.

Introduction

Functional foods subject is of general interest because it has vast implications. Consumers want to have better health and are looking for healthy foods. Industrial producers want to make a profit from the sale of these products. Scientists seek to broaden the knowledge and research, exploring the topic from various perspectives.

Both pharmaceutical and functional food industry addresses a common market segment: sick people or healthy people who are concerned about health maintenance, disease prevention and longevity. The two industries have a different approach on the subject of health. First seeks the solution in pharmaceutical laboratories, where they synthesize various chemical drugs. The second industry, based on the Hippocratic concept that our food should be our medicine, seek the same solutions as can be found in nature, which is compatible with the human body.

Definitions

The term "functional foods" was first introduced in Japan in the years 1987-1991, as Foods for Specified Health Use (FOSHU). However, the notion of food that has a positive impact on human health has been known since thousands of years ago (traditional Chinese medicine - over 1000 years BC, Hippocrates – IVth century BC).

There have been several attempts to introduce a definition for functional foods, but so far no agreement has been reached and there is no generally accepted definition. But we will present some definitions, as were set by various educational institutions, government and food authorities. Thus, a functional food is:

- A food that provides a health benefit as well as nutrients. The term can refer to whole foods, to fortified, enriched or enhanced foods, and dietary supplements that have the potential to improve mental and physical well being and reduce the risk of diseases. The ingredients responsible for this benefit can be naturally present or may have been added during processing. The levels of nutrients in foods can be increased beyond their natural levels to create an enriched product. Fortified products contain nutrients or ingredients that were not present in the original food (1).
- Natural or processed food that contains known or unknown biologically-active compounds; which in defined quantitative and qualitative amounts, provide a clinically

proven and documented health benefit, and thus are important sources in the prevention, management and treatment of chronic diseases in the modern age (2).

- A functional food is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions (3).

- Foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body. FOSHU is intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol (4).

- A modified food that claims to improve health or well-being by providing benefit beyond that of the traditional nutrients it contains. Functional foods may include such items as cereals, breads, beverages that are fortified with vitamins, some herbs, and nutraceuticals (5).

When mentioning "bioactive compounds" or "compounds with functional role," it covers food chemical compounds that may or may not play an energetic role (calories provider), but necessarily has a beneficial role in certain biological processes and good (or better) functioning of the human body.

Approval of drugs and health claims for foods

Both drugs and functional foods must be proved scientifically and clinically for beneficial effects, which are intended to be mentioned on the label or in its advertising.

For drugs are used most often synthetic chemicals that are tested first on cell cultures and animals to determine its lethal doses: DL0, DML and LD50, meaning respectively a single oral dose at which no animal dies in the test group, single oral dose at which the first animal dies and single oral dose at which 50% of the animals die. Afterwards it may be done a test of chronic administration of a substance to see its effects for several months. The recordings are made, attempting to identify at least one effect that could reduce symptoms of some diseases. Sometimes the tests are repeated for sick animal, which are taking the studied substance to verify its intended effect. The same tests can be done on humans. If the effect is confirmed, for this substance will be submitted for drug approbation a file. Other effects of the substance on the body are passed as "side effects" (6).

Currently there are approximately 6,700 approved drugs worldwide (7).

In the case of functional foods, appears the first major legislative distinction from drugs: whatever their effects on health may be, the law does not allow the use of functional foods for disease treatment. The law does not allow neither labeling these products as beneficial for diseases treatment. The only thing that is approved on label or advertisement is the effect of reducing the risk of illness or certain benefits for child health and development. All these expressions specified on the label (or other promotional messages) are defined in the legislation as "health claims" (8). To obtain permission to use a specific new health claim, a file should be submitted to the European Food Safety Authority (EFSA) (9). The file must include a detailed description of product characteristics and clinical trials carried out on it related to the claim which is meant to be used. Dossier evaluation is very restrictive, so in the more than 5,000 cases filed in 2008-2011 were considered for evaluation about 3000, and of these only 7 were approved health claims for reduced risk of a specific disease, 11 health claims on development and health benefits for children, a specific health claim, totaling 19 approved health claims. If the report is made to

the 5000 cases filed, the percentage of approved is 0.38% - a very low figure. If it is considered that files typically provide more than one health claim for approval, than the percentage of approved ones must be lowered even more (10).

The EFSA reports for few approved files show an impressive number of clinical trials conducted by different research teams, which have demonstrated the veracity of health claims on both animals and humans.

Health claims are usually restricted to a particular product for which investigations were made. For example, it was approved the beneficial effect of plants sterols and stanols to reduce blood cholesterol (which reduces the risk of cardiovascular disease). But it was approved only for the following categories of products: yellow fat spreads, dairy products, mayonnaise and salad dressings. If we have another food with the same amount of sterols and / or stanols, it's not allowed to use the claim (11).

By a simple numerical comparison of the 6700 drugs with the 19 approved health claims, the difference is about 350 times less for health claims. This major difference is one of the visible evidence of competition that exists between pharmaceutical industry and functional foods industry.

The law that has imposed such restrictive conditions for food in Europe is the Regulation (EC) No 1924/2006 issued on December 20, 2006 (12). Before this law similar guidelines were issued by the Codex Alimentarius, but never were mandatory and with so strongly impact in the EU Member States as last EC Regulation. This has sparked numerous complaints from functional food producers, scientists and the public. It was noted for example, that a part of EFSA staff members, dealing with the approval of health claims are subjected to conflict of interest due to their work in industrial companies (agro-food and pharmaceutical) (13).

The main reason claimed by this law is to remove from the market the products which falsely assume a certain beneficial effect that they do not possess. This may seem to be a benefit of the law, but compared to the disadvantages it brings, this becomes insignificant. Tradition for thousands of years of multiple disease treatment identified natural remedies that can be used successfully for treatment, prevention and amelioration of disease (where functional foods play an important role). Many of these are used successfully until today, but the EU regulation forbids practically their advertising and official use in treatment, so only the pharmaceutical industry remains on the market as absolute monopoly.

There are many scientists who sounded the alarm on the conflict of interest between the pharmaceutical industry and public health, as reflected in recent times also by the Regulation 1924/2006. For example, Prof. Dr. George Mencinicopschi, director of the Institute of Food Research from Bucharest filed a complaint with the European Commission in regard to this Regulation.

Nobel laureate, Joseph Stiglitz had addressed similar topics in his books and articles such as "Globalization and Its Discontents", "Prizes, Not Patents" etc. Other doctors, researchers and politicians who have distinguished themselves in this regard are: Louis de Brouwer, John Virapen, Michael Klaper, Rima Laibow, Colin Campbell, Matthias Rath, Charlotte Gerson, Claire Severac, Jeffrey Smith, Wolfgang Wodarg, Nigel Farage, etc.

Healing axiom

Medical system had established an axiom, which seeks to be imposed worldwide as fundamental truth: the disease can be cured only by medicines. According to this axiom, food supplements or functional foods don't have this quality (hence the restrictions of Regulation EC no. 1924/2006). The reason for establishing this axiom is not stated and can not be proven. But the economic advantages are obvious for the pharmaceutical industry and its partners (including health facilities). It removes all competitors in the medical field. Only the pharmaceutical industry retains the official right to treat patients with its products.

There are many medical authorities that recognize that drugs deal only with symptoms, not the disease itself. The drug information leaflet recognizes this, specifying that it is symptomatic treatment. Dr. John Virapen, with 35 years experience in the pharmaceutical industry, explains this principle in his book and public presentations (14).

The medical health system does not intend necessarily to understand and explain the causes of certain symptoms, but their focus resides in its elimination or mitigation. People, who use drugs and noted that some symptoms had decreased or disappeared develop trust in the effectiveness of drugs, but remain with the same disease. However their situation is worse to the time before the consumption of drugs: the issue is unresolved, but had disappeared or decreased the indicator of organism, which alert people about the problem (the symptoms).

The biggest problem is represented by the adverse effects of drugs, because they are not natural substances and are completely foreign to human body. They affect different organs or systems of the body, creating biochemical imbalances and accumulation of indigestible toxins in the tissues. These are sources of a wide range of chronic and acute diseases, cancer and even death.

Functional foods and health

Some of the famous advocates of functional foods and natural methods of maintaining health in Romania are the following: professor and academician Ovidiu Bujor, who wrote several books on this topic, doctor Virgiliu Stroescu, entitled by the media as apostle of vegetarianism, doctor Emil Radulescu, who wrote a lot of wide spread books on health and nutrition, doctor Margineanu Calin, who are renown for his public presentations and cancer healing protocols, Prof. Dr. Brad Segal, who promoted functional foods through multiple articles and books, among which is the collection of brochures "Vital". Prof. Dr. Segal Rodica, Prof. Dr. Miron Costin and other academic staff from the University of Galati continued in this direction by their works, such as "Functional foods – foods and health" (15) etc.

One of the doctors who have made a global impact through his discoveries was Max Gerson, who around 1920 has discovered the role of healthy foods in the treatment of the most dangerous diseases such as tuberculosis, diabetes, cancer and others. He applied successfully his treatment and improved it over 30-40 years, curing thousands of patients. In 1946 he was invited to the United States Senate to present the results of his treatment. The presentation had an impressive impact. Over the U.S. was publicly announced that it was discovered the cure for cancer. But doctor's therapy foresees no use of the drugs, the techniques of radio and chemotherapy or surgery. It applies primarily the adoption of a diet based on organic fruits and vegetables, juices derived there from, cereals and nuts in combination with certain natural procedures. If this therapy was widely adopted, the pharmaceutical industry would considerably reduce their profitable business of selling

drugs. For this reason doctor's therapy was denigrated by all possible means. Nevertheless Dr. Max Gerson's work was continued by his daughter Charlotte Gerson, who founded the Gerson Institute in California in 1977 and two clinics of treatment (*Clinica Nutrición y Vida* in Mexico and *The Gerson Health Centre* in Hungary). These clinics operate successfully until now (16).

There are numerous international research projects, which confirmed the role of healthy eating in preventing and treating chronic diseases and cancer. Among them: FP6 project HELENA - Healthy Lifestyle in Europe by Nutrition in adolescence (17), FUFOS: Functional Food Science in Europe (18), China study - the most comprehensive study on nutrition (19), FLORA: Flavonoids and related phenolics for healthy Living using Orally (20), etc.

The World Health Organization has issued an action plan to prevent so-called non-communicable diseases (21), which include cardiovascular disease, diabetes, cancer and chronic respiratory diseases. Among the four factors of prevention is listed diet, with emphasis on eating fruits and vegetables.

Conclusion

Agricultural, food and medical modern systems have many operational deficiencies. Governing laws are often in favor to large agro-food or pharmaceutical companies and in detriment to science and consumers. We have to analyze critically the situation in these fields and take the documented and impartial attitudes and actions, which will promote the scientific truth, the quality of food products and the health of population.

As is repeatedly stated by WHO, EFSA and other food or health organization, we must consider that not only food determines the health, but also other lifestyle factors (22) such as physical exercises, clean air, drinking water, rest, balanced work, emotional and spiritual equilibrium (23).

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