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CURRENT ISSUES AND CHALLENGES ON FUNCTIONAL FOOD

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Abstract

The article sets out the key-details in the field of functional foods, featuring their current role and relevance, which are based on their functions and associated benefits. It also lays down a wide range of issues and key-challenges - related to both consumers and producers - whose approach will determine the future trend line for this sector of food production. The paper shows a series of important elements to be taken into account by governments, experts, sellers and consumers so that the integration of functional food in human nutrition has a positive effect on health and nutritional welfare.

Key words: *functional food, benefits and concerns, legislation, consumer protection*

Introduction

At present, food market witnesses an intense diversification attributed to complying with growing consumer preferences and demands. In recent decades there has been a worldwide explosion of the assortment of food consumer goods that led to a reassessment of traditional foods with nutritional increasingly higher performance. This has led to profound changes in the conceptual range and quality criteria in the areas of food production and food technology, as it incorporates an increasing volume of scientific and technical progress. As a result, consumers are more and more confronted with a series of *terms*, not enough explained, such as: light food, fast food, novel food, convenience food, dietary food, ethno food, ecological food, alternative food, functional food, nutritional supplements etc.

Currently, food that help maintain long-term health is recognized in a new manner, which represents a new dimension to the appreciation of the positive influence that food can have on human welfare, beyond purely nutritional aspects.

This initially led to the increasing popularity of healthy food and holistic medicine,

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so, since the late '90s, we are witnessing a consolidation of this sector on the extent of relevant scientific evidence propagation (Sheehy, 1998).

In particular, consumer interest has substantially increased linked to the role of specific foods or physiologically-active components, with positive impact on health - the so-called "functional foods". Obviously, all foods are functional to some extent, because they provide taste, aroma and nutritional value (Hasler, 1998). However, in the last decade, these terms applied in the food sector acquired a different connotation - that of providing an additional physiological benefit - beyond the basic nutritional needs.

In this dynamic context, the production of functional foods is a challenge for technologists, nutritionists, biochemists, microbiologists.

From an economic perspective, functional food market is significantly dynamic worldwide, showing a higher rate than the average growth of the sector (e.g. in the U.S., annual sales amount to 20-30 billion \$, equivalent to 5% of the food market) (PWC, 2009).

Functional Foods - Concept, Meanings, Functions, Benefits

Many organizations and interested parties have proposed *definitions* for this emerging area of the food and nutrition sciences, but a common point of view could not be created due to differences of opinions.

As there is no consensus on what constitutes a *functional food*, in many parts of world (Chan, 2010), functional foods are simply referred to as foods associated with health claims. The most significant characteristic for functional food remains its potential to alleviate disease, promote health, and reduce health care costs.

The term functional food (or more correctly, "*physiologically functional foods*") (Sheehy, 1998) was first introduced in Japan in the mid 1980s (Hasler, 1998), being used by industry to describe foods fortified with specific ingredients that generate certain health benefits. So far, Japan is the only country that has formulated a specific regulatory approval process for functional foods.

In 1994, Goldberg has expressed more clearly the concept of "functional food", defined as, „*any food or food ingredient that has a positive impact on an individual's health, physical performance or state of mind, in addition to its nutritive value*” (Sheehy, 1998).

This concept aimed at *two categories*: functional foods for disease prevention and therapeutic foods. Thus, in principle, a food may be considered functional if it contains compounds that are biologically active and it is sufficiently demonstrated having one or more benefits for the body, in addition to adequate nutritional effects.

The Japanese Ministry of Health and Welfare have established *three conditions* that functional foods must satisfy (Sheehy, 1998):

- they should be foods, not capsules, tablets or powders, which are derived from naturally-occurring ingredients;
- they can and should be consumed as part of the daily diet;
- they have a particular function when ingested, serving to regulate a particular body

process, such as enhancement of the biological defense mechanisms, prevention of a specific disease (e.g. heart and artery disease, cancer, hypertension, or obesity), control of physical and mental conditions, or slowing down the ageing process.

Some authors (Hughes, 2007) consider that there are *three distinct categories* of functional foods, as follows:

- *natural* - foods that naturally contain beneficial compounds for sustaining health and disease prevention, outside the basic nutritional function (e.g. blueberries, broccoli, prunes, salmon);
- *manipulated* - resulting from the adaptation of food production systems that convert standard food to functional foods (e.g. manipulating animal feed: feeding chickens with special formula allows to obtain eggs rich in Omega-3 fatty acids; tomato genetic modification to achieve a high level lycopene reduces the risk of cardiovascular disease and cancer);
- *processed* - a set of “artificial” functional foods, whose characteristics are modified and adapted during processing technology, which may involve adding or / and extracting compounds and micro-organisms (e.g. yogurt that contains beneficial bacteria to improve function such as digestion and circulation).

Other authors (Poulsen, 1999) considers that “functional foods” is a relatively new term used to describe food products which have been enriched with natural substances / physiologically active components with a specific preventive and/or health-promoting effect.

The Institute of Medicine's Food and Nutrition Board (IOM/FNB, 1994) defined functional foods as “*any food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains*” (Hasler, 1998).

Overall, scientific research in the field showed that the *main functions* of functional food are: defending the body's health by reducing allergies; immune system activation; avoidance of disease by preventing high blood pressure, diabetes, congenital metabolic imbalances and the growth of tumors; the control of functions of the body, the nervous system functioning, appetite and nutrient absorption; reducing the duration of convalescence and the effects of aging. In addition, functional foods have the ability to better manage risk factors such as deficiencies in minerals and vitamins, blood cholesterol or various forms of digestive discomfort.

In this context, we believe we cannot develop a single definition for functional foods, because they are classified separately on categories, but their generic feature, regardless of their mode of obtaining, allows us to call as “functional” foods that have beneficial effects (scientifically proven) on the human body functions beyond the nutritional effects, promoting good health, nutritional wealth and/or reducing the risk of illness.

Functional foods group includes *examples* such as (Table 1):

Table 1. *Effects and benefits of some popular functional foods*

Examples of functional foods	Effects and benefits of functional foods
Dairy prebiotics/ probiotics	probiotic bacteria interact with intestinal flora, improving its quality, intestinal mucosa or exerting a modulating effect on the intestinal immune system
Oatmeal	source of soluble fiber which helps reduce cholesterol and thus the risk of coronary heart disease
Soy	protein source of high quality role of risk reduction for cardiovascular disease, cancer, osteoporosis and alleviate menopausal symptoms. In addition, lower blood cholesterol
Flaxseed	contain a high amount (57%) of alpha linolenic acid (omega-category 3), helps to reduce total cholesterol and bad cholesterol
Tomatoes	Lycopene and carotenoid content makes them effective in reducing the risk of cancer (prostate, breast, gastrointestinal tract, cervix, bladder and skin)
Garlic	antibiotic properties, anti-hypertensive (prevents cardiovascular diseases) and reducing cholesterol levels, effective in reducing the risk of gastric cancer and colon
Cruciferous vegetables	cancer risk reduction
Citrus	cancer risk reduction, the main important nutrients: vitamin C, folate and fiber
Cranberry (juice)	efficacious in the treatment of urinary tract infections
Tea	antioxidant polyphenolic constituents of tea have the effect of cancer prevention
Wine and grapes	maintaining good blood circulation, protects cells against the action of harmful free radicals
Fish, beef	good source of omega-3 fatty acids, cholesterol and decrease cardiovascular risk reduction and risk of cancer

Source: adaptation from (Hassler, 1998)

Currently, there are numerous *international initiatives* regarding the promotion and enhancing the role of functional foods for human consumption.

While developments in Japan are often cited as indicative of possible developments in other parts of the world (as the government instituted an approval system for functional foods in 1991), until now, functional foods in the US are not legally defined as a distinct category, which has generated a confusing regulatory framework, while Food and Drug Administration (FDA) is still reviewing functional food regulatory requirements.

Lagging US and Japan in terms of establishing a set of regulations in the field of functional food, the European Union (EU) set up a European Commission Concerted Action on Functional Food Science in Europe (FUFOSE), mainly due to increasing interest in the concept of “Functional Foods” and “Health Claims”. For the implementation of FUFOSE’s conclusions and principles a new EU Commission Concerted Action programme, the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) project was created, aiming to resolve some of the

ongoing issues of validation, scientific substantiation of claims and communication to the consumer.

Though, given the proven benefits of these foods, at European level there is an intense support of this area. Thus, the EU supports (through its framework programs) R & D on functional foods in many ways: food companies can participate in integrated projects (IPs), Networks of Excellence (NoE), specific support actions (SSAS) (eg: FFNet SSA) and research projects on specific topics (STREPs). In addition, there are two specific schemes for SMEs, for example, Co-operative Research (CRAFT) and Collective Research.

Controversies and Challenges concerning Functional Foods

There is a large controversy about functional food worldwide, especially for those obtained by artificial means, which contain added ingredients, or whose concentration is conducted.

Although increasing the availability of healthy foods, including functional food is a ubiquitous goal in the modern food and nutrition policies, *safety* remains essential, because the optimum level of the majority of biologically active components is still in the process of investigation, not being established yet. In addition, some research has highlighted the toxic and carcinogenic potential nature of certain phytochemical components beyond certain limits of concentration - this being more relevant in the context of increasing consumer's interest in nutritional supplements.

Despite the increasingly advertised benefits, there are still some *potential barriers* to widespread acceptance of functional foods, both from the perspective of consumers, and producers, as follows:

- Development of functional food and basic research for documenting marketing claims are expensive, so there can be a need to set default high prices for this foodstuff, contrary to the interest of buyers.
- Buying functional food could become the privilege of some groups of consumers with high purchasing power, with a high level of awareness about food intake (Sheehy, 1998). Thus, for functional foods not becoming an elitist group of foods (especially as, on the international level, increasing attention is given to disadvantaged consumers in terms of socio-economic status), price policies should ensure large groups of consumers' access to those foods, given their beneficial health role (by default, raising awareness and educating consumers are becoming extremely important).
- Some consumers may suspect that the promises about health benefits will be used only as a marketing ploy to justify higher pricing, or to obtain a competitive advantage. Therefore, an essential requirement is that marketed benefits should be real and correct, legally and ethically.
- There are concerns that the promotion of functional foods and marketing claims may not rely on sufficiently strong scientific evidence (Hassler, 1998); also, confusion persists between claims applied to foods and those applied to dietary supplements;
- Consumers can also raise the question if functional foods are still necessary if they

have already adopted a healthy diet style, and whether they can induce a false sense of security being used to compensate for unhealthy eating habits.

- Consumers tend to be circumspect about the information on healthy eating, using a variety of sources. Besides mass-media and label claims, messages from health professionals have a higher credibility, but there is a need that messages are more clear and specific, with quantitative information, clearly explaining the effects of food on health, as far as scientific evidence becomes available. By contrast, there is low level of trust in food companies' marketing claims, but sometimes in government and its ability to create the appropriate frame for correct food consumption.
- Consumers may show skepticism towards some unusual functional foods, so that industry experts suggest that functional foods may become attractive especially to those consumers looking to avoid unnecessary expenditure for medical care, in which case the communication of health benefits becomes critical (PWC, 2009).
- Research of interactions between supplements and functional foods or ingredients is required.

Many authors (Heller, 2001) emphasize the need for transparency toward consumers, suggesting *recommendations* regarding the safety of functional foods:

- develop and promulgate regulations or other guidance for industry on the evidence needed to document the safety of new ingredients in functional foods;
- develop and promulgate regulations or other guidance for industry on the safety-related information required on labels of functional foods;
- develop an enhanced system to record and analyze reports of health problems associated with functional foods.

Since enriched foods are becoming prevailing in the market, scientific data must be used with caution and its meaning should not be extrapolated anyway in order to avoid situations such as abstention from groups of compounds under the pretext of contribution from other sources (which is insufficient or is using an unhealthy food as a support) (eg soft drinks rich in fiber), high vitamins consumption by categories of the population to which it is not recommended (eg foods high in vitamin A for pregnant women), excess nutrients can become toxic (eg iron, folic acid, vitamin D).

In this context, the consumer's benefits and risks should be carefully evaluated in the light of the widespread use of physiologically active food (eg soy phytoestrogens), so scientific studies must provide strong evidence to minimize the risk/benefit ratio.

Today's orientations in nutrition sciences move the focus from "deficient/adequate" approach to optimal nutrition (Sheehy, 1998), whose vectors are also functional foods. However, there is an obvious need for more extensive and deeper research, so that these benefits can be measured and justified properly.

Appealing to the balance demand, a report of FAO (FAO, 2007) suggests avoiding excess of functional foods consumption that could be detrimental over other food groups necessary in the daily diet.

FAO *recommendations* in the field of functional food promote the principles and the means of Codex Alimentarius, covering significant issues, and are summarized below:

1. The need for a specific definition of functional food can be addressed by adopting an internationally valid definition and by creating an international database of biologically active components (whether naturally present or added), which should be subject to international standards based on scientific and technological developments and data on safety, bioavailability, stability and other relevant data. Such a definition had previously been formulated by FAO in 2004, stressing that functional foods should be “*a food similar in appearance to a conventional food (beverage, food matrix), consumed as part of the usual diet which contains biologically active components with demonstrated physiological benefits and offers the potential of reducing the risk of chronic disease beyond basic nutritional functions*” (FAO, 2007).
2. Health claims and nutrition claims should be clearly defined and harmonized, referring distinctively to what the product contains (nutrition claims), or to what the food or food components does or do (health claims).
3. Health claims should rely on scientific validation and substantiation, addressing *issues* such as: using scientific protocols, defining guidelines for safety and efficacy assessment, establishing the optimal levels of nutrients, identifying unwanted effects etc.

Increasing global concerns in the field is materialized in International Life Sciences Institute’s (ILSI) activity; ILSI is directly involved in organizing international conferences on the matter (1995, 2001, 2007), whose *contributions* include:

- Providing an international forum for information sharing and discussion;
- Building consensus on scientific basis for regulations, building the basis for regulatory framework in Asia, Europe (including the coordination of FUFLOSE) and USA as well as at international level through Codex;
- Coordinating and organizing workshops and expert consultations;
- Encouraging industry development;
- Promoting scientific advances;
- Coordinating functional foods publications;
- Establishing task forces/working groups to address issues related to functional foods

Throughout its substantial activity ILSI revealed a number of *key issues* and *global challenges*, including: lack of definition of the food group; lack of scientific substantiation for claims of different levels; different stages for regulatory framework; difficulties concerning consumer understanding and effective communication.

In the same time, ILSI emphasizes the increasing consumers’ interest in diet and health, a greater demand for specific foods that provide health benefits beyond normal nutrition, underlining the need for more research and development on functional foods and for better regulatory control.

Some authors (Kaplan, 2006) depict several key-concerns for marketing of functional foods that raise the most doubts, including the possibility of exaggeration their effects, the difficulties of determining the appropriate using, distribution, and regulation, and the fact that, at present, growing interest is fueled more by the food industry than by nutrition and medicine specialists, so there are reservations about possibly most benefiting sellers than consumers.

Several researches is currently focused towards understanding the impact of “functional foods” in order to identify how they could help prevent chronic diseases or enhance health, thereby reducing healthcare costs and improve quality of life for many consumers.

An emerging discipline that will have a profound effect on the future of functional foods is nutrigenomics, which investigates the interaction between diet and disease development based on an individual's genetic profile.

Another technology that will greatly influence the future of functional foods is biotechnology, which shows, according to scientists in the field, an enormous potential to improve the health of millions of consumers (eg through the creation of iron-enriched rice, golden rice, lycopene-enriched tomatoes) (Chan, 2010). But the limits of applicability and the potential of these solutions depend directly on consumer acceptance of biotechnology (currently still a major problem in Europe).

Given the information gap associated with functional foods, labeling - as in other situations - plays a decisive role in enabling consumers to make informed choices, provided a correct, clear and precise content.

Functional food success will depend, too, on understanding consumer behavior and choices.

Conclusions

However we might classify functional foods, they are an essential part of a trend in food science and marketing that is gradually changing traditional conceptions of diet and medicine. Being at the boundary between food science and technology, politics, trade, and nutrition, this group of foods generates controversy and affects numerous interests, whose results may or may not promote a healthy diet, may or may not respect the rights of consumers.

Consumers turning to functional food due to their benefits needs to understand that this option does not automatically provide access to health, while being not a panacea, especially as a healthy life also involves other aspects: physical activity, limiting stress, giving up other harmful habits.

In this context, regulation of food with special benefits, in terms of consumption, intake, marketing etc. should cautiously consider all these issues, and should be based on scientific advice for a healthy diet, in terms of consumption in normal quantities, provided that manufacturers are able to provide evidence for the promoted benefits. A strict legal framework, although at first may seem limited and constraining will serve in the long term to protect both consumers and the responsible manufacturer.

The success of functional foods will depend on various factors, including safety, effectiveness, taste, convenience, value, the real nature of the benefits. Functional foods should be promoted as components of a healthy diet, rather than as a way to offset a poor diet. The essence of a proper diet lies in the need for balance, variety and moderation, in combination with physical activity. Only in this context, the future of functional foods will be able to contribute to improving the health and vitality of large parts of the world population.

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