



What are Functional Foods and How Can They Help Us?

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Introduction

The primary role of diet is to provide sufficient nutrients to meet the nutritional requirements of an individual. There is now increasing scientific evidence to support the hypothesis that some foods and food components have beneficial physiological and psychological effects over and above the provision of the basic nutrients. Today, nutrition science has moved on from the classical concepts of avoiding nutrient deficiencies and basic nutritional adequacy to the concept of "positive" or "optimal" nutrition. The research focus has shifted more to the identification of biologically active components in foods that have the potential to optimise physical and mental well being and which may also reduce the risk of disease. Many traditional food products including fruits, vegetables, soya, whole grains and milk have been found to contain components with potential health benefits. In addition to these foods, new foods are being developed to enhance or incorporate these beneficial components for their health benefits or desirable physiological effects.

What are functional foods?

The concept of functional foods was born in Japan. In the 1980s, health authorities in Japan recognised that an improved quality of life must accompany increasing life expectancy for the expanding number of elderly people in the population if health care costs were to be controlled. The concept of foods that were developed specifically to promote health or reduce the risk of disease was introduced.

Functional foods have not as yet been defined by legislation in Europe. Generally, they are considered as those foods which are intended to be consumed as part of the normal diet and that contain biologically active components which offer the potential of enhanced health or reduced risk of disease. Examples of functional foods include foods that contain specific minerals, vitamins, fatty acids or

dietary fibre, foods with added biologically active substances such as phytochemicals or other antioxidants and probiotics that have live beneficial cultures (see Annex).

As interest in this category of foods has grown, new products have appeared and interest has turned to the development of standards and guidelines for the development and promotion of such foods.

Why do we need functional foods?

Consumer interest in the relationship between diet and health has increased substantially in Europe. There is much greater recognition today that people can help themselves and their families to reduce the risk of illness and disease and to maintain their state of health and well being through a healthy lifestyle, including the diet. Ongoing support for the important role of foods such as fruits and vegetables and wholegrain cereals in disease prevention and the latest research on dietary antioxidants and combinations of protective substances in plants has helped to provide the impetus for further developments in the functional food market in Europe.

Trends in population demographics and socio-economic changes also point to the need for foods with added health benefits. An increase in life expectancy, resulting in an increase in the number of elderly and the desire for an improved quality of life, as well as increasing costs of health care, have stimulated governments, researchers, health professionals and the food industry to see how these changes can be managed more effectively. There is already a wide range of foods available to today's consumer but now the impetus is to identify those functional foods that have the potential to improve health and well-being, reduce the risk from, or delay the onset of, major diseases such as cardiovascular disease (CVD), cancer and osteoporosis. Combined with a healthy lifestyle, functional foods can make a positive contribution to health and well being.

How is the area of health claims regulated?

Many academic, scientific and regulatory organisations are actively working on ways to establish the scientific basis to support claims for functional components or the foods containing them. Any regulatory framework will need to protect consumers from false and misleading claims and to satisfy the needs of industry for innovation in product development, marketing and promotion. For functional foods to deliver their potential public health benefits, consumers must have a clear understanding of, and a strong confidence level in, the scientific criteria that are used to document health effects and claims.

Japan has led the world in this area. In 1991, the concept of Foods for Specified Health Use (FOSHU) was established. Foods identified as FOSHU must be approved by the Minister of Health and Welfare after the submission of comprehensive science-based evidence to support the claim for the foods when they are consumed as part of an ordinary diet.

In the European Union, there is no harmonised legislation on health claims, which means that they are dealt with at a national level. The challenge in the EU Member States, under the existing regulatory framework, is to communicate messages that avoid any reference to reducing the risk of disease, even if the scientific evidence supports such statements. European labelling legislation prohibits attributing to any foodstuff the property of preventing, treating or curing a human disease or referring to such properties. In the absence of a Directive on health claims, EU Member States have applied different interpretations of the existing labelling legislation. At the same time, there is broad consensus that

health claims must be properly substantiated to protect the consumer, to promote fair trade and to encourage academic research and innovation in the food industry.

Over the last decade, starting in Sweden, a number of initiatives have been taken in order to facilitate the use of health claims, including the adoption of guidelines and codes of practice in the various Member States of the EU, including Sweden, The Netherlands and UK, the latter with the Joint Health Claims Initiative (JHCI). In most of these countries, a partnership of industry experts, enforcement authorities, consumer groups and scientists have been involved in drawing up the rules for the scientific justification, communication and presentation of health claims.

In the USA, "reduction of risk of disease" claims have been permitted since 1993 for certain foods. Health claims are authorised by the US Food and Drug Administration (FDA) on the basis of "the totality of publicly available scientific evidence and where there is significant scientific agreement amongst qualified experts that the claims are supported by the evidence". Although manufacturers may use health claims to market their products, the FDA's stated intention is that the purpose of health claims is to benefit consumers by providing information on healthful eating patterns that may help reduce the risk of disease such as heart disease and cancer. The FDA announced that claims can also be based on "authoritative statements" of a Federal Scientific Body, such as the National Institutes of Health and Centres for Disease Control and Prevention, as well as from the National Academy of Sciences.

What are the latest CODEX developments on the use of health claims on foods?

Codex Alimentarius is a joint programme between UN Organisation for Food and Agriculture (FAO) and Health (WHO), for setting food standards. It gains authority from its role in world trade, since countries that are developing new legislation as the basis for that legislation often use Codex standards. Discussions in Codex are at an early stage and the key areas that require more work before a consensus is reached include reduction of disease risk claims, the need for scientific substantiation and labelling issues.

European legal framework of functional foods and health claims

FUFOSE concerted action

Because of increasing interest in the concept of "Functional Foods" and "Health Claims", the European Union set up a European Commission Concerted Action on Functional Food Science in Europe (FUFOSE). The programme was coordinated by the International Life Sciences Institute (ILSI) Europe and the aim was to develop and establish a science-based approach to the evidence needed to support the development of food products that can have a beneficial effect on an identified physiological function in the body, that can improve an individual's state of health and well-being and/or reduce the risk of disease. The FUFOSE project looked at six areas of science and health: growth, development and differentiation, substrate metabolism, defence against reactive oxidative species, functional foods and the cardiovascular system, gastrointestinal physiology and function, and the effects of foods or behaviour and psychological performance. The final document was published in the British Journal of Nutrition.

The report takes the position that functional foods should be in the form of normal foods and they must demonstrate their effects in amounts that can normally be expected to be consumed in the diet. A

functional food can be a natural whole food, a food to which a component has been added, or a food from which a component has been removed by technological or biotechnological means. It can also be a food in which the nature of one or more components has been modified, or a food in which the bioavailability of one or more components has been modified, or any combination of these possibilities. A functional food may be targeted at the whole population or for particular groups, which may be defined, for example, by age or by genetic constitution.

The EU Concerted Action supports the development of two types of health claims relevant to functional foods, which must always be valid in the context of the whole diet and must relate to the amounts of foods normally consumed.

These are:

1. TYPE A: "Enhanced function" claims that refer to specific physiological, psychological functions and biological activities beyond their established role in growth, development and other normal functions of the body. This type of claim makes no reference to a disease or a pathological state, e.g. certain non-digestible oligosaccharides improve the growth of a specific bacterial flora in the gut; caffeine can improve cognitive performance.
2. TYPE B "Reduction of disease-risk" claims that relate to the consumption of a food or food component that might help reduce the risk of a specific disease or condition because of specific nutrients or non-nutrients contained within it (e.g. folate can reduce a woman's risk of having a child with neural tube defects, and sufficient calcium intake may help to reduce the risk of osteoporosis in later life).

Validation of claims and safety aspects

The FUFUSE conclusions and principles need to be implemented. Therefore, a new EU Commission Concerted Action programme, the Process for the Assessment of Scientific Support for Claims on Foods (PASSCLAIM) project is aiming to resolve some of the ongoing issues of validation, scientific substantiation of claims and communication to the consumer.

The project started with and will build upon the principle that "enhanced function" and "reduced risk of disease" claims should be based on well designed studies using appropriately identified, characterised and validated biomarkers. PASSCLAIM aims to establish common criteria to assess the scientific substantiation of health-claims, providing the framework to prepare scientific dossiers supporting claims. The PASSCLAIM Consensus Document will assist those making claims, those who regulate claims and it will also improve the credibility of claims for consumers. This integrated strategy will generate more consumer confidence in the science base related to claims on foods and will better address the concerns of consumers.

Although there is no European legislation regarding safety of functional foods as such, the food safety aspects are already covered by existing EU regulations. However, foods with health claims must consider the overall dietary significance, including the amount and frequency of consumption, any potential interactions with other dietary constituents, any impact on metabolic pathways and potential for adverse effects, including allergy and intolerance factors.

Conclusion

Functional foods offer great potential to improve health and/or help prevent certain diseases when taken as part of a balanced diet and healthy lifestyle. The subject of health claims is becoming increasingly important and there is broad consensus that there needs to be a regulatory framework in the EU that will protect consumers, promote fair trade and encourage product innovation in the food industry. The research opportunities in nutrition to explore the relationship between a food or a food component and an improved state of health and well-being, or reduction of disease, present the greatest challenge to scientists now and in the future. The communication of health benefits to consumers is also of critical importance so that they have the knowledge to make informed choices about the foods they eat and enjoy.

Annex

Examples of functional foods

FUNCTIONAL FOOD	ACTIVE FOOD COMPONENT	TARGET FUNCTION
Yogurts, sugar	<u>Probiotics</u> : Foods with beneficial live cultures as a result of fermentation or that have been added to improve intestinal microbial balance, such as Lactobacillus sp. Bifidobacteria sp <u>Prebiotics</u> : A non-digestible component that has beneficial affects by stimulating the growth of bacteria in the colon. Examples include inulin and oligofructose.	Optimal intestinal function and intestinal microbial balance
Margarines	Added plant sterols and stanols esters	Decreased LDL-cholesterol (bad cholesterol) Decreased risk of coronary heart disease (CHD)
Omega-3 fatty acids enriched eggs	Omega-3 fatty acids	Control of hypertension, lipids metabolism

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