

sumers will purchase nutraceuticals but require justification of safety, efficacy, and cost-effectiveness.⁵ How then can the consumer make informed choices and be protected against inferior products? More comprehensive product information and more accurate product labeling is important but better nutrition education of health professionals, the media, and the general population is the key to long-term success. Consumers will need protection from fraudulent claims or inferior quality products without unnecessarily stifling innovation and instituting long, drawn-out marketing approval procedures. Existing food regulations, Good Manufacturing Practices (GMP), and other consumer protection laws will probably suffice for now with increased enforcement, but we must remain vigilant. Consumers need to be better informed with accurate definitions, clearer nutrition advice, and better product information. It is no longer acceptable for qualified nutritionists to avoid offering specific nutrition advice because expert opinion is divided.

Twenty-first century consumers are demanding to know how much is beneficial and how much is harmful. Surveys in the US have confirmed that >60% of shoppers would value the opportunity to obtain advice from a qualified nutritionist or pharmacist if offered by supermarkets.⁶ If nutritionists fail to provide the appropriate advice then unqualified quacks can and will fill the information gap. At present, anyone without formal qualifications can offer nutrition or dietary advice to consumers in shops, newspapers, magazines, or other media. This cannot be allowed to continue. Consumers naturally seek legal advice from qualified lawyers and financial advice from qualified accountants. Nutrition advice should therefore be sought from and made more widely available by qualified professional nutritionists.

The evolving concept of nutraceuticals and functional foods raises exciting prospects for future nutrition research with associated health benefits for the general population. Manufacturers will need the freedom to innovate but must be deterred from marketing products with questionable effects. All claims must be based on sound science. Safety, quality, and cost-effectiveness must remain paramount. National and international nutrition societies must take more responsibility for educating other health professionals, the media, and the general public in a more quantitative and user-friendly fashion. A well-informed health-conscious public will ensure that nutraceuticals and functional foods follow vitamin supplements into long and mature life-cycles both for the product manufacturer and the consumer.

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A European Consensus of Scientific Concepts of Functional Foods

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To understand functional food it is first necessary to understand how the science of nutrition itself has changed. Nutrition has progressed from the prevention of dietary deficiencies and the establishment of the concept of balanced diet to the promotion of a state of well-being and health and the reduction of the risk of disease, as well as the development of the concept of optimum (optimized) nutrition.

During the 20th century, nutrition has discovered the essential nutrients and it has established nutrient standards, dietary guidelines, and food guides, mainly if not exclusively with the aim of preventing deficiencies and of supporting body growth, maintenance, and development.¹ More recently it has also made recommendations aiming to avoid excessive consumption of some of these nutrients after recognizing their potential role in the etiology of miscellaneous (mostly chronic) diseases.² Through these developments, one of the major contributions of nutrition in the 20th century has been the concept of balanced diet, "an appropriate mixture of food items that provides, at least, the minimum requirements of nutrients and a few other food components needed to

support growth and maintain body weight, to prevent the development of deficiency diseases and to reduce the risk of diseases associated with deleterious excesses."³

At the turn of the 21st century, the society of abundance, which characterizes most of the occidental/industrialized world, faces new challenges, from exponentially growing costs of health care, increase in life expectancy, improved scientific knowledge, and development of new technologies to major changes in lifestyles. Nutrition has to adapt to these new challenges by developing new concepts. Optimum (optimized) nutrition⁴ is one of these new concepts that aims at maximizing physiologic functions of each individual to ensure both maximum well-being and health, and, at the same time, confer a minimum risk of disease throughout the lifespan. On the road to optimum (optimized) nutrition, the term *functional food* refers to a new and stimulating concept.

FUNCTIONAL FOOD: A EUROPEAN CONSENSUS

Functional food cannot be a single well-defined/well-characterizable entity. Indeed, a wide variety of food products are or will, in the future, be characterized as functional food, with a variety of components affecting a variety of body functions relevant to either a state of well-being and health and/or to the

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reduction of the risk of a disease. Thus functional food has to be understood as a concept that appears unique and that deserves a category of its own, a category different from nutraceutical, f(ph)armafood, medifood, designer food, or vitafood, and a category that does not include dietary supplements. It is also a concept that belongs to nutrition and not to pharmacology. Functional foods are and must be foods, not drugs; they have no therapeutic effects. Moreover, their role regarding disease will, in most cases, be in reducing risk rather than preventing it.

It is in that general context that the European Commission's Concerted Action on Functional Food Science in Europe (FU-FOSE), coordinated by ILSI Europe, developed in early 1996 to reach a consensus on Scientific Concepts of Functional Foods, which was published in 1998.⁵ The unique features of a functional food include the following:

- being a conventional or everyday food,
- being 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 benefit so as to improve the quality of life, including physical, psychologic, and behavioral performances,
- having authorized and scientifically based claims.

Because functional food is a concept rather than a well-defined group of food products, the European consensus document proposes this working definition: "A food can be regarded as functional if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either improved stage of health and well-being and/or reduction of risk of disease. A functional food must remain food and it must demonstrate its effects in amounts that can normally be expected to be consumed in the diet: it is not a pill or a capsule, but part of the normal food pattern."⁵ That definition encompasses all the main features of functional foods and it is aimed at stimulating research and development in the field of nutrition so as to contribute adequately to the scientific knowledge that will be required to define optimum (optimized) nutrition. But it should be emphasized that a functional food shall not necessarily be functional for all members of the population, and that matching individual biochemical needs with selected food component intakes may become a key task as we progress in our understanding of the interactions between genes and diet.⁶

From a practical point of view, a functional food can be

- a natural food,
- a food to which a component has been added,
- a food from which a component has been removed,
- a food where the nature of one or more components has been modified,
- a food in which the bioavailability of one or more components has been modified, or
- any combination of these possibilities.

FUNCTIONAL FOOD: STRATEGY FOR DEVELOPMENT

Being foods, functional foods need to be safe according to all criteria defined in current food regulations. But in many cases, new concepts and new procedures will need to be developed and validated to assess functional food risks. In Europe, some, but certainly not all, functional foods will be classified as novel foods.⁷

As described in the European Consensus Document,⁵ "The design and development of functional foods is a key issue, as well as a scientific challenge, which should rely on basic scientific knowledge relevant to target functions and their possible modulation by food components." Emphasis is then put on the importance

of the effects of food components on well-identified and well-characterized target functions in the body that are relevant to well-being and health, rather than solely on the reduction of disease risk. By reference to basic knowledge in nutrition and related biological sciences, such a development requires the identification and, at least partly, the understanding of the mechanism(s) by which a potential functional food or functional food component can modulate the target function(s) that is/are recognized or proven to be relevant to the state of well-being and health, and/or the reduction of a disease risk. Epidemiologic data demonstrating a statistically validated and biologically relevant relationship between the intake of specific food components and a particular health benefit will, if available, be very useful. The conclusion of that first step will be the demonstration of a functional effect that should serve to formulate hypotheses to be tested in human nutrition studies aimed to show that relevant (in terms of dose, frequency, duration, etc.) intake of the specified food will be associated with improvement in one or more target functions, that are, either directly or indirectly in terms of a valid marker, relevant to an improved state of well-being and health and/or to a reduced disease risk.

The new-generation human nutrition studies should be hypothesis driven, but in many cases they will differ quite substantially from what is classically referred to as clinical studies. The main differences are that nutrition studies aim at testing the effect of a food as part of the ordinary diet, that they may concern the general population or, generally, large, at-risk target groups, that they are not diagnostic or symptom based, and that they are not planned to evaluate a risk versus benefit approach. Most of these studies will rely on change(s) in validated/relevant markers to demonstrate a positive modulation of target functions after (long-term) consumption of the potential functional foods. A (double-) blind type of design based on parallel groups rather than crossing-over will generally be appropriate. Data of these studies should be collected and handled according to standards for data management, and data analysis should prove statistical as well as biological significance. Finally, the long-term consequences of the interaction(s) between functional foods and body function(s) will have to be carefully monitored.

The markers to be used for the development of functional foods need to be identified and validated for their predictive value of potential benefits to a target function or the risk of a particular disease. Markers of correlated events are called indicators, whereas markers representing an event directly involved in the process are considered factors.⁵ When related to the risk of a disease, indicators and even factors might, in some instances, be equivalent to surrogate markers, defined as a biological observation, result, or index that predicts the development of a chronic disease.⁸

FUNCTIONAL FOODS AND CLAIMS: A COMMUNICATIONS AND SCIENTIFIC CHALLENGE

As stated in the European Consensus on Scientific Concepts of Functional Foods,⁵ "As the relationship between nutrition and health gains public acceptance and as the market for functional foods grows, the question of how to communicate the specific advantages of such foods becomes increasingly important." Its importance also lies in avoiding problems associated with consumer confusion about health messages. Regarding functional foods, claims associated with specific food products are the preferable means of communicating to consumers. In application of the fundamental principle, any claim must be true and not misleading, and must be scientifically valid, unambiguous, and clear to the consumer. Even though a general definition of *claim* is widely accepted in the field of nutrition, as "any representation, which states, suggests or implies that a food has certain characteristics

relating to its origin, nutritional properties . . . or any other quality,⁹ one of the difficulties in communicating the benefits of functional foods is that distinct types of claims exist, and that especially the term *health claim*, which is traditionally used to communicate the benefits of a food, is understood differently in different part of the world. Seeking clarity, Codex Alimentarius⁹ has recently classified and defined four different categories of claims (i.e., claims that relate to dietary guidelines, claims that relate to nutrient content, claims that are comparative, and claims that describe nutrient function) but excluding the term *health claim*. These claims refer to known nutrients and their role in growth, development, and normal functions as well as to the concept of adequate nutrition. They are based on established, widely accepted knowledge but they do not refer to a particular effect over and above that expected from consuming a balanced diet. These claims are thus not really helpful to communicate the specific benefits of functional foods. Indeed, the claims for functional foods should be based on the scientific classification of markers (indicators and/or factors) for target functions and on the effects on these markers. If such an effect, which goes beyond what could be expected from the established role of diet, concerns a target function or a biological activity without direct reference to a particular disease or pathologic process, claim will be made for an *enhanced function*. But, if the benefit is clearly a reduction of the risk of a disease or pathologic process, claims will be made for a *disease risk reduction*. These two types of claims, which are specific for functional foods, are the *type A* and *type B* claims, respectively.⁵ In its last proposed draft recommendations for the use of health claims, Codex Alimentarius¹⁰ has included type A and type B claims and defined them. Type A are claims that concern specific beneficial effects of the consumption of foods and their constituents on physiologic or psychologic functions or biological activities but do not include nutrient function claims. Such claims relate to a positive contribution to health or to a condition linked to health, to the improvement of a function, or to modifying or preserving health. Type B or "risk of disease reduction claims," are those that concern the reduction of a disease risk related to the consumption of a food or a food constituent in the context of the daily diet that might help reduce the risk of a specific disease or condition.

One of the major issues still to be resolved, especially with these two types of claims, concerns the biological level at which evidence can be accepted as satisfactorily demonstrating an enhanced function or a reduction of disease risk. This evidence should rely on all data available that can be grouped in three categories: biological observations, epidemiologic data, and intervention studies, mostly based on markers. All supporting evidence, however, should be consistent in itself; able to meet accepted scientific standards of statistical as well as biological significance, especially dose-effect relationship, if relevant; plausible in terms of the relationship between intervention and results, especially in terms of mechanism(s) of action; and provided by a number of sources (including obligatorily human studies) that give consistent findings able to generate scientific consensus.

FUTURE TRENDS AND CONCLUSIONS

In reference to the conclusions of the FUFOSSE concerted action,⁵ the following future trends have been suggested:

- Components in foods have the potential to modulate target functions in the body so as to enhance these functions and/or contribute to reducing the risk of disease, and functional food science will contribute to human health in the future, provided evidence is supported by sound scientific, mostly human, data.
- Nutritionists and food scientists have the possibility through the development of functional foods to offer beneficial opportunities related to well-being and health and to the reduction of the risk of disease. However, the success of this new approach to nutrition will require the identification, characterization, development of methodologies to measure, and validation of relevant markers as indicators or factors to be used in human nutrition studies. The design of such studies still needs to be carefully analyzed and developed specifically with reference to, but differently from, classical clinical studies that have been elaborated to help develop drugs, but not food products.
- Major target functions in the body that are or can be modulated by specific food products will have to be identified or characterized. The basic science to understand these functions and how they relate to well-being and health or to a particular pathologic process needs to be developed to give the necessary scientific base to developing new functional food products.
- Progress in food regulation, which is the means to guarantee the validity of the claims as well as the safety of the food, will have to be made.

On the road to optimized nutrition, which will be one of the major challenges of nutrition in the 21st century, functional foods have their own role to play. But the development of claims for already existing food products, as well as the development of new products and their specific claims, should remain a scientific, not just a marketing, challenge. This is the condition for its success, to the benefit of both human health and of the food industry.

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