PERGAMON

www.elsevier.com/locate/foodchemtox

Food and Chemical Toxicology 37 (1999) 1039–1041

Food and Chemical Toxicology

What is Beneficial for Health? The Concept of Functional Food

M. B. ROBERFROID

Université Catholique de Louvain, Département des sciences pharmaceutiques, UCL-BCTC 7369, Avenue Mounier 73, B-1200 Brussels, Belgium

Summary—'Functional Food' is now a very popular term. The conceptual approach developed in the EU-founded FUFOSE (Functional Food Science in Europe) project is rather restrictive, making functional food a food product to be part of the usual dietary pattern. Functional food science that supports the develoment of functional foods is and must remain part of the science of nutrition. Finally, all that exercise, that extended over the last 3 years, was function-driven because the functions and their modulation are universal, as opposed to a food or food component-driven approach,which is likely to be very much influenced by local, traditional or cultural characteristics.

Scientific basis for functional food development

In the industrialized world, the concepts in nutrition are changing significantly. From a former emphasis on survival, through hunger satisfaction, and more recently food safety, food sciences now aim at developing foods to promote well-being and health while at the same time reducing the risk of some major diseases. That is because scientific evidence supports the hypothesis that, by modulating specific target functions in the body, diet can have beneficial physiological and psychological effects that go beyond adequate nutritional effects. Such evidence is already supported by scientific data that show that both nutritive and non-nutritive components in food have the potential to modulate target functions in the body which are relevant to well-being and health and/or reduction of disease risk.

Functional food: a concept rather than a product

The recently released European consensus publication proposes (Diplock *et al.*, 1999) a 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 which is relevant to either the state of well-being and health or the reduction of the risk of a disease''.
>
> The beneficial effects could be either maintenance or promotion of a state of well-being or health and/or a reduction of the risk of a pathologic process or a disease.

A food can be made functional by applying any technological or biotechnological means to increase the concentration of, add, remove or modify a particular component as well as to improve its bioavailability, provided that component has been demonstrated to have functional effect(s) as described in the definition.

The development of functional foods is a scientific challenge requiring interdisciplinary research and collaboration between academic and industry scientists. One of the key issues is the identification and validation of relevant markers for use within a new generation of hypothesis-driven human nutrition studies to demonstrate benefits relevant to well-being and health and/or reduction of disease risk. Obviously the food or food component to which that concept is applied must be safe according to all standards of assessing food risk. But the risk versus benefit approach which is an essential part of drug development cannot be applied to functional food development. Moreover, if a traditional toxicity testing approach might be adequate to assess the safety of phytochemicals, the daily intake of which is likely to remain low, it is not applicable for functional nutrients which might account for a rather significant percentage of the total food intake. Indeed the classical dose–effect relationship can hardly be applied to them because it might lead to physiological/nutritional disturbances which are irrelevant to safety assessment. Consequently, a more nutritonally relevant approach to hazard

0278-6915/99/$ - see front matter
PII S0278-6915(99)00080-0

identification and risk assessment need to be elaborated.

Functional food science

The initial step in research and development of a functional food is the identification, specifically and potentially beneficial for health, of an interaction between one or a few component(s) of the food and a function in the organism. This step belongs to fundamental research and must lead to one or a few proposal(s) for hypothetical mechanism(s) of the identified interactions. On such a base, a functional effect will then be defined which needs to be demonstrated in relevant models. The conclusion of this experimental part of functional food development is a new hypothesis with regard to the relevance of the functional effect to human health, which needs to be tested in well designed nutritional studies involving well- chosen volunteers. Among the promising targets for functional food science, the defence against reactive oxidative species occupies an important position.

Claims for functional foods

The obvious conclusion of research and development in the field of functional foods is the recognition that the results of these scientific activities justify **"claims"** which will be translated in messages to the consumers. Indeed, claims are vital to the development of functional foods and two types of claims are of greatest relevance:

Enhanced-function claims (type A)
Disease risk reduction claims (type B).

An **enhanced-function claim (type A)** refers to the positive consequence(s) of the interaction(s) between a food component and specific function(s) in the body without direct reference to reduction in the risk of any disease. Examples include preventing oxidative stress (antioxidants).

A **disease risk reduction claim (type B)** refers to reduction in the risk of a disease by consuming a specific or a mixture of specific food component(s) or food ingredient(s). Examples of such claims are the reduction of risk of cardiovascular disease or cancer. Even though it may depend on the particular pathology for which risk reduction will be claimed, the demonstration of such effects remains a very difficult task which may require long-term experiments using a scientific approach based on sound hypothesis supported by reasonable information on the mechanism(s) of the effect to be expected.

The most pertinent aspect in communication of health benefits is that any claim must be based on sound scientific evidence that is objective, consistent in itself, able to meet accepted scientific standards of statistical and biological significance, and plausible in terms of the relationship between intervention and results. The demonstration of an effect to justify claims for human will require **nutritional studies** designed according to protocols and evaluation criteria which are not necessarily those presently used in clinical studies for drug development. Indeed, the target populations of these **nutritional studies** are, in most cases, "healthy persons" or "persons supposedly healthy" for which the "usual" (hopefully near to balanced) diet will be modified to demonstrate a (statistically but also and, perhaps more importantly, biologically) significant change in parameters/markers indicative of a state of "good health". In the vast majority of the cases these parameters/(bio)markers are still to be discovered and, certainly, validated.

Conclusions

By reference to these concepts and their application in the context of antioxidants and their potential applications in functional food, the following questions were submitted to the discussion of the round-table that concluded the meeting:

What are the mechanisms of the actions of these antioxidants?

Is it really radical scavenging?

Is it through rebalancing the cellular redox systems?

Is it more a metabolic effect?

Is it via changes in intracellular cell signalling?

Is it by affecting cell–cell communication?

Does synergy exist between these antioxidants being vitamin or non-vitamin compounds?

Do they all affect the same body functions?

Are radicals the common denominators for the effect of these antioxidants in reducing the risk of different diseases?

Do we already have validated biomarkers to quantify the effects of these antioxidants *in vivo*?

How relevant are these markers to the state of well-being and health?

How relevant are they with regard to the risk of diseases?

What kind of biomarkers do we need in the future?

Do we still have safety issues with these antioxidants?

What do we already know about safety limits of vitaminA, carotenoids, licopene, vitamin E... but also hydroquinone, polyphenols?

If we have to evaluate potential hazard of such products, how do we do it?

What kind of tests do we need? Are classical animal toxicity testings relevant?

Finally, the last question concerns the classification of these products. Are they functional food ingredients? Are thay food supplements? Do we consider these products being more active in their natural environment like fruits and vegetables than as purified supplements? In such natural matrices, these active ingredients are most of the time present as mixture, is this part of their efficacy? Are they really the active components of fruits and vegetables or are they simply markers of intakes of these foods that are beneficial because of other components?

The development of functional food is a scientific challenge before being a marketing challenge. It requires a new way of looking at nutrition and food science.

REFERENCE

Diplock A. T., Aggett P. J., Ashwell M., Bornet F., Fern E. B. and Roberfroid M. B. (1999) Scientific concepts of functional foods in Europe: Consensus Document. *British Journal of Nutrition* **81** (Suppl. 1), S1–S27.