

What makes a functional food functional?

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Functional foods are foods that, by nature or design, can deliver benefits beyond that of sustenance. They bridge the traditional gap between food and drugs, offering consumers greater opportunity to take their health care into their own hands. Rapidly increasing knowledge of the physiological effects of nutrients and their potential health benefits offers exciting prospects for the food industry and consumers alike. However, we must ensure that newly developed functional foods are indeed functional. The mere presence in a food of nutrients with well-publicised health attributes can infer that the food will deliver health benefits. We need to be certain that it will be efficacious for the indication specified and the nature and extent of benefit will be clearly understood by consumers. With the introduction of health claims, the onus will be on food manufacturers to provide scientific substantiation based not only on the literature related to an active nutrient, but also on intervention trials that demonstrate bioavailability and efficacy of the nutrient when delivered in a specific type of food. Such an approach, while demanding in terms of research and development investment, offers significant opportunities for product innovation. We can extend the variety of foods through which consumers may source a particular health-giving nutrient. Moreover, recognizing that a particular condition such as heart or bowel health may be influenced by more than one type of nutrient, manufacturers can design and evaluate unique foods with appropriate combinations of nutrients to optimise health status. Even though a new type of food may be shown to be efficacious in short-term, controlled clinical trials, can we be certain that consumers will derive long-term benefits free from adverse affects? Will food manufacturers undertake postmarketing surveillance or will this task be left to consumer watchdogs? The transition from traditional foods and herbal remedies of uncertain value to designer foods with guaranteed health benefits could be facilitated by adopting aspects of the pharmaceutical approach to substantiation and regulation.

Key words: functional foods, health claims, scientific substantiation.

Functional foods: Where did they come from and where are they headed?

Functional foods are the ultimate product of an evolution in nutritional science that shared its infancy with the baby boomers. Wartime experiences of deprivation and food rationing had emphasised the importance of population-based strategies to prevent nutritional deficiency disorders. Free school milk was introduced and the addition of vitamins and minerals to appropriate foods was permitted to facilitate compliance with recommended intakes. Thus fortified breakfast cereals became an accepted part of the lifestyle of a new generation of healthy young Australians. We had entered an era of functional foods — defined simply as foods that, apart from providing sustenance, can have a positive impact on consumers' health.

In the 1970s, however, as the baby boomers reached adulthood, the focus of nutritional science was shifting from concern about dietary deficiencies to dietary excesses and their likely contribution to obesity, cardiovascular disease and diabetes — so-called diseases of affluence that are commonly clustered in the metabolic syndrome.¹ Foods with high salt content or rich in animal fats and cholesterol were portrayed for the first time as undesirable, even harmful. Hence, manufacturers started modifying foods to remove these unacceptable nutrients and the era of low-fat, salt-reduced alternatives came into being. At the same time, new products with healthier nutrient profiles, such as polyunsaturated margarines, were being formulated.

By the 1990s there had been an explosion in knowledge about the physiological functions and health benefits of nutrients, offering exciting prospects for the food industry and consumers alike. With the recognition that a single nutrient may exert a range of actions which impact on more than one health condition, the potential benefits for individuals with differing health needs were seen to be very wide ranging, very complex and, equally, very confusing! Yet consumers have clearly demonstrated their interest in and expectations of functional foods as a further means to take their health care into their own hands.² Therefore, it is essential to establish reliable mechanisms for obtaining and communicating the information needed by consumers to make informed choices about their diet and to have realistic expectations of the health benefits to be derived from functional foods.

The promise of functional foods for innovative food manufacturers is one of almost unlimited scope to add value through nutrition knowledge to existing foods and to formulate unique new food products. The world market for functional foods has grown by more than 50% in the last 5 years to US\$31 billion per annum and is expected to further increase to US\$51 billion per annum by 2004.³ At the same time, the growth in expenditure on food service and fast

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foods in Australia has far outstripped that of supermarket spending.⁴ If our desire to optimise health through dietary management is to keep pace with our rapidly changing patterns of food preparation and eating behaviour, we must look for new opportunities to introduce functionality into our evolving food supply, particularly through home meal replacements. However, realisation of these opportunities will depend on having regulatory mechanisms that can keep abreast of developments and facilitate the promotion of healthier foods to consumers while at the same time protecting their interests. Thus, the new opportunities offered by functional foods are inextricably linked to health claims.

Health claims for functional foods: Consumer aid or regulatory hurdle?

How do we convey the good news about functional foods to consumers? A totally unregulated approach would expose consumers to misinformation and exploitation. The *British Medical Journal* warned in an editorial last year that 'evidence suggesting beneficial effects of [nutrients] and the public's great interest in alternative health remedies...coupled with weak government regulation, attract marketeers who see big profits in functional foods...Functional foods may prove a major health boon or result in a new generation of quackery. Which outcome prevails will depend on whether governments ensure that the foods are safe, nutritious and honestly labelled. Unfortunately, regulatory authorities around the world are light years behind the marketeers.'⁵

Traditionally, consumers have gained their nutritional knowledge through articles in books and popular magazines, commercials and from health professionals. Today, these are still the main sources of consumer information.⁶ However, the high volume of media coverage has failed to increase clarity or improve understanding about the health benefits of foods; not surprising, considering that public health education is not a primary function of the commercial media. Disappointingly, the approach favoured by consumers to inform them of the nutritional value and health potential of a food product; that is, authorized statements on food packaging, plays a relatively minor role.^{6,7}

In Australia, such statements take the form of nutrient claims approved by the Australian–New Zealand Food Authority; for example, 'this food is a good source of calcium', which are based on the content of a specified nutrient (as recorded in the nutrition information panel) and may be accompanied by nutrition messages such as 'calcium helps build strong bones and teeth'.⁸ It is then left to the consumer to surmise that eating this food may help to reduce the risk of osteoporosis and tooth decay, as any extrapolation of the nutritional advice to the prevention or treatment of disease would be paradoxically classified as a health claim, which current legislation prohibits. Can consumers without expert knowledge be expected to use the nutritional information on a food package and assess what impact, if any, consumption of the food will have on the health status of an individual or what level of intake might be needed to prevent or treat a specific disorder?

In the United States, the Nutrition Labelling and Education Act (NLEA) was passed in 1990 to clear up confusion in the market place, to help consumers choose more healthy diets and to offer the food industry incentives to improve the

nutritional composition of food.⁹ Nutrition labelling became mandatory on almost all processed foods and health claims, which were defined as statements characterizing the relationship between a food, a nutrient or other substance in a food and the risk of a health-related disease or condition, were allowed for the first time.⁹ The first claims authorized by the Food And Drug Administration (FDA) appeared as somewhat generic statements on the effects of nutrients, e.g., 'Diets low in saturated fat and cholesterol and rich in fruit, vegetables and grain products that contain some types of dietary fibre may reduce the risk of heart disease, a disease associated with many factors.' For a food to carry one of these claims, it has to meet strict requirements regarding minimum content of an active nutrient and upper limits for disqualifying nutrients. Food advertising, on the other hand, is regulated by the US Federal Trade Commission, which takes a more lenient approach than the FDA to claims about diet–disease relationships.¹⁰ Thus the media can make health claims which would be disallowed on food packaging.

In Australia, all such claims both on food packaging and in associated advertising are prohibited by standard A1 (19) of the Food Standards Code. However, as in Europe and Canada, the issue of functional foods and related health claims is currently being reviewed by ANZFA in the context of their duty to protect public health and safety and enable consumers to make informed choices.¹¹ The recent introduction and testing of a pilot health claim for folate and its prevention of foetal abnormalities¹² is a recognition of the inadequacy of the currently permitted nutrient claims to encourage individuals at risk of a disorder to increase their intake of a protective nutrient.

Considering the enthusiastic lobbying by the food industry for the introduction of health claims as a means of promoting their products to health-conscious consumers, the limited uptake of the pilot health claim for folate is somewhat surprising. Although many products claim folate content, only 10 have adopted the health claim, which suggests that a proliferation of misleading claims following legalisation of health claims is unlikely.¹³ The limited uptake may reflect the limited applicability and, hence, market associated with the approved indication; that is, pregnant or potentially pregnant women. Future claims for folate based on its potential to counteract the harmful effects of homocysteinaemia in cardiovascular disease and diabetes, a vastly greater risk population, may attract wider acceptance.¹⁴ However, it is premature to be considering such a claim until the extent of benefit and the intake requirements have been fully defined.

Introduction of individual health claims in the United States has been painstakingly slow. Approval by the FDA of a folate claim took 4 years. The process has now been facilitated, however, with the passage of the FDA Modernization Act of 1997.¹⁵ Food manufacturers in the United States can now propose claims based on consensus statements by authoritative government bodies, which will take effect within 4 months unless vetoed by the FDA. Claims now make reference to the name of the food, the content and the intake requirement of an active nutrient. For example, a recently approved claim for soy¹⁶ states: '25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of (food name) provides xx grams of soy protein.'

While the introduction of new claims may have been expedited, it is uncertain whether they are any more palatable to consumers. A review by the FDA of its earlier claims suggested that the lengthy, rather academic messages being used had minimal impact on consumers.¹⁷ A United Kingdom survey found that consumers respond to briefer statements and tend to distrust the more complex claims.¹⁸ Simple logos such as the Heart Foundation's 'Tick' would appear to convey health messages more effectively to busy supermarket shoppers with little time to study food labels.¹⁹

Substantiating health claims

The critical element underpinning health messages is scientific substantiation. There is international agreement that they should be based on a consensus of evidence by independent scientific bodies. However, the extent of such evidence may be expected to vary according to the nature of the claim.²⁰ For example, the somewhat generic statements approved in the United States describe well-documented benefits of modifying the intake of a single nutrient or type of nutrient present in the labelled food. Substantiation is therefore fairly straightforward, being based on a general intake recommendation (e.g. the recommended daily intake; RDI) for the active nutrient.

Such a recommendation, however, may not be readily available. Take the example of omega-3 fatty acids (ω -3). Although numerous health benefits have been ascribed to the very long-chain ω -3 found in fish and fish oil,²¹ an RDI for these nutrients has not yet been established. An attempt was made last year to reach consensus on the estimated average requirement for ω -3, applying new definitions of the National Academy of Science's Food and Nutrition Board.²² However, it became evident that such definitions, which are based on the intake required to avoid nutritional deficiency, will not necessarily reflect the intake required to achieve optimal health. In fact, in the presence of an adequate intake of the precursor to ω -3, α -linolenic acid, symptoms of ω -3 deficiency are unlikely to occur in adults. Yet there is epidemiological evidence that current ω -3 intakes are sub-optimal for reducing the risk of cardiovascular disease and cancer.²³ Based on this limited evidence, consensus was reached that 650 mg/day is an 'adequate intake' of very long chain ω -3, which has now formed the basis of a new health claim submission to the FDA²⁴ and a new nutrient claim proposed by ANZFA.²⁵

While a claim of this nature would be beneficial to the wider population, it fails to convey the better substantiated and probably more significant benefits of dietary ω -3 supplementation in the treatment of specific conditions such as rheumatoid arthritis, immune nephropathy, Crohn's disease and hypertriglyceridemia.²¹ Consider the latter case in which extensive clinical trials have shown that ω -3 supplementation is the most effective therapy available for triglyceride reduction.²⁶ Yet, no food or dietary supplement can make such a claim. Instead, the manufacturers of one such supplement, Omacor, took the rather unorthodox step of registering their product as a pharmaceutical to treat this condition.²⁷ Moreover, it is recognized that ω -3 can act via several independent mechanisms to reduce the risk of cardiovascular disease. The recent GISSI-Prevenzione study in Italy has stimulated great interest by showing that taking only 1 g/day of Omacor can

reduce the risk of subsequent mortality in survivors of a heart attack.²⁸ Thus a product-specific health claim on a food or supplement which has been tailored for the management of a specific health condition might be expected to have far greater impact on an at-risk individual than a generic health claim.

Substantiation of product-specific claims will require evidence in the form of intervention trials to demonstrate efficacy of the particular food or type of food for the stated indication. Despite the increased cost, some food manufacturers have indicated a preference for this approach,²⁹ which would allow more scope to develop and market unique products. For example, consider designer foods which might contain active nutrients not normally found in high levels in those foods. It would be necessary to ensure that consumption of such a food would deliver the active nutrient as effectively as the typical source of the nutrient on which an RDI has been based.

Provided that the relationship between the tissue concentration of an active nutrient and its physiological effects have already been well established, it may only be necessary to conduct bioavailability studies to demonstrate that consumption of the food results in adequate levels of the nutrient in the circulation or in tissue stores. Such studies are foreshadowed by the abovementioned health claim for soy protein, as the relationship between soy protein and isoflavones in mediating various health benefits ascribed to soy is yet to be resolved.³⁰ Clearly, the forms of soy used in different food products are likely to influence their efficacy for a proposed health outcome.

For other products, such as foods or even entire meals formulated with combinations of several active nutrients that are intended to convey a single health benefit, it will be necessary to conduct product-specific trials to evaluate the extent to which the effects of the nutrients are additive or even synergistic. Traditional examples of such products are breakfast cereals that have been fortified with a range of nutrients. Cereal products such as the recently launched Uncle Toby's 'Healthwise' range are tailored for specific health indications. Health claims for such products, if ultimately permitted, would need to be based on an assessment of the effects of regular consumption of the products on appropriate biomarkers in controlled intervention trials. 'Aviva', a similar product range recently launched in the United Kingdom by Novartis, carries a 'clinically proven' logo indicating that their products for bowel health, bone health and heart disease are backed by in-house trials as well as information from independent trials on the effects of the ingredients.³¹ No doubt health claims legislation, if introduced in Australia, would set rigorous standards with independent scientific appraisal of any intervention trials conducted for product evaluation either in-house or externally.

Thus the level of substantiation will need to be appropriate for the type of product and health claim proposed. Clearly, food manufacturers who seek marketing advantages from health claims will need to make significant investments in research and consumer education, not only to obtain approval for a health claim, but also to ensure its effectiveness and safety in long-term use.

To establish and effectively utilize health claims for functional foods, it may prove necessary to adopt elements of the

approach used for pharmaceutical registration, including establishment of dose–response relationships for efficacy, eligibility criteria for approved indications, identification of adverse interactions and contraindications and, in particular, postmarketing surveillance of long-term safety, efficacy and compliance. The latter is accepted as a major responsibility by the pharmaceutical industry. There is little point in investing large sums of money developing a product and marketing it for a health benefit if the benefit is not achieved. Without effective monitoring, it may be many years before the extent of benefit — or lack of it — is realised. Consider, for example, the recent introduction of spreads containing plant sterols such as ‘Pro-Activ’ and ‘Logicol’ for cholesterol reduction. Many consumers consider these foods to be an attractive alternative to the very well tested and very effective cholesterol-lowering drugs (statins). However, a decade after the introduction of statins, it was disappointing to find that 60% of patients prescribed these heavily subsidized drugs had discontinued their use within a year.³² What arrangements are in place to monitor the long-term efficacy, safety and compliance of the food alternatives?

An optimal therapeutic approach?

Consumer organisations have questioned whether we should be treating foods as medicine. When ‘Pro-Active’ was launched, Dr Dick Copeman of the Consumer Food Network warned consumers that it was ‘being promoted as if it were a drug, yet it has not been tested for safety to anywhere near the same extent as a drug would be’.³³ However, he also argued that ‘self-medication is not the way to treat any medical condition’ and ‘we should not be turning foods into medicine’, a view which is seemingly at odds with the ancient philosophy of Hippocrates: ‘let food be thy medicine and medicine be thy food’.³⁴

I believe that the intention of the latter was to consider food with medicine as part of a therapeutic continuum. It is time to break down the somewhat arbitrary regulatory barriers that discriminate between food used for sustenance alone, functional foods, dietary supplements, traditional or herbal medicines, other over-the-counter products and prescription drugs. Surely manufacturers, health providers and consumers alike would be better served by establishing a unified approach for evaluating the health potential — and limitations — of all these products. With this approach, we could aim to develop a range of integrated diet and lifestyle options for achieving and maintaining optimal health and, should treatment be necessary, we could use the most efficacious combinations of active nutrients with medication. Obvious examples are the use of low fat diets with cholesterol-lowering drugs and low salt foods with blood pressure medication. However, drug companies are hardly encouraged by the current regulatory environment to evaluate the potential benefits of nutrient/drug combinations. Adoption of such an approach would require an unprecedented level of cooperation between the regulatory authorities and all stakeholders.

A view expressed recently by a marketing manager that ‘we can spend money on research or we can play a bit with the words’ would be untenable in a better regulated environment. I believe that a responsible food industry keen to respond to consumer demand for functional foods is seeking to move in that direction. However, while opportunities for

both industry and consumers are clearly evident, they will require substantial investment and commitment on both sides to be realised, and there are bound to be unforeseen pitfalls in the process. The necessary regulatory controls will no doubt require ongoing revision as our food supply, eating habits, lifestyle and health continue to evolve.

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