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# Functional Foods: Consumer Issues and Future Challenges

**Keith W. Singletary and Michelle A. Morganosky**

Scientific progress in understanding the relationship of diet to disease, along with increasing health-care costs and consumers' desires to make healthy lifestyle improvements, provides a significant impetus for the development of novel foods with health benefits (functional foods). Combining sound science, effective and balanced communication strategies, and changes in the regulatory environment, important benefits could be realized for the entire food system, including producers, food manufacturers, retailers, and consumers.

This paper is an overview of issues and future challenges related to functional foods. Functional foods are generally defined as food products to be taken as part of a diet that provides health benefits beyond traditional nutritional effects (Roberfroid 2002). There are several reasons for the growing interest in "functional" foods. First, according to Willett (2002), over 60 percent of the risk for chronic diseases such as heart disease, stroke, colon cancer, and type II diabetes is potentially preventable by life-style modifications, including changes in diet. This scientific progress in understanding the relationship of diet to disease, along with increasing health-care costs and the consumer's desire to initiate healthy eating and lifestyle habits, makes this a potentially fertile ground for the development of food products that meet these demands. The concept of functional foods is not actually that new—for more than a decade the Japanese Ministry of Health, Labour and Welfare has been regulating Foods for Specified Health Uses (FOSHU), which number in the hundreds (Nakajima 2004).

## Major Health Issues—Is There A Role for Functional Foods?

Based on decades of scientific inquiry, it is clear that diet plays an important role in affecting our risk for a variety of chronic diseases and disorders, including cancer, heart disease, type II diabetes, and obesity (World Health Organization 2003), and there is continued interest in characterizing the contribution of diet to bone, joint, and eye health as well as to cognitive function. Increased consumption of

fruits/vegetables\* is associated with a lowering of risk for a variety of cancers (Steinmetz and Potter 1996). Although this health benefit is most likely due to the collective presence of many nutrient and non-nutrient plant components (a "cocktail of phytochemicals"), there is considerable ongoing research aimed at determining how individual phytochemicals such as lycopene in tomatoes, polyphenolics in fruits, isothiocyanates in broccoli, and antioxidants, to name a few, contribute to this cancer-protective effect. In relation to heart health, increasing consumption of plant-based foods is again considered a key lifestyle recommendation for Americans, for whom heart disease is a leading cause of death. Food products enriched for soy protein\*, plant sterols and stanols\*, omega-3 fatty acids, antioxidants, and fiber\* are being formulated and offered to the consumer (Meister 2002).

With a growing number of aging American baby-boomers, food products are being promoted that purport improvements in the health of joints, muscles, and bones due to the actions of such ingredients as glucosamine, calcium\*, and anti-inflammatory and anti-oxidant nutrients and phytochemicals. Furthermore, there is intriguing evidence that xanthophylls (such as lutein) may play a role in eye health (e.g. decreasing the development of macular degeneration) and that conjugated linoleic acid (CLA) and tea phenolics may improve weight maintenance and the balance between muscle mass and fatty tissue. Yet, as discussed below, the amount and quality of scientific data supporting such claims can vary, and in some cases there is a lack of scientific agreement as to the efficacy of the specific constituents. In addition, there may be inadequate information affirming overall safety, especially when consumed in purified forms by individuals

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\*An asterisk indicates especially strong scientific evidence.

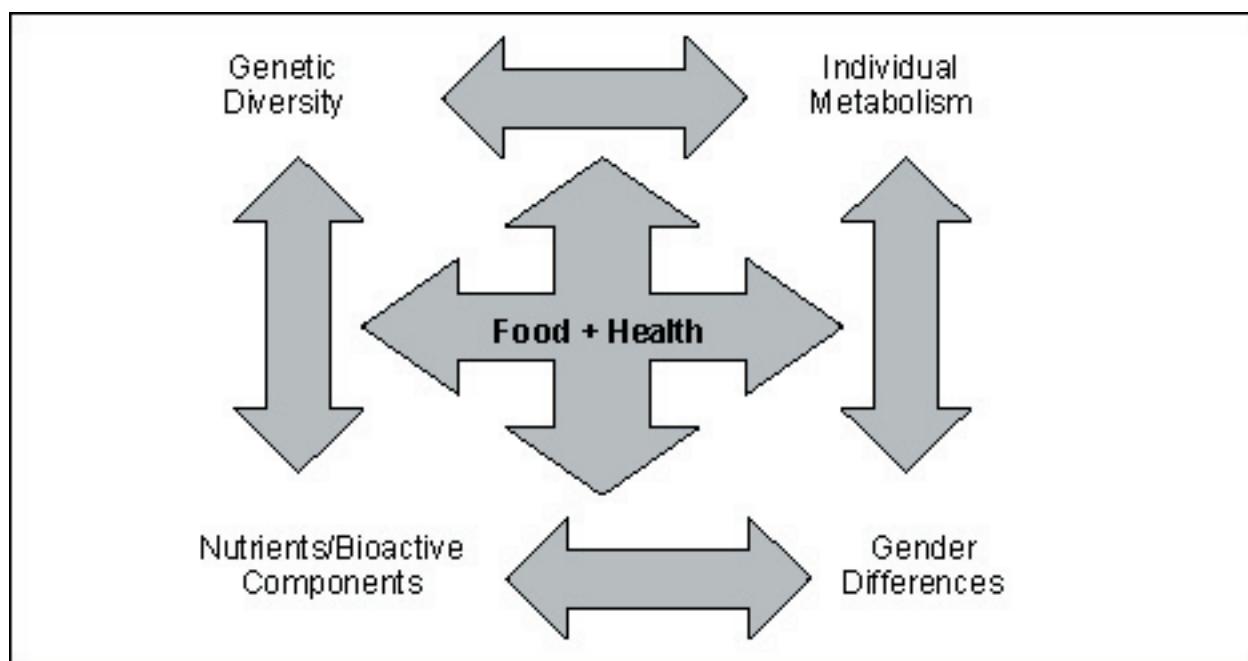
in different stages of the life cycle and/or at high levels of intake.

Keeping these caveats in mind, progress in understanding the role of diet, lifestyle, and health, as well as in developing a number of creative new food technologies, has enabled food manufacturers to craft and market health-improving food products with strong consumer appeal. Foods with a low glycemic index, low levels of trans-fatty acids, enhanced color stability and pleasing texture characteristics and mouth-feel exemplify advances that offer consumers a greater variety of healthy and attractive foods from which to choose (Milo Ohr 2003; Pszczola 2003).

### The Challenge of Unlocking the Food/Health Equation

A number of challenges exist for the vitality of the functional foods market in the years ahead. First, there are a number of scientific challenges for those attempting to unlock the food/health "equation." How do these food components act to modify disease processes and for whom are these benefits most pronounced? The food/health equation includes a complex set of interactions that must be better understood so that new food product efficacy can be appropriately characterized (Figure 1). The factors contributing to disparities in individual health

responses to foods need to be clarified. These include genetic variation, gender differences, individual differences in metabolism, and how bioactive phytochemicals alter the routine functions of traditional nutrients. This challenge is underscored by the emergence of the field of nutrigenomics, in which investigators worldwide are studying how food constituents acting as "dietary signals" can modulate multiple gene-expression patterns in our cells and tissues, and ultimately reduce disease risk (Kaput and Rodriguez 2004). Another scientific challenge involves understanding our complex behaviors associated with food consumption. For example, the sheer magnitude of sensory dynamics is illustrated by the fact that we may consume over 10,000 different food chemicals in our diet which can interact with thousands of chemosensor receptors around our bodies (Le Coutre 2003). How is this information coded in the human brain and how does it impact eating behaviors? Related to this issue—and perhaps one of the greatest challenges confronting those attempting to unlock the food/health equation—is gaining a meaningful understanding of the contributors to the international prevalence of obesity. According to the World Health Organization, more people are now overweight than underweight worldwide (World Health Organization 2003). What are the psychological, sociological, and cultural influences on food consumption? What are



**Figure 1. Food/Health Interactions.**

the metabolic, dietary, and sensory factors? To what extent do genes play a role? Will providing sound and understandable (scientific) information change consumer behavior? What public health policies, if any, need to be implemented? (Chopra, Galbraith, and Darnton-Hill 2002). Collective efforts by multiple disciplines will be needed in order to tackle this problem and to design strategies, some possibly including functional food products.

### **The Challenge (and Opportunity)—Communicating with Consumers**

In communicating with consumers about the food/health relationship, it is important to remember that functional foods are part of an effective strategy for health, not a substitute for good health habits. This is particularly important in light of the numerous health claims and product statements that regularly confront the consumer. Since the enactment of the Nutrition Labeling Education Act (NLEA) in 1990, only specific health/disease claims have been authorized for use on conventional foods and dietary supplements based on the U.S. Food and Drug Administration's (FDA) determination that significant scientific agreement must exist for such claims (Deis, 2003; Lucchina, 2003; Table 1). An example of a claim relating soy protein intake with risk of coronary heart disease could read, "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 \_\_\_ supplies \_\_\_ grams of soy protein." Also, based on the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994 and a related act in 1997, foods and dietary supplements may communicate "structure/function"

claims and "authoritative statement" claims linking a product's ingredients with health outcomes. For example, stating that consumption of a food product "helps to maintain normal cholesterol levels" would qualify as a structure/function claim, for which prior FDA approval is not required. On the other hand, communicating that this product "lowers cholesterol levels and reduces heart disease risk" is a health claim for which FDA approval is mandated. Of considerable interest is the announcement in late 2002 by the FDA of its Initiative on Consumer Health Information for Better Nutrition (FDA 2003), a plan intended to improve consumer access to scientifically sound and understandable information, thus assisting consumers in making appropriate diet choices, and stimulating competition within the food industry toward developing and marketing healthier food products. A component of the initiative involves expanding the current authorization system to include "qualified" health claims (giving scores of B, C, and D; Figure 2) based on a consensus of qualified experts after examination of the quality and consistency of scientific evidence (Meister 2002; Figure 3). The highest level of health claim ("A") would continue to be reserved for those statements meeting the current FDA standard of significant scientific agreement (an unqualified health claim). An example of a "qualified" health claim for nuts could read "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts, such as walnuts, as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease." It remains to be determined whether these changes will indeed contribute to the FDA's goals and/or reduce the amount of information confusion that currently exists for some consumers.

**Table 1. NLEA Authorized Health Claims.**

Calcium & osteoporosis
Sodium & hypertension
Dietary fat & cancer
Dietary saturated fat and cholesterol & risk of coronary heart disease
Fiber-containing grain products and fruits and vegetables & cancer
Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, & risk of coronary heart disease
Fruits and vegetables & cancer
Folate & neural tube defects
Dietary sugar alcohol & dental caries
Dietary soluble fiber & coronary heart disease
Soy protein & coronary heart disease
Plant sterols and plant stanol esters & coronary heart disease

## Conclusions

This paper addresses a potential role for functional foods in addressing health issues that increasingly confront many consumers worldwide. Steady progress is being made in unlocking the food/health equation, so that a sound scientific foundation can be laid for the development of safe and efficacious functional foods. However, communicating with consumers in a changing regulatory environment presents both challenges and opportunities. By combining good science, effective and balanced communication strategies, and change in the regulatory environment, important benefits could potentially be realized for the entire food system, including producers, food manufacturers, retailers, and consumers.

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Health Claims Report Card		
<b>A</b>	<b>High</b> Significant scientific evidence	<b>1</b>
<b>B</b>	<b>Moderate</b> Evidence is not conclusive	<b>2</b>
<b>C</b>	<b>Low</b> Evidence is limited and not conclusive	<b>3</b>
<b>D</b>	<b>Extremely Low</b> Little scientific supporting this claim	<b>4</b>

Figure 2. Proposed Health Claims Report Card (FDA 2003).

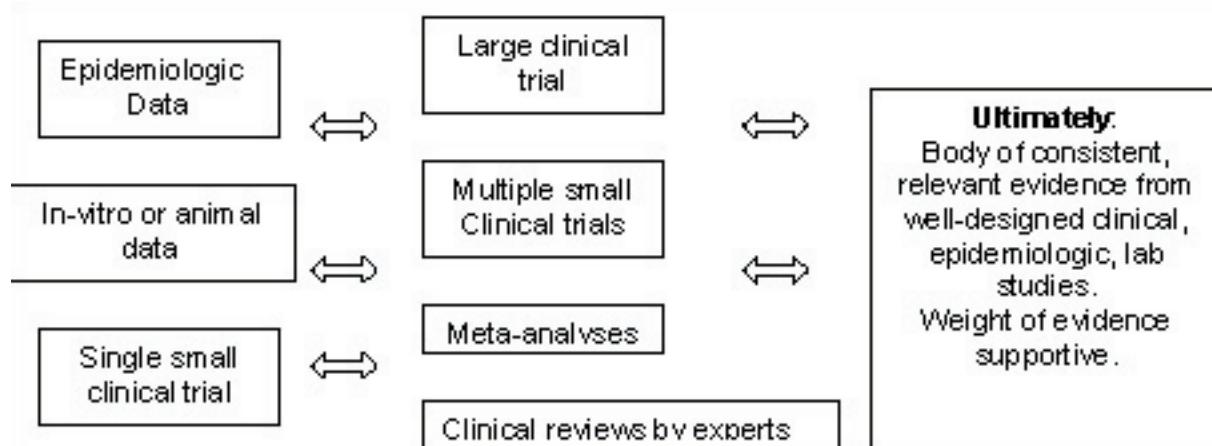


Figure 3. Examples of scientific evidence considered for approval of health claims. (Modified from Meister 2002).

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