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Overview of Functional Foods: Emphasis on Probiotic Bacteria

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ABSTRACT

Foods which promote health beyond providing basic nutrition are termed 'functional foods'. These foods have potential to promote health in ways not anticipated by traditional nutrition science. The international marketplace is the development ground for these products, even though scientific or regulatory consensus on their definition or significance has not been advanced. This article defines, provides examples of, discusses the consumer interest in, and considers the difficulty of developing scientific substantiation for effectiveness of functional foods. Probiotic bacteria are specifically used as an example in scientific approaches toward determining efficacy. © 1998 Published by Elsevier Science Ltd. All rights reserved

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INTRODUCTION

> Food probably has a very great influence on the condition of men. Wine exercises a more visible influence, food does it more slowly but perhaps just as surely. Who knows if a well-prepared soup was not responsible for the pneumatic pump or a poor one for a war?

This late-1700s quote by G. C. Lichtenberg hints at the power of food. Today, we are seeing a return of the Western world to the awareness that food can influence health and behavior in greater ways than were suspected by early nutritional scientists. There is a clear relationship between the food we eat and our health. But beyond supplying a source of calories and nutrients to prevent nutritional diseases such as malnutrition, scurvy and rickets, it is clear that the food we eat can contribute in less overt ways to maintenance of health and prevention of a broad range of diseases (Table 1). These 'ancillary' effects, exhibited by 'functional foods', occur through modulation of our basic physiology, including immune, endocrine, nerve, circulatory, and digestive systems.

It has been estimated that one-third of cancer cases relate to diet (Eddy, 1986), and there is strong evidence for the role of diet in the risk of cardiovascular disease, hypertension and obesity as well. In addition to disease prevention, the role of foods in improving performance (mental acuity, physical stamina), slowing the aging process, weight loss and recovering from disease have been proposed. This article will explore the foods which influence these activities, with a special emphasis on one particular functional ingredient, probiotic bacteria.

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FUNCTIONAL FOODS: DEFINITIONS

This field of functional foods has evolved rapidly and many new terms have emerged in response. Although in many cases these terms have no legal definition, common usage definitions are shown in Table 2. One issue seems clear, however, and that is that the domain of functional foods is promoting health, not curing disease.

How different classes of foods are differentiated can sometimes present problems for tracking the marketing trends with these products. Some products can easily be classified under specific categories: calcium-supplemented orange juice is clearly a functional food. However, other foods, such as oatmeal, may be more difficult to classify. Although oatmeal is clearly a food with functional properties, market surveys generally would not include oatmeal sales in the functional food category. It, along with tomatoes, broccoli and other natural foods, are considered common foods, and have not been modified beyond their normal state. However, Head *et al.* (1996) state that 'functional foods could be naturally occurring... foods', not just enriched or modified foods. Similarly, Roberfroid (1996) indicated that a 'food is functional if it contains a food component (whether a nutrient or not) that affects one or a limited number of functions in the body ... so as to have positive effects ...'. No requirement of modification or deliberate manipulation of the food from its natural state was made. Consensus on the definition and classification of functional foods would be a worthy accomplishment.

Arts (1996) approaches this classification challenge by including consumer intention as a criterion for classification of a food as functional. A food purchased primarily for its health functional properties (e.g., All Bran® cereal) was considered a functional food. One purchased primarily as a mainstream food (such as iodized salt) was not.

Table 1. Common Food Ingredients being Examined for Functional Attributes

Target	Functional food ingredient
Arthritis	Ω-3 Fatty acids Ginger extracts Collagen
Hypertension	Gamma amino butyric acid Pectin
Osteoporosis	Calcium Boron Casein phosphopeptides
Heart disease	β-Carotene Garlic extracts Sterols Phenolic compounds Psyllium
Cholesterol reduction	Soy fiber Probiotic bacteria Pectin
Modifiers of oxidative damage	Lycopene Anti-oxidant-vitamin-containing fruits and vegetables
Anticarcinogens	Garlic Green tea Probiotic bacteria Psyllium
Anti-infective agents	Probiotic bacteria Ionized zinc Elderberry extract

Table 2. Definitions of Functional Food Terms

Term	Definition
Functional food	A modified food or food ingredient that provides a health benefit beyond satisfying traditional nutrient requirements
Foods for specified health use (FOSHU)	An English language translation of a Japanese classification of functional foods. The Japanese government defines FOSHU as 'foods which are expected to have certain health benefits, and have been licensed to bear a label claiming that a person using them for a specified health use may expect to obtain the health use through the consumption thereof.' As of June, 1997, 80 foods and 67 ingredients have been officially registered as FOSHU.
Nutraceutical	A nutraceutical is a food or part of a food that offers medical and/or health benefits including prevention or treatment of disease
Colonic food	Undigested food which reaches the colon, usually in the form of a non-digestible carbohydrate
Prebiotic	A colonic food which encourages the growth of favorable intestinal bacteria (e.g., bifidobacteria or lactobacilli)
Probiotic	A mono or mixed culture of microorganisms which when applied to animal or man affect the host beneficially
Medical food	A special classification of food dictated in United States food law which: • Must be used under medical supervision • Must be for a disease with well defined, specific nutrient characteristics • Based on recognized scientific principles • Must provide medical evaluation (an example is a formula for dietary management of phenylketonuria)

Differentiated from the functional foods market were also categories described as 'lesser evil foods' which included foods with the negative properties removed (foods free of or with reduced levels of fat, cholesterol, salt or sugar) and 'market standard foods' which included foods which enjoy a >50% market share. Although useful, this approach to classifying functional foods has clear limitations. As markets develop, it is conceivable that certain functional foods will earn a >50% market share, but should still be included in the category. Furthermore, really good tasting functional foods may be purchased as much for their taste as their ancillary effects, making consumer intention a slippery slope for categorizing functional foods. The size of the functional foods market in the United States was estimated at $13.4 billion (Arts, 1996).

WORLD-WIDE PERSPECTIVES

Perhaps no other country has as progressive an approach to functional foods as Japan. Possessing an affirmed legal status and specific labeling benefits, functional foods (known in English as Foods for Specified Health Use, or FOSHU) are currently marketed in Japan. Although many foods which would be considered functional foods have not been submitted for formal FOSHU certification, as of June, 1997, 80 FOSHU foods have been approved (Bailey, 1997). Table 3 summarizes FOSHU foods and ingredients in Japan.

In the United States, although consumer and corporate interest is high, functional foods have no legal definition. This has not stopped food companies from entering into the functional foods market. Paramount to product success is product efficacy and safety. But equally important for product success is a product targeted toward an issue consumers care about. Surveys (Gilbert, 1996) have provided some insight into percentages of Americans with health concerns in the following areas: heart disease (57%), cancer (56%), stress (48%), high cholesterol (43%), obesity (43%), osteoporosis (39%) and diabetes (35%). Successful functional food products which echo these concerns can be found on the grocery store shelves: Egg Beaters® from Nabisco (an egg substitute with no cholesterol), Minute Maid Orange Juice plus calcium (targeted at osteoporosis concerns), Healthy Choice® Entrees (hot dinner entrees designed to help calorie consumption), and many types of sugar-free candy (targeted for weight management and diabetic consumers). Campbell Soup Co. recently introduced a line of frozen, mail-order meals designed to reduce high blood pressure, cholesterol and blood sugar, called 'Intelligent Cuisine'. This product is designed to aid consumers in reducing cholesterol and high blood pressure and is backed by clinical studies conducted at eight universities. Arts (1996) reported that cost of research to substantiate claims was estimated at $20 million.

Table 3. Functional Foods in Japan: Examples of Foods and Ingredients for Specified Health Use (Bailey, 1997)[a]

FOSHU foods[b]	FOSHU ingredients	Examples of label statements
24 Soft drinks	Fibers	Bifidobacteria/bifidogenic factors:
19 Table sugars	Oligosaccharides	'helps to maintain a good intestinal environment'
7 Sausages/meats	Sugar alcohols	
5 Yogurts/yogurt drinks	Ω-3- and Ω-6-fats/oils	
3 Carbonated beverages	Peptides and proteins	Chitosan or soy protein:
3 Chocolates	Sugar derivatives	'helps inhibit absorption of cholesterol'
3 Biscuits/cookies	Alcohol chemicals	
2 Candies	(green tea poly phenols)	
2 Powdered soft drinks	Vitamins, isoprenoids	Green tea polyphenols:
2 Chewing gums	Choline	'non-cariogenic ingredient'
2 Fried tofu coatings	Lactic acid bacteria	
1 Non-allergenic rice	Minerals	
1 Low phosphorus milk		
1 Lactic acid drink		
1 Coffee		
1 Pudding		
1 Vinegar		
1 Fish cake		
1 Ready-to-eat cereal		

[a] The approval process for FOSHU foods requires data on both the safety and efficacy of products, is handled by the Japan Health and Nutritional Food Association and the Japanese Ministry of Health and Welfare, and limits claims to health maintenance, not disease cures.
[b] FOSHU foods must be in common food form (not tablet, capsule or dietary supplement form), must be able to be consumed on a daily basis, and should be priced competitively with common foods for daily consumption.

The product was developed in consultation with the American Diabetes Association and the American Heart Association.

In addition to the United States and Japan, diet and health is a trend in Europe as well. Grijspaardt-Vink (1996) identified health and convenience as the two major trends in the European food market, citing keen awareness of the European consumers to the relationship between diet and health. A leadership role in approaching the functional foods area is being taken by the International Life Sciences Institute (ILSI), which is managing a project started in November of 1995 to establish a science-based approach for targeted modifications of food and food constituents. The hope is to establish a Europe-wide consensus on the concept and application of functional food science. This project will result in the development of theme papers on the characterization and description of six areas of human physiology with emphasis on critical assessment of the science required to prove that specific nutrients positively affect human functions and identification of further research. The categories to be reviewed are:

1. Gastrointestinal system
2. Defense against reactive oxidative species
3. Cardiovascular system
4. Substrate metabolism
5. Development, growth and differentiation
6. Behavioral and psychological functions

In addition to the theme papers, a consensus document will be produced on 'Concepts in Functional Food Science and Options for Their Application'. The brain power for this project is drawn from 54 scientists representing industry, academia, and research institutions from 10 different European Union countries.

WHY THE MOVE TO FUNCTIONAL FOODS?

Driving forces which are fueling interest in functional foods are numerous. To provide perspective on this trend in foods, however, it is important to realize that among American shoppers, it is estimated that 51% have never heard of functional foods and 80% have never heard of nutraceuticals. But 70% agree that some foods contain active components that reduce risk of diseases and improve long term health (Gilbert, 1996), and these foods are attractive to consumers for the following reasons.

1. *Consumers want to prevent, rather than cure, disease.* Traditional medicine is viewed as being focused on curing disease once it occurs rather than preventing it from occurring. In the United States, maintenance of health is no longer seen as the exclusive domain of the medical profession. Consumers are looking for ways to promote their own optimal health, to enhance their 'health-span', not just life span.
2. *Rise of medical costs.* Effective approaches to disease prevention appeal to the pocketbook as well. Access to healthcare has become more difficult in the climate of managed care and employer interest in controlling health care costs. It makes business sense to focus on prevention and not just cures. A focus of medical care dollars spent on late-stage disease-focused chronic care and heroic intervention efforts is beginning to be questioned.
3. *Consumers are more aware of link between health and nutrition.* Coverage of food and nutrition by the popular media can be confusing to the general public. Oversimplification of scientific discoveries of food safety concerns and preliminary links between diet and health can lead to false senses of both fear and

hope. Notwithstanding, the popular media have done an effective job bringing health issues to the attention of the average consumer, and putting these issues into terms a lay person can understand. In the United States, government and professional associations have increased communication of health messages. In the past 10 years, the Department of Health and Human Services issued the food pyramid guide to a healthy diet, the National Cancer Institute launched its 'Five-A-Day' campaign, encouraging the consumption of five servings of fresh fruits and vegetables each day, Congress enacted the Nutrition Labeling and Education Act changing food labeling law and empowering the Federal Drug Administration (FDA) to review and approve health claims for food labels, and the Dietary Supplement Health and Education Act was passed with the purpose of facilitating the availability and communication of benefits of dietary supplements.

4. *Aging population.* Populations in certain industrialized nations are aging rapidly. In the United States, the oldest of the 78 million baby boomers (Americans born between 1945 and 1963) have reached the age of 52, and surveys indicate that they are interested in strategies to hold aging at bay. In Japan, predictions are that 26% of the population will be over 64 years of age, by the year 2025.
5. *Want to counteract the perceived increase of environmental hazards from pollution, microbes and chemicals in air, water and food.* Environmental factors are thought to play a role in many different cancers and consumers are concerned about the effects of air, water and land pollution on their health. 'Newly emerging' microbial pathogens suggest the need for optimal immune defenses. Even our own microbiota may work against us in the fight to avoid carcinogens: intestinal microbes have been postulated to possess the ability to convert dietary procarcinogens into carcinogens. Foods which might help our body resist these risks are attractive to modern consumers.
6. *Increased scientific evidence for efficacy.* Perhaps the most important item on this list, nutrition research aimed at understanding the diet:health link has expanded, providing a rational basis for food selection, and confirming healthful effects of foods long consumed for these reasons.

SCIENTIFIC APPROACH TO ESTABLISHING FUNCTIONAL BENEFITS OF FOODS: THE COMPLICATED CASE FOR PROBIOTIC BACTERIA

As with many functional foods or ingredients, the healthful properties of lactic acid bacteria were a part of folklore before scientific investigation. However, as modern scientists took on the challenge of identifying what effects, if any, probiotic bacteria (defined in Table 2) had on human health, data began to accumulate. Research on exploration of mechanisms and human clinical studies have all contributed to increased understanding of physiological activity of these bacteria. However, research has been complicated due to a variety of factors.

One complicating factor is the heterogeneous nature of the microorganisms being evaluated as probiotics. Unlike purified compounds, probiotic microbes differ according to the genera, species and strain. Driven by commercial and/or scientific motives, research has targeted many different probiotic preparations. Multiple species of *Lactobacillus* (*acidophilus*, *rhamnosus*, *casei*, *plantarum*, and *reuteri*, to name a few), bifidobacteria (*infantis*, *longum*, *adolescentis*), *Enterococcus*, and even a yeast, *Saccharomyces boulardii* have all been evaluated for probiotic effects. Blends of multiple strains or species of bacteria have also been evaluated. While each individual study may provide insight into the specific probiotic preparation tested, taken together as a body of research, it is difficult to make general conclusions about probiotic bacteria as a whole. Findings likely cannot be extrapolated from one strain to even another strain of the same species.

Another complicated aspect of probiotic research rests with the diversity of endpoints being studied. Probiotic microorganisms have the potential to influence the many aspects of human physiology affected by indigenous microbes, including the alimentary canal, the vagina and the skin. The mechanisms by which probiotic bacteria are proposed to act include alteration of populations or metabolic activity (e.g. activity reduction of fecal enzymes such as β-glucuronidase) of indigenous or contaminating microflora, delivery of enzymes (e.g. lactase), interference with pathogen or opportunistic pathogen virulence via colonization resistance (e.g. *Clostridium difficile*), or influence on different components of the immune system (e.g. increases of secretory IgA). Table 4 lists areas of research on health effects of probiotic cultures. Clearly, with research targeting this many clinical endpoints, the strength of the many publications in this area is diluted, making it difficult to reach scientific agreement on the effect of probiotics on any one target. (One exception may be the role of yogurt cultures in aiding the digestion of lactose consumed by subjects intolerant to lactose (Sanders, 1993)). In recent years, the focus of research has been with clinical evaluations in controlled human trials. For example, the strain *Lactobacillus rhamnosus* GG, commercialized by Valio Dairies in Finland, has been the subject of over 30 peer-reviewed human clinical trials, providing insight into the physiological effects of this strain.

In addition to the numerous endpoints being studied, is the complication of the distinction between true clinical endpoints and 'surrogate endpoints'. A surrogate endpoint was defined in the Keystone Dialogue (Keystone Center, 1996) as 'a biological observation, result, or index that predicts the development of a chronic disease'. It is an 'intermediate' or 'substitute' indicator for a chronic disease, such as serum cholesterol levels serving as predictors of coronary heart disease.[1] This dialogue called for research that provides new, meaningful surrogate markers, with the hope that these markers would facilitate the evaluation of healthful effects of foods and food components. In some cases, surrogate markers are the only recourse open to investigation, since direct experimentation on humans for certain clinical conditions is not possible, such as colon cancer or effect on infectious disease. However, the challenge is to develop surrogate

[1]The FDA considers several surrogate markers so closely associated with the disease as to be regulated as disease claims. Therefore, statements on foods or dietary supplements regarding reduction of cholesterol is not allowed without approval of a specific health claim.

Table 4. Targets for Health Effects of Probiotic Bacteria

Target	Substantiation of effect determined in the following systems
Diarrhea	Human clinical studies
Antibiotic Associated Diarrhea (AAD)	Healthy humans
Clostridium difficile	Diseased humans
Travelers	Healthy humans
Rotovirus	Diseased humans
Integrity of the intestinal mucosa	Suckling rat model
Vaginitis (yeast and bacterial)	Healthy humans
Colon cancer	Surrogate markers: fecal enzyme levels, aberrant crypt formation in the colon, antimutagenic activity
Immune system modulation	Surrogate endpoints
Resistance to infection	Survival in pathogen-challenged animals
Blood components	Animal and human studies on levels of macrophages, interferon, immunoglobulins, or other blood components
Vaccine adjuvant activity	Healthy humans
Allergic reaction to milk	Healthy humans
Small bowel bacterial overgrowth	Diseased humans
Hypertension	Animal models: spontaneously hypertensive rats
Lactose intolerance	Healthy humans with lactose intolerance
Cholesterol lowering	Hypocholesterolemic humans; *in vitro*
Urinary tract infections in women	Human clinical studies
Survival after irradiation in mice	Mouse model
Endotoxemia and alcoholic liver disease	Intragastric feeding rat model
Repair of DNA in UV damaged skin	

markers that have physiological significance. The extent of an effect may be statistically significant, such as a 30% decrease in levels of fecal β-glucuronidase activity, but may not have physiological relevance (substantive significance), such as a perceptible reduction in the risk of colon cancer in humans. Furthermore, there is scientific agreement on the meaning of certain surrogate markers, whereas there is not for others. For example, analysis of blood lipid fractions is widely used and relied upon as a predictor of risk for coronary artery disease. This cannot be said for levels of activated macrophages or circulating interferon as an indicator of health.

The move to studies in human subjects for analysis of probiotic effects is laudable. The investment in these studies reflects the commitment on the part of the sponsors in understanding the clinical effects of probiotics. However, it can be argued that since the focus of probiotic bacteria seem to be the promotion of health and not curing disease,[2] one could question the clinical focus of many recent studies on diseased rather than healthy populations. This focus can be justified from the point of view that too large a population of healthy subjects would be needed. Furthermore, if a physiological effect can be substantiated in a diseased population, it is reasoned that a similar, albeit smaller scale, effect might be seen in less diseased or healthy populations. However, this situation brings to mind a story: A man came upon his friend furtively looking on the ground for an item he lost. The man willingly joined the search and asked his friend what he was searching for. 'I lost a key', was the response. 'Where did you last see it', the friend enquired. 'In the house'. 'Well, why are we looking out here?' his friend asked, confused. The man answered with authority, 'Because it's dark inside'. We would be well advised to not waste resources doing research that does not yield meaningful results.

Although the proposition of healthful effects of probiotic bacteria first came from Metchnikoff's observation of longevity of Bulgarian people consuming fermented milk, no controlled epidemiological study has been conducted on probiotic bacteria and any clinical targets. Although the opportunity to conduct such research presents itself in regions where probiotic consumption has reached a significant level, such as in Japan, the only studies available to date follow primarily fermented dairy products and incidence of colorectal cancer (Kampman *et al.*, 1994; Peters *et al.*, 1992) and breast cancer (Monique *et al.*, 1986; van't Veer *et al.*, 1989). The effects of consumption of live bacteria could not be determined from these studies. Without epidemiological evidence, the strength of surrogate endpoints is weakened. Additionally, it is possible that determinents of healthful effects of probiotic-containing dairy products are multifactorial, due not just to live bacteria but also to other components of fermented milk, such as highly absorbable calcium, conjugated linoleic acids, butyric acid and bioactive peptides. Isolation of a single component, may not yield the positive benefits of a whole food, supporting the approach of functional foods over dietary supplements as a means of delivering functional ingredients.

Another opportunity surrounding the application of probiotic research to the development of food products is communication of benefit to the consumers. In the US, in addition to the predominantly negative perceptions consumers have of bacteria, bacterial names are not 'lay-person-friendly'. Although surveys showed that about 50% of United States consumers are interested in foods that boost the immune system, prevent cancer and reduce the risk of disease, only 30% are interested in active cultures in yogurt (Gilbert, 1996). A communications

[2]There are notable exceptions to this generalization, pimarily in the area of biotherapeutics. The use of *Saccharomyces boulardii* as a treatment for *Clostridium difficile* induced pesudomembranous colitis is perhaps the best known example.

challenge exists for advancing the probiotic product area in the United States.

SIGNIFICANT SCIENTIFIC AGREEMENT

The phrase 'significant scientific agreement' is a term used in the United States Nutrition Labeling and Education Act of 1993 to establish the standard that will be expected to be reached prior to government validation of a health claim. Applying this standard to evaluation of the legitimacy of health statements (Table 5) can be very difficult, although the standard does not require consensus. A group of industry, government and academic professionals considered the use of this standard (Keystone Center, 1996). Their opinion follows:

> Data may not always be consistent, some studies may not be optimally designed, and, taken individually, not all studies may be of sufficient strength to be persuasive. Application of the standard should continue to take into account these and other possibilities, as long as the accumulated data are sufficiently consistent and powerful and enough studies are appropriately designed to convince qualified scientists that the asserted relationship exists.

Suggested here is a scientific approach to reviewing data which acknowledges that at times results from a flawed experimental design may still yield pertinent information. This is not an excuse for sloppy science, but is a rational approach to consideration of the less-than-perfect research.

An alternative opinion on the application of the standard of significant scientific agreement was expressed by the Institute of Food Technologists (IFT Voices, 1997). IFT disagreed with a United States Commission on Dietary Supplement Labels which recommended (August 1, 1997) that the standard of significant scientific agreement should not be so strictly interpreted as to require unanimous or near-unanimous support. IFT believes that 'significant scientific agreement implies near-unanimous support.' IFT fears that this interpretation may create an opportunity for the use of single or flawed studies to substantiate a label claim, with the added appearance of having had government review and approval. This concern stems from the perception that the United States Dietary Supplement Health and Education Act (DSHEA) of 1994 provides manufacturers of dietary supplements wide latitude to make unsubstantiated labeling claims through publications used in connection with sales, a freedom not allowed foods.

FUTURE OF FUNCTIONAL FOODS

Evidence for the increased awareness on the role of foods and food ingredients in a healthy diet is the upward trend in sales of 'healthy consumables'. In the United States in 1996, the natural products market (which includes dietary supplements, vitamins, organic foods, personal care items, and housewares sold in natural foods stores) showed an estimated increase of 22% (as estimated from survey of retail outlets). This same study showed that the dietary supplement portion of this market grew by 38%. Arts (1996) estimated the nutraceutical market to be $80 million, with functional foods at $13.4 billion. The current probiotic portion of this market for the U.S. has been estimated between $50–$200 million (New Hope Natural Media, Boulder, CO; Arts, 1996). The European market for probiotic cultures has seen a trend toward increased numbers of dairy products containing probiotics and have been marketed with the strategy of improving general gut health, lowering blood cholesterol, or improving the body's natural defenses (Young, 1997). In the United Kingdom, the current market for probiotic and prebiotic-containing products is estimated at $2 billion (Young, 1997).

However promising, consumers remain unenthusiastic about some functional categories. For example, sales of fluid milk containing *Lactobacillus acidophilus* account for only 0.6% of total milk sales in the United States. The product was first introduced in the mid-1970's, but has not succeeded in becoming a mainstream milk product. This is likely due to minimal efforts to communicate the uniqueness of this product, but may also reflect the complicated nature of communicating the benefits of probiotic bacteria. Products built on this same basic concept have been much more successful worldwide,

Table 5. Definitions of Different Health-Related Statements Allowed on Foods in the United States

Health claim	A claim that characterizes the relationship of any substance to a disease or health related condition. Health claims must first be approved by an FDA regulation. Ten claims have been allowed by the United States FDA	'Dietary fiber reduces the risk of coronary artery disease' which could be displayed on the label of a high fiber breakfast cereal
Nutrient content claim	A claim that, either expressly or by implication, characterizes the level of any nutrient required to be listed on the nutrition label	'A good source of calcium' on the label of a yogurt product; because no reference daily intake has been established for omega-3 fatty acids, no nutrient content claim for this substance can be legally made
Structure-function claim	Describes the effect of a food or food substance on a structure or function of the body. Allowable on foods and dietary supplements in the United States	
Dietary guidance	Messages about general food choices or achievement of a health lifestyle that typically are not regulated as health claims under NLEA	

suggesting that a marketing opportunity exists to renew this product category in the United States.

Young (1997) listed criteria important for future growth of health promoting ingredients: proof of safety, proof of efficacy, consumer education, market positioning, price, health claims strategy,[3] and developing commercial structures. It will be through development, with sensitivity to these issues, that functional foods will move from a marketing niche to mainstream food. Convincing health professionals that these foods provide significant benefits to consumers, and providing these benefits at a reasonable cost will also be important.

CONCLUSIONS

In a movie released in the summer of 1997, 'Men In Black', Secret Agent K introduces a new recruit to alien life forms. In an attempt to calm the dumbfounded agent, Agent K says, 'A thousand years ago, everybody knew as a fact that the Earth was the center of the universe. Five hundred years ago they knew it was flat. Fifteen minutes ago you knew we humans were alone on it. Imagine what you'll know tomorrow'. This quote is very applicable to what consumers hear about food. Ten years ago, consumers 'knew' dietary fat was bad. The image of many foods was tarnished. But today scientists are discovering important roles of many fat-based food components, such as conjugated linoleic acid, butyric acid, and omega-3-fatty acids, and some antioxidant vitamins. Far from a liability, dietary fat, in moderation, may be an important source of functional food ingredients. We should take a lesson from the past and stay humble about the 'wisdom' which underlies the natural composition of food, and recognize the importance of the whole food approach over a magic bullet approach to functionality.

The functional food area is filled with opportunity. Development in this field will no doubt address concerns of nutritionally sufficient consumers hoping to improve their health and performance, and avoid disease. Hopefully also addressed will be developments that will impact health of people in less developed countries where concerns with sanitation, water quality, vaccine availability, diarrheal illnesses, nutrient availability, and other basic health issues are the more overriding concerns. Products which could reduce the incidence of infant diarrhea or enhance immune system functioning could make a measurable difference in the health status of these individuals. Several functional ingredients seem to have this potential and efficacy needs to be investigated in these populations as well.

In closing, it is well to remember the importance of careful scientific study and scrutiny of all aspects of the functional foods arena. Without it, this neo-industry will lose the confidence of the government, the interest of the larger food companies, the curiosity of the media, and most importantly, the faith of the consumer. 'Building a strong, sustainable market ... inevitably comes back to one thing: information. And in nutrition, information must be linked back to science' (Arts, 1996). We have a responsibility (plus it makes good marketing sense) to promote products based on science, not faith.

[3]Although each country has different regulations concerning what can be said about the link between a food and health, it should be remembered that the food label is only one mechanism of communicating to consumers about healthful attributes of products. Supplementary product literature, advertising, popular media (both printed and electronic), and communication with health professionals (doctors, pharmacists, nurses and dieticians) are additional mechanisms of communication.

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