Position of the American Dietetic Association: Functional Foods

ABSTRACT
It is the position of the American Dietetic Association that functional foods, including whole foods and fortified, enriched, or enhanced foods, have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis, at effective levels. The Association supports research to define further the health benefits and risks of individual functional foods and their physiologically active components. Dietetics professionals will continue to work with the food industry, the government, the scientific community, and the media to ensure that the public has accurate information regarding this emerging area of food and nutrition science. Knowledge of the role of physiologically active food components, from both phytochemicals and zoochemicals, has changed the role of diet in health. Functional foods have evolved as food and nutrition science has advanced beyond the treatment of deficiency syndromes to reduction of disease risk. This position reviews the definition of functional foods, their regulation, and the scientific evidence supporting this emerging area of food and nutrition. Foods can no longer be evaluated only in terms of macronutrient and micronutrient content alone. Analyzing the content of other physiologically active components and evaluating their role in health promotion will be necessary. The availability of health-promoting functional foods in the US diet has the potential to help ensure a healthier population. However, each functional food should be evaluated on the basis of scientific evidence to ensure appropriate integration into a varied diet.
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POSITION STATEMENT

It is the position of the American Dietetic Association (ADA) that functional foods, including whole foods and fortified, enriched, or enhanced foods, have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis, at effective levels. The Association supports research to define further the health benefits and risks of individual functional foods and their physiologically active components. Dietetics professionals will continue to work with the food industry, the government, the scientific community, and the media to ensure that the public has accurate information regarding this emerging area of food and nutrition science.

Expanding knowledge of the role of physiologically active food components, from both plant (phytochemicals) and animal (zoochemicals) sources, has notably changed the role of diet in health. The development of "functional foods" has evolved as food and nutrition science has advanced beyond the treatment of primary deficiency syndromes (1). Although functional foods remain undefined under current US food regulations, they are usually understood to be any potentially healthful food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains (2). The term "functional" implies that the food has some identified value leading to health benefits, including reduced risk for disease, for the person consuming it. Regardless, leaders in the field agree that, despite the absence of a consensus definition, functional foods will continue to have a major impact on the American and international food supply (3,4). A random telephone survey of US consumers conducted for the American Dietetic Association supported the notion that a significant percentage of consumers are interested in diet and its potential role in improving health. In fact, about 50% identified functional foods such as soy and berries as having "health-related effects" (5). In addition, the International Food Information Council March 2002 survey reported that 94% of consumers agree that certain foods have health benefits that go beyond basic nutrition, and 85% of survey participants expressed interest in learning more about functional foods (6).

As the food industry has responded to consumer demand for a more healthful food supply, the variety of functional foods that are currently available to consumers has grown tremendously, and functional foods account for an increasing percentage of all new food products (7). The American Council on Science and Health recently reviewed the scientific evidence for the health-promoting effects of specific functional foods and established a Likert-type scale for classification ranging from very strong evidence to weak evidence (8). Dietetics professionals, with broad training and expertise in foods and nutrition, will be integral to interpreting the science and then educating consumers regarding how to most appropriately integrate functional food products into an overall varied and healthful eating plan.

DEFINING FUNCTIONAL FOODS

There is no universally accepted definition of functional foods; however, several organizations have attempted to define this emerging food category. The International Food Information Council (IFIC) defines functional foods as foods that provide health benefits beyond basic nutrition (2). This definition is similar to that of the International Life Sciences Institute of North America (ILSI), which has defined functional foods as foods that, by virtue of physiologically active food

components, provide health benefits beyond basic nutrition (9). Health Canada defines functional foods as "similar in appearance to a conventional food, consumed as part of the usual diet, with demonstrated physiological benefits, and/or to reduce the risk of chronic disease beyond basic nutritional functions" (10). The Institute of Medicine of the National Academy of Sciences limits functional foods to those in which the concentrations of one or more ingredients have been manipulated or modified to enhance their contribution to a healthful diet (11).

According to these definitions, unmodified whole foods such as fruits and vegetables represent the simplest form of a functional food. For example, broccoli, carrots, or tomatoes would be considered functional foods because they are rich in such physiologically active components as sulforaphane, beta carotene, and lycopene, respectively. Modified foods, including those that have been fortified with nutrients or enhanced with phytochemicals or botanicals, also fall within the realm of functional foods. In addition, food biotechnology will continue to provide new venues for functional food development. The Table provides a brief listing of selected functional foods currently available in US markets. Trends in functional food product development have been actively monitored by Food Technologists (12,13).

Although the term "functional foods" may not be the ideal descriptor for this emerging food category, focus-group research conducted by the IFIC showed that this term was recognized more readily and was also preferred by consumers over other commonly used terms such as "nutraceutical" or "designer foods" (14). Widespread use and general acceptance of the term "functional foods" by the media, scientists, and consumers have led the ADA to work within this framework rather than introduce a new, more descriptive term.

As the largest organization of dietetics professionals, the ADA classifies all foods as *functional* at some physiologic level (15). The term *functional food* should not be used to imply that there are good foods and bad foods. All foods can be incorporated into a healthful eating plan—the key being moderation and variety.

RATIONALE

Development of functional food products will continue to grow throughout the 21st century as consumer demand for healthful products grows (16). Factors contributing to this reshaping of the food supply include the following:

- an aging population;
- increased health care costs;
- self-efficacy, autonomy in health care, and an awareness and desire to enhance personal health;
- advancing scientific evidence that diet can alter disease prevalence and progression (17); and
- most importantly, changes in food regulation.

Nutrients and nonnutritive food components have also been associated with the prevention and/or treatment of chronic diseases such as cancer, coronary heart disease, diabetes, hypertension, and osteoporosis (18). As the data supporting the role of diet in health promotion and disease prevention continue to mount, it is likely that the quantity of enhanced foods will expand substantially. Functional foods are viewed as one option available to Americans seeking cost-effective health care and improved health status, and they will continue to transform the American food supply.

Regulation of Functional Foods

The Food and Drug Administration's (FDA) involvement with functional foods has expanded in recent years; however, the regulation of functional foods remains confusing (19,20). Under current regulations, functional foods or components can be placed into a number of existing regulatory categories, including conventional foods, food additives, dietary supplements, medical foods, or foods for special dietary use. These categories fall under the Federal Food, Drug and Cosmetic Act (FDCA) of 1938, as amended, and are implemented under regulations from the FDA. The category used to define a specific functional food or component depends on how the manufacturer selectively positions and markets the product for its intended use and the specific label claim associated with the food item.

The most well established and scientifically sound approach to labeling and marketing a functional food is through the use of FDA-approved health claims delineated by law under the Nutrition Labeling and Education Act (NLEA) of 1990 (21). The health claims authorized under the NLEA are statements that describe a relationship between a food substance and a disease or other health-related condition (ie, a "risk reduction" relationship). The law mandates that a health claim be authorized in the labeling of FDA-regulated products only if significant scientific agreement among qualified experts exists about the validity of the relationship described in that claim. Under the NLEA, companies petition the FDA to consider new health claims. Thirteen NLEA health claims authorized by the FDA currently exist (Figures 1 and 2). Substantial clinical efficacy and documentation are an important part of a company's petition submission to the FDA. For example, 43 human clinical intervention trials were included in the soy health claim petition approved by the FDA (22). On the basis of the strong scientific underpinning of the NLEA health claims provisions, the ADA supports the use of such preauthorized claims on food products, including functional foods.

A provision in the FDA Modernization Act of 1997 (FDAMA) (23) provides an additional expedited process for manufacturers to use health claims if such claims are based on current, published, authoritative statements from predefined federal scientific bodies (Figure 3). These bodies include only those "with official responsibility for public health protection or research relating to human nutrition" such as the National Institutes of Health, the Centers for Disease Control and Prevention, and the National Academy of Sciences (23). Under this law, manufacturers must notify the FDA 120 days before using a particular claim. The notification must identify the statement and provide the specific wording of the claim. During the 120-day period, the FDA is expected to review the notification and, if appropriate, prohibit or modify the claim. In the absence of FDA action, the claim is authorized by statue. These provisions are intended to expedite the process by which manufacturers can use health claims. On July 6, 1999, the first

Table. Strength of evidence for functional foods currently on the US market[a,b]

Functional food	Bioactive component	Health benefit	Type of evidence	Strength of evidence	Recommended amount or frequency of intake	Regulatory status
Fortified margarines	Plant sterol and stanol esters	Reduce total and LDL[c] cholesterol (43)	Clinical trials	Very strong	1.3 g/d for sterols 1.7 g/d for stanols	Health claim
Psyllium	Soluble fiber	Reduce total and LDL cholesterol (38)	Clinical trials	Very strong	1 g/d	Health claim
Soy	Protein	Reduce total and LDL cholesterol (22,42)	Clinical trials	Very strong	25 g/d	Health claim
Whole oat products	β-glucan	Reduce total and LDL cholesterol (38)	Clinical trials	Very strong	3 g/d	Health claim
Cranberry juice	Proanthocyanidins	Reduce urinary tract infections (64,65)	Small number of clinical trials	Moderate	300 mL/d	Conventional food
Fatty fish	n-3 fatty acids	Reduce TG,[d] reduce heart disease cardiac deaths and fatal and nonfatal myocardial infarction (47,48,50,51)	Clinical trials; epidemiologic studies	Strong to very strong	Two fatty fish meals per week; 0.5-1.8 g EPA[e] + DHA[f]	Qualified health claim for dietary supplement
Eggs with omega-3 fatty acids	n-3 fatty acids	Reduce cholesterol (55,56)	Clinical trials	Weak to moderate	Unknown	Conventional food
Garlic	Organosulfur compounds	Reduce total and LDL cholesterol (49)	Clinical trials	Weak to moderate	600-900 mg/d (dietary supplement) or approximately 1 fresh clove/d	Conventional food and dietary supplement
Jerusalem artichoke, onion powder, ripe banana	Prebiotics/ fructooligo-saccharides	Blood pressure control; serum cholesterol reduction (59,60)	Animal studies; clinical trials	Weak	3-10 g/d	Conventional food
Green tea	Catechins	Reduce risk of certain types of cancer (57)	Epidemiologic randomized crossover study design	Moderate	4-6 cups/d	Conventional food
Black tea	Polyphenols	Reduced risk of coronary heart disease (58)				
Spinach, kale, collard greens	Lutein/zeaxanthin	Reduce risk of age-related macular degeneration (67)	Epidemiologic	Weak to moderate	6 mg/d as lutein	Conventional food, dietary supplement
Tomatoes and processed tomato products	Lycopene	Reduce prostate cancer risk (52-54)	Epidemiologic	Moderate	½ cup/d (30 mg or 10 servings/week)	Conventional food
Lamb, turkey, beef, dairy	CLA[g]	Reduce breast cancer (62,63)	In vivo and in vitro studies	Weak	Unknown	Conventional food
Cruciferous vegetables	Glucosinolates, indoles	Reduce risk of certain types of cancer (39,40,66)	Epidemiologic and in vitro	Weak to moderate	>½ cup/d	Conventional food
Fermented dairy products	Probiotics	Support GI[h] health (61)	In vivo, in vitro, and clinical data	Moderate	1 to 2 billion colony-forming units per day	Conventional food or dietary supplement
Tree nuts	Monounsaturated fatty acids, vitamin E	Reduced risk of coronary heart disease (45,46)	Clinical trial	Moderate	1-2 oz/d of nuts	Qualified health claim
Grape juice or red wine	Resveratrol	Platelet aggregation reduction (83-85)	Epidemiologic, in vivo and in vitro	Moderate to strong	8-16 oz/d	Conventional food

[a]Foods that have a Food and Drug Administration-approved health claim (sterol/stanol esters, oats, psyllium, soy) generally are supported by two dozen or more well-designed published clinical trials. For example, the soy health claim petition contained more than 40 clinical trials, whereas there are only a few clinical trials on cranberry juice and urinary tract infections.
[b]Reprinted with permission and adapted from the American Council on Science and Health: From: Hasler CM. *J Nutr.* 2002;132:3772-3781.
[c]LDL=low-density lipoprotein.
[d]TG=triglyceride.
[e]EPA=eicosapentaenoic acid.
[f]DHA=docosahexaenoic acid.
[g]CLA=conjugated linoleic acid.
[h]GI=gastrointestinal.

Diet	Disease	Model claim
Calcium	Osteoporosis	Regular exercise and a healthful diet with enough calcium help teens and young adult white and Asian American women maintain good bone health and may reduce their risk of osteoporosis.
Sodium	Hypertension	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
Dietary fat	Cancer	Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
Dietary saturated fat and cholesterol	Coronary heart disease	While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.
Fiber-containing grain products, fruits, and vegetables	Cancers	Low-fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.
Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber	Coronary heart disease	Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.
Fruits and vegetables	Cancer	Low-fat diets rich in fruits and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.
Folate	Neural tube birth defects	Healthful diets with adequate daily folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

Figure 1. Diet-disease relationships mandated for review by the US Food and Drug Administration under the Nutrition Labeling and Education Act and currently approved as health claims. (Reprinted with permission from the American Council on Science and Health: From: Hasler CM, *J Nutr.* 2002;132:3772-3781.)

Diet	Disease	Approved health claim
Sugar alcohols	Dental caries	"Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name of product] used to sweeten this food may reduce the risk of dental caries."
Foods that contain fiber from whole-oat products	Coronary heart disease	"Diets low in saturated fat and cholesterol that include soluble fiber from whole oats may reduce the risk of heart disease."
Foods that contain fiber from psyllium	Coronary heart disease	"Diets low in saturated fat and cholesterol that include soluble fiber from psyllium seed husk may reduce the risk of heart disease."
Soy protein	Coronary heart disease	"Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides 6.25 grams of soy protein."
Plant sterol/stanol esters	Coronary heart disease	Plant sterols: "Foods containing at least 0.65 grams per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _ grams of vegetable oil sterol esters." Plant stanol esters: "Foods containing at least 1.7 grams per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _ grams of plant stanol esters."

Figure 2. Health claims approved by the US Food and Drug Administration following petitions submitted by the food industry. (Reprinted with permission from the American Council on Science and Health: From: Hasler CM, *J Nutr.* 2002;132:3772-3781.)

health claim under the FDAMA was authorized: It addressed the relationship between whole grains and reduced risk of coronary heart disease and cancer (24). On October 31, 2000, a second health claim was allowed under the FDAMA for the relationship between potassium intake and reduced risk of high blood pressure and stroke (25). The FDA has issued guidance to industry regarding the FDAMA health and nutrient content claims provisions and has held numerous stakeholder meetings on this subject (26). Final rules implementing the claims provisions of the FDAMA have not yet been published. The ADA played an active role in dis-

Diet	Disease	Model claim
Potassium	Blood pressure and stroke	Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke.
Whole grains	Heart disease and cancer	Diets rich in whole-grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and certain cancers.

Figure 3. Health claims authorized by the Food and Drug Administration under the Food and Drug Administration Modernization Act of 1997. (Reprinted with permission from the American Council on Science and Health: From: Hasler CM, *J Nutr.* 2002;132:3772-3781.)

cussions surrounding passage of the FDAMA and continues to support the need for all claims to be based on significant scientific agreement, irrespective of whether the claims are authorized via the NLEA petition process or the FDAMA notification process (27).

In a radical departure from the "significant scientific agreement" standard of evidence required under the NLEA for health claims approval, the FDA announced on December 18, 2002, that they will allow "qualified health claims" on conventional foods (28). Qualified health claims were first authorized for dietary supplements under a 1999 court decision in the case of *Pearson v Shalala* and are shown in Figure 4. In the December guidance document for industry, the FDA outlined the criteria necessary for a qualified health claim and stated that the body of data need not rise to the level of significant scientific agreement defined previously. However, health claim petitioners need to demonstrate, based on a fair review by scientific experts of the totality of information available, that the "weight of the scientific evidence" supports the proposed claim. Thus, if the FDA determines that the significant scientific standard is not met, but that the scientific evidence in support of the claim outweighs the scientific evidence against the claim, the FDA will consider approving the claim with appropriate qualifying language. The FDA anticipates that this policy will facilitate the provision of additional, scientifically supported health information to consumers. The point of this initiative was to have the FDA review claims in which scientists generally agree that considerable evidence exists to support the claim despite that fact that the evidence has not reached a level at which the evidence will "never be reversed or modified" (29). In July 2003, the FDA announced a ranking system and proposed language for qualified health claims. Under the new scheme, the highest level of scientific evidence (significant scientific agreement) would be categorized as an "A" claim. Health claims that do not reach the level of significant scientific agreement would be scientifically ranked as B, C, or D level claims with appropriate qualifying language, as shown in Figure 5. The ADA believes that health and nutrient content claims authorized for foods and dietary supplements should be based on the totality of the publicly available scientific evidence, including results from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles; it should not be preliminary or speculative (30). Thus, the ADA does not support this more recently evolved approach to functional food labeling.

The marketplace for functional foods expanded significantly with the enactment of the Dietary Supplement Health and Education Act (DSHEA) of 1994 (31). The DSHEA exempts dietary supplements from the stringent approval required for foods and food additives. This legislation permits the use of dietary supplement "structure/function" claims on foods as well as dietary supplements without prior FDA authorization. Such statements describe how a food component or ingredient affects the structure and/or function of the body (eg, calcium builds strong bones) without linking it to a specific disease. Because these statements can be made without prior FDA approval, many companies are choosing to market functional foods as dietary supplements under this legal loophole. This practice is permissible as long as the company notifies the FDA 30 days after first marketing the product bearing the claim. The label with the claim must also include the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, mitigate, cure or prevent any disease" (31). Although manufacturers are required to notify the FDA within 30 days of marketing a product, there is currently no requirement for the notification packet to include the scientific evidence in support of a structure/function claim. Therefore, the scientific underpinning of such claims is often limited at best and potentially disputable.

Currently, there is a paucity of consumer research regarding the impact of structure/function claims on consumer knowledge and purchasing behaviors. Until such information is known, and until there is full assurance that structure/function claims are based on significant scientific agreement, dietetics professionals must be cautious about accepting such claims when recommending the consumption of functional food products using this labeling approach.

On a limited basis, the FDA has attempted to regulate or control inappropriate use of DSHEA regulations to market conventional foods. One example of a functional food marketed as a dietary supplement has been soups containing St John's Wort or echinacea, which purport to improve mood or immunity, respectively. However, the FDA notified the manufacturer that these soups are not legitimately dietary supplements and must not be sold and labeled as such because the products clearly represent conventional foods (32). Furthermore, the FDA has issued warning letters to industry when botanicals and other novel ingredients in conventional foods have not met the requirements of the generally recognized as safe (GRAS) provisions (33). A second example is that of cholesterol-lowering margarines, which were initially marketed as dietary supplements until the FDA informed the manufacturer that the plant stanol esters contained in the product were considered unapproved food additives (34). Thus, the

Diet-disease relationship	Disease	Qualified health claim
Omega-3 fatty acids	Coronary heart disease	Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive (100).
Folic acid, B6, B12	Vascular disease	As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease. *FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive (101).
Selenium	Cancer	Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive (102,103).
Phosphatidylserine	Dementia	Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia [cognitive dysfunction] in the elderly. FDA concludes that there is little scientific evidence supporting this claim (104).

Figure 4. Currently approved qualified health claims for dietary supplements.

Scientific ranking	Level of scientific evidence	FDA category	Proposed qualifying language
First level	High	A	Category A claims are unqualified claims supported by evidence that meets the current standard of significant scientific agreement.
Second level	Moderate	B	". . . although there is scientific evidence supporting this claim, the evidence is not conclusive."
Third level	Low	C	"Some scientific evidence suggests . . . however, FDA has determined that this evidence is limited and not conclusive."
Fourth level	Very low	D	"Very limited and preliminary scientific research suggests . . . FDA concludes that there is little scientific evidence supporting this claim."

Figure 5. Scientific ranking and proposed language for qualified health claims.

product's manufacturer was required to demonstrate to the FDA, through sufficient scientific documentation, that these additives are GRAS before the product could be marketed as a food in the United States.

Several food products have used structure/function claims in their marketing approach regardless of the quantity or quality of scientific evidence to support such claims. The ADA recommends cautious evaluation of the clinical efficacy of individual products and dietary supplements before recommending their use to promote a specific health outcome. The proliferation of claims on a variety of food products and dietary supplements has created an environment of confusion and distrust among health professionals and consumers (35).

Another route to marketing functional foods that is used by food manufacturers to disseminate information about their products is advertising, which is regulated by the Federal Trade Commission (FTC). The FTC has a more lenient standard for advertising claims about diet-disease relationships than does the FDA for food labeling. Therefore, the potential exists for the advertising medium to permit mention of an association between a food product and prevention of disease. A good example is the advertisement that appeared in magazines a few years ago stating that "lycopene (found in tomato products) may help reduce the risk of prostate and cervical cancer." The FDA would have refused such a labeling claim until the scientific evidence was substantial and supported by a sufficient number of controlled, clinical intervention trials that currently do not exist. The ADA supports efforts for consistency in functional food labeling and strongly recommends an evaluation of the body of available scientific evidence prior to the development of consumer diet-health messages. To meet this goal, collaboration among the food industry, health professionals, and government agencies will be required to accurately and effectively communicate the health benefits (or potential risks) of consuming specific functional foods.

The ADA recommends that all foods and dietary supplements, including functional foods, be regulated to ensure that the products are safe; that the products have been manufactured using recognized good manufacturing practices; and that all label claims—health, nutrient content, and structure/function—are truthful, not misleading, and are based on significant scientific agreement. Regulating functional foods as such will protect consumers, will provide informative and scientifically sound labeling claims that will allow for educated food selections, and will potentially promote wellness. The food industry should be provided specific guidelines that, in turn, will direct research and development for future functional foods. Current and future functional foods should be labeled with specific information regarding any ingredient (eg, nutrient, phytochemical, zoo-

chemical, or botanical) used to market the product as well as the specific amount available in an average serving. Without disclosure of this information, consumers, along with dietetics and other health professionals, will be unable to make an educated assessment as to the appropriate use of the product.

In short, the regulation of functional foods is currently ambiguous and in need of clarification through collaborative efforts between the FDA, the FTC, the food industry, health care professionals, and consumers. Dietetics professionals are positioned to take a leadership role in this process and to disseminate information on the safety and efficacy of functional foods to the public.

Scientific Research

The scientific evidence for functional foods and their physiologically active components can be categorized into four distinct areas: (a) clinical trials, (b) animal studies, (c) experimental in vitro laboratory studies, and (d) epidemiologic studies. Regardless of the research design, a hypothesis-driven approach to the development of and evaluation of the efficacy of functional foods is paramount to advancing science in this area (36,37). Much of the current evidence for functional foods lacks well-designed clinical trials; however, the foundational evidence provided through the other types of scientific investigation is substantial for several of the functional foods and their health-promoting components. A summary of select functional foods and the strength of scientific evidence supporting their health benefit(s) are presented in the Table. Only a brief overview of the research is presented here.

The strongest scientific evidence of clinical efficacy is for functional foods that are available or have been developed in accordance with the NLEA guidelines for preapproved health claims as discussed previously. For such foods, there is substantial scientific agreement among scientists that a diet-disease relationship exists. Scientific support under the NLEA includes all types of research from in vitro to randomized, controlled clinical trials and focuses on the reduction of common chronic diseases in the United States. Basic examples of functional foods that fall into this realm are foods naturally rich in soluble fiber, such as oat bran or psyllium, which have been associated with reduced incidence of coronary heart disease (38). Another example would be fruits and vegetables and the association between increased consumption and reduced risk for cancer (39,40) or coronary heart disease (41). Soy protein (42) and the sterol and stanol esters (43) are additional examples for which final (22) and interim final (44) health claims regarding cholesterol reduction or cardiovascular disease risk reduction have been approved. Other functional foods may have a qualified health claim such as nuts (45,46) or have substantial scientific support but currently lack an FDA-approved health claim. Examples include n-3 fatty acids found in fish (47,48), which have been shown in clinical trials to reduce serum cholesterol levels in subjects with elevated levels. Garlic may also reduce cholesterol levels; however, the evidence is less compelling (49). The 2000 American Heart Association Dietary Guidelines recommend two servings of fatty fish per week for a healthy heart (50), and a "qualified" health claim on dietary supplements linking the consumption of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) n-3 fatty acids to a reduction of coronary heart disease risk was recently authorized by the FDA (51). It states the following: "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive." A "qualified" claim was authorized because of certain safety concerns regarding the consumption of high levels of n-3 fatty acids, including the following: (a) increased bleeding times, (b) increased risk for hemorrhagic stroke, (c) the formation of biologically active oxidation products from the oxidation of n-3 fatty acids, (d) increased levels of low-density lipoprotein (LDL) cholesterol, and (e) reduced glycemic control among people with diabetes. The FDA has concluded that use of n-3 fatty acid supplements is safe, provided daily intakes of EPA and DHA from food and supplements do not exceed 3 g per day.

A third category of functional foods are those that have been fortified to enhance the level of a specific nutrient or food component that has been associated with the prevention or treatment of a disease or other clinical condition. Many of these products bear authorized health claims for product marketing. This category would include products such as calcium-fortified orange juice, pasta, or rice marketed to maintain good bone health and reduce osteoporosis risk, as well as fiber-supplemented snack bars, folate-enriched cereals, or stanol- or sterol ester-enhanced margarine. Many other functional foods in this category may lack sufficient evidence to warrant an authorized health claim at this time. This would include, for example, beverages with added vitamin E for reduced heart disease risk and salad dressings with n-3 fatty acids to reduce the inflammatory response associated with rheumatoid arthritis.

A fourth category of functional foods includes whole foods that have been associated with reduced risk of disease. For these whole foods, in vitro, in vivo, or epidemiologic research is available to support their health benefits; however, no health claim exists, partially because of the limited or improperly designed clinical trial data or lack of scientific agreement about the strength of the evidence (Table). This category includes the following:

- tomato products rich in lycopene, a carotenoid, whose consumption is associated with reduced cancer rates in epidemiologic studies (52-54);
- eggs with n-3 fatty acids, which may potentially reduce cholesterol levels (55,56);
- black and green teas, which are rich in polyphenols, have been associated experimentally and in human studies with cancer prevention and control and more recently with reduced LDL and total cholesterol levels (57,58);
- nondigestible oligosaccharides (prebiotics), especially fructans, which may potentially provide health benefits for cardiovascular disease, type 2 diabetes, and intestinal infectious diseases (59,60);
- fermented dairy products (probiot-

ics), which have been shown to improve gastrointestinal health (61);
- dairy products and meat from ruminant animals containing conjugated linoleic acid, which may alter carcinogenesis (62,63);
- cranberry juice to reduce bacteruria (64,65);
- cruciferous vegetables to reduce cancer risk (39,40,66); and
- lutein-rich vegetables to reduce macular degeneration (67).

For each of these, an association with reduced disease risk has been observed but has not reached scientific consensus.

Finally, there exists a growing selection of functional food components marketed under the umbrella of dietary supplements. For the majority of these products, evidence for their structure/function claims is currently limited, incomplete, or unsubstantiated. Examples include antioxidant-enriched beverages or candies, chewing gum with phosphatidylserine, and snack bars with chromium. This category also includes a large number of herbal-enriched products that make a variety of structure/function claims. Examples include cereal fortified with ginkgo biloba, which is marketed as reducing symptoms of dementia, or juices with echinacea, which are marketed for boosting the immune system. Both claims have support in controlled clinical trials (68,69). Other clinical trials on botanical-enriched products have shown conflicting results, such as the use of echinacea to reduce cold and flu symptoms (70) or kava to reduce anxiety (71). Still other structure/function claims have no clear therapeutic efficacy, such as the use of ginseng for energy or enhanced physical performance (72). Others, such as ma huang, may be harmful (73). Historically, evidence for the clinical efficacy of select botanicals was limited primarily because of poor research design (eg, inconsistency in dosage form or amount, small sample size, and frequently the lack of a placebo control, in part resulting from insufficient funding for research in this area). Yet many of these botanicals are being introduced into our food supply—sometimes irresponsibly—in the form of functional foods. The ADA must call on industry to fund additional research in this emerging area.

Ideally, the evaluation of the efficacy of individual functional foods must be completed using a scientifically valid risk-benefit model that clearly assesses all physiologic effects, both positive and negative. Review of the in vitro, animal, epidemiologic, and clinical data is essential before functional foods or food components are marketed to consumers for their health-promoting qualities (74).

Value of a Varied Diet

The weight of scientific evidence indicates that the optimal approach for achieving a health benefit from the intake of nutrients and other physiologically active constituents is through the consumption of a varied diet that is rich in plant foods. In reality, each vegetable contains numerous different nutrients and phytochemicals—a biologic circumstance that is not currently replicated in pill form. In addition, the assumption that a combination of plant constituents that are naturally occurring is maintained at equivalent levels of biologic activity when extracted, dried, and compacted into pill form is likely unfounded.

Pharmaceutical companies have isolated many food components into supplement form, including allylic sulfides (garlic), isoflavones (soy), anthocyanin (bilberry extract), and glycyrrhizin (licorice), to name only a few. In the United States, tens of billions of dollars are spent annually on dietary supplements (76). The rapid growth in functional foods might be considered the food industry's response to growing sales of dietary supplements. Supplements can provide nutrients and other physiologically active components in a potentially unbalanced and concentrated form that may be far different from the form used in research studies. Nutrients and other bioactive food components that occur naturally in foods act synergistically with other dietary elements such as fiber to promote health. The food industry and dietetics professionals have a unique opportunity to promote whole foods as an alternative to dietary supplementation through the integration of appropriate functional foods into a varied eating plan for consumers. In addition, using sound scientific evidence, functional food products can be developed that further enhance the health benefits of food. In some circumstances, a combined food supplement approach may afford the greatest protection, and, to this end, the Office of Dietary Supplements at the National Institutes of Health has developed a strategic plan to encompass such a research focus (77).

Levels of Intake

Safe levels of intake must be considered when evaluating functional foods in the context of a healthy diet. For the majority of research studies, the optimal levels of nutrients and other physiologically active components in functional foods have yet to be determined in humans. Animal research has provided some indication of desired intake; however, these data are difficult to extrapolate to human dietary requirements. The Table lists the approximate levels of intake whole foods or select nutrients, phytochemicals, and other food constituents used in the development and marketing of functional foods generally associated with health promotion or disease prevention (78-85). However, for the majority of functional food components, precise levels of recommended intake will be established only when adequate scientific evidence exists.

Many functional foods or food components will require continued in vivo and in vitro research, as well as pharmacokinetic studies, before specific levels can be determined for clinical trial investigations. Once clinical trials have been completed, more specific recommendations can be formulated. In addition, a large percentage of dietary data collected historically provide limited information regarding the exact intake of physiologically active food components because few databases for nonnutritive food components have been developed (86).

Current dietary measurement tools are somewhat limited in terms of providing evidence for levels of intake of dietary constituents necessary to reduce disease risk. For example, data collection, particularly for large epidemiologic studies that rely on food frequency questionnaires (FFQs), does not include specific data related to herb, spice, condiment, and/or flavoring intake, despite the fact that several physiologically active compo-

nents have been identified in these foods. Recently, FFQs focused on collecting data for select foods such as teas and citrus (87) have been developed and validated and, thus, will allow for expanded efforts to measure exposure and its relationship to disease prevention. However, a second limitation is that the USDA nutrient/phytochemical database has only recently been expanded to include phytochemicals such as carotenoids (88), isoflavones (89), and flavonoids (90). It still remains insufficient for most nonnutritive food constituents.

Another issue of importance is that dietary constituents appear to act synergistically to improve absorption of nutrients or physiologically active dietary components (91). One example is lycopene in tomatoes and the enhancement of its absorption when consumed along with fat (92). The specific intake levels recommended to reduce the risk of disease in a healthy population can be altered in the presence of a disease such as cancer or cardiovascular disease. Therefore, dietary advice regarding approximate levels of intake for functional foods and their components will need to be evaluated on the basis of currently available scientific information in the context of the specific populations or individual variance.

ROLE AND RESPONSIBILITIES OF THE DIETETICS PROFESSIONAL

Consumer interest in and awareness of functional foods and the associated health benefits have been demonstrated in qualitative focus-group research (5,14,93). The data indicate that consumers are increasingly aware of conventional functional foods and are supportive of such products, particularly if the health benefits can be realized through consumption of traditional foods. Consumers have identified the media as their primary source of nutritional, phytochemical, and functional food information (94). Similar sources have been identified by the Nutrition Trends surveys conducted for the ADA (5). This observation heightens the importance of dietetics professionals' involvement in media-generated reports in this area.

Clearly, dietetics professionals can no longer evaluate foods solely in terms of macro- and micronutrient content. Consideration of other physiologically active components or herbal additives will be necessary when assessing the overall health benefit of a particular food. In the future, a wide range of select foods may be "prescribed" to enhance the health of an individual. This is a shift from our earlier employed nutrition education approach that focused on limiting intake of foods high in "unhealthful" components such as fat and cholesterol.

Dietetics professionals have extensive educational training in foods and nutrition, and most have clinical experience to make recommendations for the appropriate dietary intake of functional foods in the context of a healthful diet. Dietetics curricula increasingly integrate functional food research and information into dietetics and nutritional sciences courses. Continuing dietetics education has also expanded in this vital area. In the future, greater emphasis should be placed on gaining competence in functional food research and within dietetic and nutrition science training programs. The ADA has demonstrated support of this advancing area of food and nutrition science.

Dietetics professionals have a unique opportunity to play a vital and central role in the evaluation and implementation of research studies that are focused on functional foods and their physiologically active components. Research findings will need to be translated into practical information for consumers by knowledgeable dietetics professionals. Expanding roles for dietetics professionals include the following:

- advising consumers on the appropriate intake of functional foods and how best to achieve dietary intake goals, in the context of a healthful diet, to optimize health and potentially decrease the risk of preventable diseases;
- participating in research in this evolving field;
- providing expertise to the food industry related to the development of future functional foods;
- providing education to health care professionals, the public, the food industry, and policy officials regarding the role of functional foods in health promotion/disease prevention;
- working collaboratively with food and nutrition organizations as well as the government to develop and enhance regulatory standards for functional foods that assume such foods are safe and label claims are scientifically sound and not misleading; and
- being a resource for the media as the research evolves and specifically to provide guidance regarding integration of functional foods into a balanced and varied diet.

ADA members should make informed decisions about functional foods on the basis of available evidence-based research findings. Now and in the future, dietetics professionals will increasingly be called on to develop meal plans and prescribe diets that optimize functional food intake where appropriate. Dietetics practitioners will need to evaluate each functional food for its role in meeting preventive and therapeutic needs for healthy persons and/or those with diagnosed with clinical symptomatology and/or chronic diseases. The dietetics professional's response to functional food-related inquiries must be scientifically sound, with a focus on optimizing individual and public health outcomes.

SUMMARY

Never before has the focus on the health benefits of food or food components been so strong. The philosophy that food can have health-promoting properties that go beyond its traditional nutritional value is well known among scientists and health professionals (95-99). Dietetics professionals are uniquely qualified and positioned to translate scientific evidence into practical dietary applications for consumers and to provide the food industry, policy makers, and the media with valuable insight and expertise for future research, product development, regulation, and communication regarding functional foods. Increasing the availability of health-promoting foods in the US diet will help to ensure a healthier population. Dietetics professionals must be leaders in this evolving area of food and nutrition.

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ADA Position adopted by the House of Delegates on October 16, 1994, and reaffirmed on September 7, 1997 and June 15, 2001. This position will be in effect until December 31, 2007. ADA authorizes the republication of the position, *in its entirety*, provided full and proper credit is given. Requests to use portions of this position must be directed to ADA Headquarters at 800/877-1600, ext 4835, or ppapers@eatright.org. With the 2001 reaffirmation, it was recommended to only update the position paper sections, such as references and regulatory information to reflect current knowledge. Therefore, a limited review of the position was conducted and included the APC Workgroup, ADA Government Relations and the Knowledge Center. *Authors:* Clare M. Hasler, PhD, MBA (Robert Mondavi Institute for Wine and Food Science, University of California, Davis, CA); Abby S. Bloch, PhD, RD, FADA (Nutrition Consultant, New York, NY); Cynthia A. Thomson, PhD, RD, FADA (University of Arizona, Tucson, AZ). *APC Workgroup:* Evelyn Enrione, PhD, RD; Carolyn Manning, MAg, RD.