Position of the Academy of Nutrition and Dietetics: Functional Foods

ABSTRACT
It is the position of the Academy of Nutrition and Dietetics to recognize that although all foods provide some level of physiological function, the term functional foods is defined as whole foods along with fortified, enriched, or enhanced foods that have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis at effective levels based on significant standards of evidence. The Academy supports Food and Drug Administration–approved health claims on food labels when based on rigorous scientific substantiation. All food is essentially functional at some level as it provides energy and nutrients needed to sustain life. However, there is growing evidence that some food components, not considered nutrients in the traditional sense, may provide positive health benefits. Foods containing these food components are called functional foods. Functional food research holds many promises for improving the quality of life for consumers; however, to achieve such outcomes, scientific research must effectively establish the bioavailability and efficacy of these compounds at levels that are physiologically achievable under typical dietary patterns. This Position Paper reviews the complexities of defining functional foods; categories of foods marketed as functional; regulation of functional foods; the scientific substantiation of and advancement of functional food research; as well as a message to registered dietitians and dietetic technicians, registered, on how to remain current in their knowledge of functional food research and the translation of this information to consumers.


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EATING FOR HEALTH AND wellness can be an elusive goal for many consumers, especially given the complex marketplace and the influx of mixed messages from varied information outlets. Nevertheless, the desire for health and pain-free living has enabled market penetration of functional foods containing increased amounts of bioactive food compounds or physiologically active nutrients and non-nutrients within food that impart proven health benefits. Antioxidant vitamins and n-3 fatty acids are examples of nutrient-based bioactive food compounds receiving intense market share, while flavonoids, isoflavones, and other lesser known phenolic phytochemicals are examples of non-nutrient bioactive food compounds that are being incorporated into various products marketed as functional foods.

Within the last 20 years, nutrition research has focused on both nutrients and non-nutritive compounds and their role in disease prevention and risk reduction. This is in contrast to preceding decades in which deficiency diseases and the nutrients needed to cure these diseases were the central research focus. Much of the shift in focus is attributable to advances in science and technology coupled with a growing desire by consumers to self-treat. Based on market research within the food industry, one third of consumers surveyed in 2011 planned to self-treat more and go to the doctor less. In addition to independent market research, the Institute of Food Technologists’ Food Technology magazine ranked “prescriptive eating,” which involves food selection based on the knowledge of healthy attributes ascribed to specific nutrients within food, as one of the top 10 food trends among consumers. According to these and other data, consumers are looking more to foods for health benefits, especially consumers with higher education levels. According to the 2011 Functional Foods/Foods for Health Consumer Trending Survey, 73% of consumers “believe that food and nutrition play a ‘great role’ in maintaining and improving overall health,” with 70% of those surveyed naming fruits and vegetables as the most recognized functional food. Among those surveyed, 80% of consumers agree that functional foods and beverages can help to maintain or improve health and wellness, including bone health (81%), heart and circulatory health (79% and 74%, respectively), immune health (79%), digestive health (78%), and eye health (66%). In addition, 87% of Americans believe that certain foods have health benefits beyond basic nutrition.

Factors driving the functional food market include rising health care costs and the growing trend to self-medicate to keep costs lower, the increasing age of the population, the obesity epidemic, and the high levels of lifestyle diseases afflicting millions of Americans. In general, functional foods have the potential to minimize health care costs while improving health and wellness, and giving consumers greater control over their health by providing a convenient form of health-enhancing

POSITION STATEMENT
It is the position of the Academy of Nutrition and Dietetics to recognize that although all foods provide some level of physiological function, the term functional foods is defined as whole foods along with fortified, enriched, or enhanced foods that have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis at effective levels based on significant standards of evidence. The Academy supports Food and Drug Administration–approved health claims on food labels when based on rigorous scientific substantiation.
As a result of scientific advances and consumer trends, the US functional food market continues to grow. For example, based on primary and secondary market research from more than 300 food companies, the global functional food and drink market is expected to reach $130 billion by the year 2015. Despite the increased market penetration of functional foods, the term functional foods has no legal meaning in the United States. It is currently a marketing, rather than a regulatory, idiom. Thus, with an ever-expanding functional foods market coupled with the lack of regulatory terminology for defining functional foods, significant new issues and opportunities exist for registered dietitians (RDs) to convey reliable information to consumers and policy makers, as well as to become actively engaged in the research and development of functional foods. For this reason, this Position Paper reviews the complexities of defining functional foods, categories of foods marketed as functional, regulation of functional foods, the scientific substantiation of and advancement of functional food research, as well as a message to dietetics practitioners on how to remain current in their knowledge of functional food research and the translation of this information to consumers.

**DEFINITION OF FUNCTIONAL FOODS**

The term functional foods is considered a marketing term by many, and there is no consistent definition that is recognized globally by regulatory bodies. All food is essentially functional as it provides energy and nutrients needed to sustain life. However, there are a number of working definitions used to define functional foods. These include the definition by the Academy of Nutrition and Dietetics as: “Foods defined as whole foods along with fortified, enriched, or enhanced foods that have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis at effective levels.”

**Table: Working Definitions of Functional Foods**

<table>
<thead>
<tr>
<th>Organization</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academy of Nutrition and Dietetics</td>
<td>“Foods defined as whole foods along with fortified, enriched, or enhanced foods that have a potentially beneficial effect on health when consumed as part of a varied diet on a regular basis at effective levels.”</td>
</tr>
<tr>
<td>International Food Information Council</td>
<td>“Foods or dietary components that may provide a health benefit beyond basic nutrition and may play a role in reducing or minimizing the risk of certain diseases and other health conditions.”</td>
</tr>
<tr>
<td>Institute of Food Technologists</td>
<td>“Foods and food components that provide a health benefit beyond basic nutrition (for the intended population).”</td>
</tr>
<tr>
<td>International Life Sciences Institute</td>
<td>“Foods that by virtue of the presence of physiologically active food components provide health benefits beyond basic nutrition.”</td>
</tr>
<tr>
<td>European Commission</td>
<td>“A food that beneficially affects one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease. It is part of a normal food pattern. It is not a pill, a capsule or any form of dietary supplement.”</td>
</tr>
<tr>
<td>Health Canada</td>
<td>“A functional food is similar in appearance to, or may be, a conventional food, is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions.”</td>
</tr>
<tr>
<td>Japanese Ministry of Health, Labour, and Welfare</td>
<td>“FOSHU [food for specified health uses] refers to foods containing ingredient with functions for health and officially approved to claim its physiological effects on the human body. FOSHU is intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control health conditions, including blood pressure or blood cholesterol.”</td>
</tr>
</tbody>
</table>

**Figure 1.** Working definitions of the term functional foods.

**ROLE OF FUNCTIONAL FOODS IN THE HEALTH CARE CONTINUUM**

Consumers continued interest in prevention of disease and optimal health will likely increase the consumption of dietary ingredients with health benefits beyond basic nutrition. Health no longer means the absence of disease, but rather refers to the optimization of mental and physical well being. Presently, nutrition science has more focus on optimal nutrition than just the...
<table>
<thead>
<tr>
<th>Dietary component(s)</th>
<th>Qualifying source</th>
<th>Qualified health claim language</th>
<th>Claim level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Folic acid, vitamins B-6 and B-12</td>
<td>Supplements containing vitamin B-6, B-12, and/or folic acid</td>
<td>As part of a well-balanced diet that is low in saturated fat and cholesterol, folic acid and vitamins B-6 and B-12 may reduce the risk of vascular disease. The 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.</td>
<td>B</td>
</tr>
<tr>
<td>Almonds, hazelnuts, some pine nuts, peanuts, pecans, pistachios</td>
<td>Whole or chopped nuts</td>
<td>Scientific evidence suggests but does not prove that eating 1.5 oz per day of most nuts such as [name of specific nut] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. (See nutrition information for fat content.)</td>
<td>B</td>
</tr>
<tr>
<td>Walnuts</td>
<td>Whole or chopped walnuts</td>
<td>Supportive but not conclusive research shows that eating 1.5 oz per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of CHD. (See nutrition information for fat and calorie content.)</td>
<td>B</td>
</tr>
<tr>
<td>n-3 fatty acids</td>
<td>Fish, other conventional foods, supplements</td>
<td>Supportive but not conclusive research shows that consumption of EPA and DHA n-3 fatty acids may reduce the risk of CHD. One serving of [name of the food] provides [x] grams of EPA and DHA n-3 fatty acids. (See nutrition information for total fat, saturated fat, and cholesterol content.)</td>
<td>B</td>
</tr>
<tr>
<td>Monounsaturated fat from olive oil</td>
<td>Salad dressings, vegetable oil, olive oil-containing food, shortenings</td>
<td>Limited and not conclusive scientific evidence suggests that eating about 2 tbsp (23 g) of olive oil daily may reduce the risk of CHD due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.</td>
<td>C</td>
</tr>
<tr>
<td>Unsaturated fatty acids from canola oil</td>
<td>Canola oil, vegetable oil spreads, dressings for salads, shortenings, canola oil-containing foods</td>
<td>Limited and not conclusive scientific evidence suggests that eating about 1 1/2 tbsp (19 g) of canola oil daily may reduce the risk of CHD due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of canola oil.</td>
<td>C</td>
</tr>
</tbody>
</table>

*Figure 2.* Qualified health claims for cardiovascular disease in terms of dietary component, qualifying source, language, and claim level.
**Categories of Foods Marketed as Functional**

Functional foods fall into three general categories:

- Conventional foods containing natural bioactive food compounds. Most vegetables, fruits, grains, dairy, fish, and meats contain bioactive food compounds that provide benefits beyond basic nutrition. Examples would be the antioxidant vitamins in orange juice, isoflavones in soy-based foods, and probiotics and probiotics in yogurt.

- Modified foods containing bioactive food compounds through enrichment or fortification, such as n-3 fatty acids in margarine spreads and eggs.

- Food ingredients that are synthesized, such as indigestible carbohydrates, which provide prebiotic benefits like oligosaccharides or resistant starch.

**Regulation of Functional Foods**

Japan has been the leader in regulation of functional foods. For example, the Japanese Ministry of Health, Labor, and Welfare was the first regulatory agency to recognize functional foods as a unique food category. The Food for Specified Health Uses (FOSHU) program, which began in 1991, was the first to use scientific evidence to allow health claims for functional foods. Products approved as FOSHU are allowed to use the FOSHU seal of approval on their product labels. As of 2010, the number of FOSHU-approved products has risen steadily to more than 950 foods.

In the United States, foods are regulated under the Federal Food, Drug, and Cosmetic Act of 1938, which makes no provision for a definition of functional foods. This is because of the thought that there are already regulations concerning the use of food ingredients that are adequate to cover functional food ingredients. According to the Food and Drug Administration (FDA), the intended use of a food is the main determinant for regulatory status. Products determined to be foods are regulated as food in conventional form, which includes functional foods and foods for special dietary use. The Nutritional Labeling and Education Act of 1990 includes both conventional foods and foods for special dietary use.

There are currently four categories of claims that food manufacturers can use on labels to communicate health information to consumers. These categories include:

- nutrient content claims;
- structure/function claims;
- health claims; and
- qualified health claims.

All four types of claims are allowed on functional food labels if the claim meets the defined criteria outlined for each claim type. More information about types of claims that can be used on functional foods in the United States can be found on the FDA website.

According to the Nutritional Labeling and Education Act, a product is allowed to bear a health claim after extensive review of the scientific evidence submitted to the FDA. Such claims are authorized based on significant scientific agreement or on an authoritative

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**Table: Dietary Component(s) and Qualified Health Claim Language**

<table>
<thead>
<tr>
<th>Dietary component(s)</th>
<th>Qualifying source</th>
<th>Qualified health claim language</th>
<th>Claim level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn oil and corn oil-containing products</td>
<td>Very limited and preliminary scientific evidence suggests that eating about 1 tbsp (16 g) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. The FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil.</td>
<td>D</td>
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FROM THE ACADEMY

statement from a scientific body of the US government or the National Academ y of Sciences. Health claims must be authorized by the FDA before they can be used on food labels. Currently, there are 12 health claims that meet this significant scientific standard and 4 health claims that are authorized on an authoritative statement. These health claims are summarized on the FDA website.25

Qualified health claims are intended to provide information about diet–disease relationships when the scientific support has not reached the highest level of scientific evidence. Currently, qualified health claims are allowed for six disease categories, including atopic dermatitis risk, cancer risk, cardiovascular disease risk, cognitive function, diabetes, and hypertension. Figure 2 shows the dietary components that are authorized for a qualified health claim for cardiovascular disease, the specific language for the claim and the level of scientific evidence.

SCIENTIFIC SUBSTANTIATION

Functional food research holds many promises for improving the quality of life for consumers; however, to achieve such outcomes, scientific research must effectively establish the bioavailability and efficacy of these compounds at levels that are physiologically achievable under typical dietary patterns. To date, numerous types of research have been employed to characterize functional compounds within food and their potential benefits.

Research Establishing Bioavailability and Efficacy

Research designs used to investigate the bioavailability and efficacy of bioactive food compounds in food range from soft to hard science methodologies or from epidemiological studies to in vitro (test tube) studies using cell cultures or in vivo studies using animal models, and, ultimately, humans. Among primary research studies employed to elucidate the effects of bioactive components, each study design can be strengthened by employing the principles of sound science, which include appropriate test controls, blinding (single or double), and analysis of the bioactive compound or its byproduct of metabolism within the intended target organs or tissues.

According to the FDA, bioavailability is defined as the rate and extent to which the active or therapeutic moieties of a compound are absorbed and become available at the intended site of action.26 In essence, bioavailability is a measure of the absorption and availability for utilization of a specific substance. However, overly simple this may appear, bioavailability of a functional food compound (nutrient or non-nutrient) is governed by the physical properties of the food matrix and composition of the diet or mixed meal, as well as physiological differences among individuals in terms of absorption and metabolism of food. With regard to the food matrix or the vehicle housing the bioactive food compounds, the physical properties of the food matrix have been shown to affect the efficiency of the physical, enzymatic, and chemical digestion processes.27

Once bioavailability is established, studies are employed to evaluate the efficacy of these compounds at producing desirable outcomes of interest in the intended target populations. Among the more challenging aspects of functional food research is substantiation of the science behind compound functionality by providing the compound at levels that are physiologically achievable within a food system or matrix. As such, human intervention trials become paramount to the advancement of functional food research for several reasons, including the fact that the whole food or whole formulated functional foods cannot be provided in cell culture. To date, numerous bioactive compounds have been isolated and evaluated using in vitro models to elucidate functional properties; however, the primary concern arising from use of in vitro models only is that the concentration of the individual compounds given to elicit an effect is typically outside of the context of normal in vivo dietary doses. Not only are these intake levels not achievable under most dietary patterns, but when supplied outside of a food matrix, unrealistic results may be touted and other more likely interactions may be overshadowed or can cause harm, as in the case of several supplementation trials.28-30 To further strengthen the position of food as the vehicle for functional bioactive compounds, research has shown that some compounds can reach a point of saturation or toxic levels within the body, which limits any potential benefit.31 For example, under conditions of excessive intake, bioactive compounds with antioxidant properties can shift the antioxidant–oxidant balance within the body, such that antioxidants can behave as pro-oxidants and contribute to oxidative stress.32-34 For these reasons, the field of functional food research must aid in establishing appropriate intake levels for these potentially beneficial compounds.

Consistency in Reporting Standards

Although randomized, double-blind, placebo-controlled clinical studies are the gold standard for determining efficacy and safety of functional foods, a person can potentially compare results of multiple studies involving functional foods when researchers along with journal editors ensure that a standard checklist of information is reported within each study. Such information should include a minimum of the following items:

- subject (eg, type, number, and age);
- use of a control;
- dosage form (ie, food composition, active compound within the formulated food, source of the active compound);
- standardized source (eg, compositional verification via chromatographic analysis or some other appropriate testing method, including genus, species, and variety/accession for plants/herbs, or supplier identification);
- frequency of intake;
- duration (weeks vs months); and
- measurable outcomes dependent on quantitative end points.

Measurable outcomes must also relate to the hypotheses proposed in the study design when evaluating the efficacy of functional foods. In addition, measurable outcomes or end points should make use of standardized measures of testing or biomarkers. By providing this type of detailed information within each study, comparison
and duplication of research results, along with statistical modeling and meta-analyses, can be conducted to fully substantiate the science behind functional foods and bioactive food compounds. Such consistency in reporting would assist in providing the preferred reporting items for systematic reviews and meta-analyses. This is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses.

**Advancing Functional Foods Research**

Extensive research has shown that the bioavailability of nutrients within a given food is governed by the composition and microstructure of the food, commonly referred to as the food matrix. More specifically, numerous studies investigating the development of functional foods have shown that the interactions between nutrients and non-nutrients within the food matrix can be synergistic, additive, or neutralizing in nature. For example, vitamin C regenerates vitamin E and enhances the antioxidant effect of carotenoid compounds. Likewise, in vitro studies have shown that flavonoids, a subcategory of phenolic phytochemicals, behave synergistically with vitamin E to prevent low-density lipoprotein oxidation. Thus, given the diversity of interactions that exist among nutrient and non-nutrient compounds, the interactive effects of these compounds must be fully elucidated in order to develop functional foods with the greatest potential to synergistically impact human health.

**Phytochemicals**

To date, putatively positive effects of functional vitamins and minerals have been extensively reported, yet research in the area of functional phytochemicals is much less expansive due to several significant research challenges. In general, phytochemical research follows the same scientific approach that aided nutrition science in identifying the role of essential macro- and micronutrients for health and wellness during the preceding century. This approach, known as the reductionist approach, attempts to reconstruct science by analyzing the parts such that the whole can be explained by the sum of its parts. Unfortunately, understanding and capitalizing on the potential synergy of these functional compounds with other well-characterized functional compounds in food systems or matrices may not be completely understood by solely investigating individual phytochemicals. For example, carotenoid compounds, specifically beta-carotene, have been extensively studied for their influence on cancer development and cell growth. Based on epidemiological studies, beta-carotene was hypothesized to be among the most active compounds in fruit and vegetables responsible for decreased incidence of lung cancer; however, intervention studies that focused exclusively on beta-carotene’s functionality in the supplemental form resulted in adverse health effects. From studies such as these, it has become increasingly evident that the reductionist approach may not be the best strategy for advancing the science behind bioactive food compounds and the development of functional foods; therefore, given the sheer number of functional compounds and the resulting interactions that exist within different developed food matrices, functional food research requires rigorous time-consuming testing methods that take into account the multiplicity of interactions, both positive and negative, that may exist within the developed food.

With respect to phenolic phytochemicals, more than 8,000 of these compounds have been isolated from fruits and vegetables. These include the more well-known flavonoids, isoflavones, and catechins and the less well-recognized stilbenes, hydroxycinnamic acids, and coumarins. In general, foods rarely contain one or two bioactive compounds, but rather an array of structurally diverse phytochemicals functioning in concert with other functional nutrients and non-nutrients. It becomes increasingly difficult to isolate the most influential compounds within a plant’s matrix for the purpose of research and development of functional foods containing these isolated compounds. In the hypothesis-driven world of nutrition research, accurate selection of specific functional phytochemicals within fruits and vegetables will take years to ascertain, especially given the fact that environmental conditions during plant growth modify the phytochemical profile of individual commodities. As a result, the science behind functional foods continually evolves through research studies that comprehensively investigate the synergistic and additive interactions among bioactive food compounds within various natural and developed foods.

**TAKE-HOME MESSAGE FOR RDS AND DIETETIC TECHNICIANS, REGISTERED**

With the advances in science and technology, the functional food market has grown significantly in recent years and, as a result, the landscape of the food and nutrition field continues to develop. Foods are no longer solely viewed in terms of macro- or micronutrients or even nutrient deficiencies or excesses. An emergence of functional foods into the consumer market underscores the need for RDs and dietetic technicians, registered (DTRs) to update their knowledge base on functional foods and bioactive food compounds to remain the nutrition experts. In addition, they must actively share their knowledge of emerging research on functional foods and their roles in human health with new RDs, DTRs, clients, consumers, corporations, and public policy makers.

**Staying Informed**

As new research continually emerges, it becomes imperative for RDs and DTRs to update their knowledge base on functional foods and bioactive food compounds to remain the nutrition experts. There are many ways for RDs and DTRs to stay informed about this growing field of study within food and nutrition sciences. Recent research can be accessed directly through either PubMed or the *Journal of the Academy of Nutrition and Dietetics* research abstracts in the back of each issue called “New in Review” and by reading science-based books on the subject. It may also be helpful to stay current with functional food advancements in other countries. Other avenues of staying connected include joining the Academy’s Dietitians in Integrative and Functional Medicine dietetic practice group, where functional foods are part of their scope of study and practice. Additional resources for research and/or regulations are the Academy’s Evidence Analysis Library (www.adaevidencelibrary.com), the National Center for Complementary and Alternative Medicine, Natural Medicines
Comprehensive Database, Cochrane Reviews, and the FDA.

Medical Nutrition Therapy Client Education
Enhancing the health of individuals can occur by continuing to incorporate functional food information into the mainstream medical nutrition therapy practices outlined in the Academy’s Nutrition Care Manual. Also, the Academy’s Evidence Analysis Library is a unique source of information that will continue to expand. It is the role of RDs and researchers to search the current literature and incorporate solid evidence-based scientific support into the manual. RDs familiar with the four current categories of health claims can now start incorporating such foods into the diets of patients with certain medical conditions and/or optimizing the health of clients interested in disease prevention and health promotion.

Public Policy and Government
Functional food regulation is paramount to public policy involving foods that can optimize human health. The role of RDs and DTRs is to safeguard the public by protecting the definition, use, and regulation of functional foods. Getting involved politically through the Academy of Nutrition and Dietetics and US Congress is key to developing and enhancing regulatory standards for functional foods. Ensuring their safety and making sure label claims and marketing are based on scientifically sound data are critical.

CONCLUSIONS
Advances in science and technology have enabled the functional food market to grow in recent years and, as a result, the landscape of the food and nutrition field continues to develop. Likewise, consumer interest in the health benefits of foods and food components is at an all-time high and will continue to grow. RDs and DTRs are uniquely qualified to interpret scientific findings on functional foods and translate such findings into practical dietary applications for consumers, other health professionals, policy makers, and the media. For this reason, they must actively keep abreast and share their knowledge of emerging research on functional foods and their roles in human health.

References
21. Labrecque J, Charlebois S. Functional foods an empirical study on perceived health


The Academy of Nutrition and Dietetics positions adopted by the House of Delegates Leadership Team on October 16, 1994 and reaffirmed on September 7, 1997; June 15, 2001; June 11, 2006; and February 1, 2011. This position is in effect until December 31, 2016. The Academy authorizes republication of the position, in its entirety, provided full and proper credit is given. Readers may copy and distribute this paper, providing such distribution is not used to indicate an endorsement of product or service. Commercial distribution is not permitted without the permission of the Academy. Requests to use portions of the position must be directed to the Academy headquarters at 800/877-1600, ext. 4835, or ppapers@eatright.org.

Authors: Kristi M. Crowe, PhD, RD, LD (University of Alabama, Tuscaloosa); Coni Francis, PhD, RD (University of Northern Colorado, Greeley, CO). Reviewers: Suzanne Abendroth, MS, RD (Consultant, Algonquin, IL); Sports, Cardiovascular, and Wellness Nutrition dietetics practice group (Jenna A. Bell, PhD, RD, Pollock Communications, New York, NY); Sharon Denny, MS, RD (Academy Knowledge Center, Chicago, IL); Academy Quality Management Committee (Barbara Kamp, MS, RD, Johnson & Wales University, Miami, FL); Mary Pat Raimondi, MS, RD (Academy Policy Initiatives & Advocacy, Washington, DC); Robin Ralston, MS, RD (Ohio State University, Columbus, OH); Karen Schmitz, PhD, RD (Madonna University, Livonia, MI); Alison Steiber, PhD, RD (Academy Research & Strategic Business Development, Chicago, IL).

Academy Positions Committee Workgroup: Terri Verason, MS, RD (chair); Penny E. McConnell, MS, RD, SNS; Kim Stote, PhD, MPH, RD (content advisor).

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