

Discovering and Promoting Commodity Health Attributes:  
Programs and Issues

by

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### Executive Summary

Increased consumer interest in selecting foods based on health and nutritional attributes provides economic incentives to food processors and manufacturers to provide label and promotional information on the benefits of consuming their product(s). Faced with consumers' confusion over a wide array of product claims using undefined and often misleading terms, governments in both the U.S. and the EU have established regulations regarding health and nutrition claims for food products. The requirements for nutrient content claims, such as "calorie free," "low fat," and "light/lite," have been defined and health claims can only be used when supported by sound scientific findings.

Producers of four California crops, almonds, avocados, strawberries, and walnuts, are using mandatory assessments collected by their commodity organizations to fund health and nutrition research. Recent budgets have totaled over \$3 million for a portfolio of projects on relationships between consuming each product and cardiovascular disease, weight and obesity, cancer prevention, diabetes, antioxidants, aging, prostate health and bone health. Almonds and walnuts have received qualified health claims from the FDA regarding consumption of almonds or walnuts to reduce the risk of heart disease. Producer organizations for avocados and strawberries each have a stated goal of obtaining the research results needed to secure a health claim for their product. Public relations programs based on health and nutrition research have proven to be a very cost-effective method of communicating with consumers. Advertising programs using a health and nutrition message have also been effective for almonds and strawberries.

There is some controversy over food health claim regulations. U.S. rules are still evolving after several years while EU rules are just becoming effective. The interest in evolving rules is warranted since potential costs and returns can be high for food manufacturers, producers, and consumers.

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### Abstract

There is a growing consumer segment demanding healthy foods and diets, health and nutrition messages can expand food demand, and governments in the U.S. and EU, faced with increasing obesity and associated health outcomes, want consumers to have reliable information to choose healthy diets. California commodity organizations, charged with expanding the demand for almonds, avocados, strawberries and walnuts, are funding health and nutrition research as a means to discover a unique selling proposition for each product. Research and promotion effects are attracting interest by other commodity groups. Policy and regulatory issues abound.

Key words: health, nutrition, food, marketing, promotion

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## Introduction

Sharply increasing numbers of consumers who are selecting food based on health and nutritional attributes are an international phenomenon fueled by a number of factors. Included are increasing consumer incomes with a decreasing share spent on food, globalization of food supplies, worldwide health problems associated with diet (including obesity, heart disease, diabetes, and cancer), increased introductions of “new” processed food products, food safety incidents, and a proliferation of information and health claims by producers, processors, commodity organizations and other groups attempting to expand demand for their products. This increased emphasis on food attributes poses a series of issues and opportunities for food systems around the world.

Growing consumer concerns about the health attributes of food products, improving awareness about the possible impacts of diet on health, and growing demand for functional food products has been met with increased information and, sometimes misleading promotion concerning product attributes. In response, the U.S. Food and Drug Administration and the European Commission have issued and proposed new rules directed at inaccuracies, confusion, and false information related to the functional and disease risk reduction claims on food packaging and in commodity promotional materials. Several U.S. commodity groups are funding health and nutrition research programs to support health claims for their products. These actions raise policy questions regarding the appropriate bodies to be conducting health and nutrition research for food products, the nature of expected returns from health and nutrition research, and the dissemination of research results.

## Objectives

This paper has three objectives. They are to:

1. Summarize the evolution of U.S. and EU rules for health claims on food.
2. Present case study examples of health and nutrition research and promotion programs conducted by California commodity organizations.
3. Outline some policy issues related to health and nutrition research by commodity organizations.

## Government Rules

The U.S. Government and the European Commission have both found it necessary to develop and issue rules concerning health and nutritional claims for food products as an attempt to reduce the confusion facing a consumer attempting to select a “healthy diet” for his or her family. As pointed out by Michael Pollan in a New York Times article, “Once, food was all you could eat, but today there are lots of other edible food-like substances in the supermarket. These novel products of food science often come in packages festooned with health claims .... “. Prior to the

issuance of rules and definitions, consumers faced an array of manufacturer product claims concerning fat, calories, cholesterol, sugar, sodium, and various nutrients using undefined terms such as “fat free,” “90% fat free,” “reduced fat,” and “light/lite”. Continued attempts by governments to reduce misinformation and confusion in the marketplace are often controversial with both consumer advocates and food manufacturers criticizing the rules. Following is a brief description of the evolution of U.S. Food and Drug Administration (FDA) and European Commission regulations regarding health and nutrition claims for food products.

## U.S. Government Regulations

The U.S. Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) share authority to regulate the health information that food manufacturers and marketers place on labels and in their advertising. The FDA regulates health claims and authorizes nutrient content claims for food products while the FTC has authority over advertising messages and enforces “truth in advertising” for all business entities. Note that an advertising claim that satisfies applicable FDA requirements will typically satisfy FTC requirements.

## Health Claims

The Nutrition Labeling and Education Act (NLEA) of 1990, gave the FDA specific authority to permit health claims in the labeling of foods, where health claims are always phrased in terms of “may reduce the risk of” some disease or health-related condition and not about treating, mitigating or curing diseases (Nickerson). Prior to Congressional action, foods that had certain science-backed claims about disease prevention in their labeling risked being regulated as drugs (defined as articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man). There are two types of health claims, unqualified health claims and qualified health claims. Both require detailed FDA review of scientific evidence submitted in a health claim petition.

Unqualified health claims are also referred to as SSA health claims, where SSA stands for significant scientific agreement, and that comes from the Nutrition Labeling and Education Act's standard for FDA to authorize health claims by regulation. It is significant scientific agreement among qualified experts (Nickerson). For example, the unqualified health claim for low sodium foods and high blood pressure reads: “diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.”

Qualified health claims are health claims that are based on scientific evidence that is credible but that does not meet the significant scientific agreement standard. These health claims include a disclaimer or other qualifying language to prevent consumers from being misled about the level of support for the claim or other important facts, which could be, for example, conditions of use that are necessary to get the risk reduction benefit. Qualified health claims are considered under FDA's exercise of enforcement discretion (Nickerson). The health claims secured through petition by California commodity organizations, to date, are qualified health claims.

## Dietary Guidance

The FDA regards statements addressing dietary patterns or general categories of foods and health to be dietary guidance rather than health claims. Dietary guidance statements made on food labels must be truthful and not misleading, but do not require submission or notification to FDA. Claims about the effect of a food on the normal function or structure of the human body (structure-function claims) are also outside the FDA submission process. An example of a structure-function claim is that “calcium builds strong bones.” These claims cannot link a specific substance to a disease or health-related condition or to disease prevention or cure.

## Nutrient Content Claims

The NLEA also permits use of authorized “nutrient content claims,” which characterize the level of a nutrient in a food. These claims, which must be in accordance with FDA’s authorizing regulations, can describe the level of a nutrient or dietary substance quantitatively or by using terms relative to an absolute such as free, high, low, or a good source. For example, FDA regulations define “calorie free” as less than 5 calories per serving, “fat free/sugar free” as less than ½ gram fat or sugar per serving, “low calorie” as less than 40 calories per serving, and “light” as 1/3 fewer calories or ½ the fat of the usual food (Mehlberg).

## European Commission Regulations

European and American consumers have experienced the same issues regarding health and nutrition claims for food products, but European regulators have been faced with the additional problems of dealing with diverse national rules. The European Commission put forward the proposal for the Health Claims Regulation on July 16, 2003 and on June 3, 2005, EU health ministers unanimously endorsed the Commission’s proposal, including the provision for nutrient profiles and the authorization procedure, during a first reading vote at the Health Council. Then on May 17, 2006 the European Parliament gave its support to the Health and Nutrition Claims Regulation, in its 2nd reading. Final adoption of the Regulation on Health and Nutrition Claims by the Council of Ministers was on December 20, 2006.

## Regulation on Health and Nutrition Claims

Health & Consumer Voice, the Commission’s newsletter (Jan. 2007) states: “The new legislation on health and nutrition claims will ensure that any claim made on a food label in the EU is clear, accurate and substantiated. Strict conditions are laid down for the use of nutritional claims such as “low fat”, “a good source of protein” or “reduced sugar”, and only foods that are consistent with agreed nutritional profiles will be allowed to carry such claims. For health claims, the Commission will draw up a positive list of well-established claims, such as “calcium is good for your bones”, which may be used on a label as long as they are proven to apply to the food in question. New health claims or disease reduction claims, such as “reduces the risk of cardiovascular diseases” or “reduces the risk of osteoporosis”, will have to undergo a specific authorization procedure before they can be used.” Provisions in the Regulation are effective on July 1, 2007.

The European Food Safety Authority is charged with carrying out a scientific assessment of the evidence submitted to support health claims. The Regulation (2006) states that, “Health claims should only be authorized for use in the Community after a scientific assessment of the highest possible standard.” It adds that, “In order to ensure that health claims are truthful, clear, reliable and useful to the consumer in choosing a healthy diet, the wording and the presentation of health claims should be taken into account in the opinion of the European Food Safety Authority and in subsequent procedures.” Note that disease reduction messages, currently prohibited by EU legislation, would be possible under new rules if they could meet the scientific standards for substantiation.

The Annex to the Regulation on Health and Nutrition Claims (2006) includes a rather extensive list of nutrition claims and conditions that must be satisfied to use them. These claims include, for example, low energy, low fat, low sugar, low saturated fat, low sodium-salt, fat-free, saturated fat-free, sugar-free, energy-free, sodium-free, salt-free, source of protein, source of [named vitamins or minerals], natural, light/lite, etc.

Given the similar goals for the U.S. and European regulations for health and nutrition claims for food products, it is not surprising to find similar terms, requirements, and procedures. The European Regulations, which include provisions for adjustments from existing national rules, are not fully effective for several years. In addition, the European Regulations may be more restrictive than U.S. rules in that they do not appear to allow for the qualified health claims approved by the FDA. This will depend on the standards for approval developed and used by the European Food Safety Authority.

## Sources of Scientific Evidence

The relatively recent adoption of standards for nutritional and health claims for food places new pressures on producer organizations and food manufacturers to conduct, fund, or lobby government for funding health research. The perceived value of a health and nutrition message for expanding product demand provides an economic incentive for firms and commodity groups to support health and nutrition research. Acquiring the research necessary for a health or nutrition claim, however, can be a long and expensive process. Following are case studies of health and nutrition research and promotion programs conducted by the Almond Board of California, the California Avocado Commission, the California Strawberry Commission, and the California Walnut Commission.<sup>1</sup> Each of these commodity groups is funding research to determine the health attributes of their products and then using research results in their public relations and promotional programs. The research and promotional programs for the four commodities will be compared and contrasted. The potential contributions of producer funded research and promotion of healthy diets will be outlined. Successful programs for the case study commodities that have potential applications for other producer groups will be highlighted.

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<sup>1</sup> The Almond Board is a Federal Marketing Order and the three State Commissions each has their own separate enabling legislation. All four programs were established by a 2/3 vote of covered producers and participation is mandatory for all California producers of each commodity.

## Research Focus

The California Walnut Commission (CWC) was one of the first commodity groups to fund health and nutrition research when it decided to counter diet recommendations urging consumers to reduce or constrain consumption of nuts because of their high oil content. The CWC funded their first project on the protective effect of nut consumption on the risk of coronary heart disease with researchers at Loma Linda University in 1990. The Almond Board of California (ABC) established a Nutrition Research Program and Nutrition Subcommittee in 1995 to review the scientific validity of proposals and recommend studies for funding. During 1997, the California Avocado Commission (CAC) made a strategic change to proactively communicate the nutritional benefits of avocados through national public relations/outreach efforts. The California Strawberry Commission (CSC) began funding nutrition research proposals in 2003. Results from this research are being used in the CSC advertising and promotion programs.

The four commodity groups each have analyses detailing their chemical and nutritional composition, including such things as amount and type of fat, calories, vitamins, phytochemicals, antioxidants, minerals, etc. The presence of particular components, already associated with favorable health outcomes, has helped focus research on important health topics. Health and nutrition research topics pursued by the four commodity groups have similarities as well as differences (Table 1). Each commodity group has or is seeking evidence on the value of consuming their product on reducing the risk of heart disease. Each group has evidence that product components may lower the risk of certain cancers and each of the commodities contains antioxidants that are known to slow the aging process and protect against heart disease and various forms of cancer. Almonds, avocados and walnuts can be a component of diets to control weight gain and each can be part of a diet for managing and controlling diabetes.

Expenditures on health and nutrition research by almond, avocado, strawberry and walnut producers have been substantial. A review of budgets for the five-year period 2001/02 to

Table 1. Current Health and Nutrition Areas of Interest Mentioned by Four California Commodity Groups.

Research Area	Commodity			
	Almonds	Avocados	Strawberries	Walnuts
Cardiovascular Disease	X	X	X	X
Weight & Obesity	X	X		X
Cancer Prevention	X	X	X	X
Diabetes	X	X		X
Antioxidants	X	X	X	X
Aging	X	X	X	X
Prostate Health				X
Bone Health				X

2005/06 indicates that these four commodity groups spent a total of over \$9.08 million on health and nutrition research. The most recent budgets show annual expenditures on health and nutrition research of \$1,000,000 by the ABC for almonds, \$605,000 by the CSC for strawberries, and \$1,468,857 by the CWC for walnuts. Each commodity group has formed a nutrition or scientific advisory committee that includes well-known and knowledgeable nutritionists and medical researchers to provide ideas and advice on research areas, nutrition based programs, and outreach efforts. Each commodity also maintains a website that provides detailed information on the nutrition/health benefits of consumption of the commodity and each has a nutritionist on staff or on retainer.

Results from commodity group sponsored health and nutrition research is accumulating, as illustrated by a summary posted by the CWC for walnuts. The California Walnut Commission began with studies on the relationships between walnut consumption and cholesterol levels and walnut consumption and the risk of coronary heart disease. The CWC funded epidemiological and clinical studies at Universities in the U.S., France, New Zealand, Spain, Norway, and Japan. Results of these studies, published in medical, nutrition, and scientific journals, indicate that consumption of walnuts improves the function and reduces inflammation in arteries, reduces LDL cholesterol, reduces blood pressure and reduces heart disease risk. There is also evidence that that melatonin in walnuts protects against cancer and heart disease, that walnuts can help in weight management, that consumption of walnuts are protective for people with type 2 diabetes, and that the form of vitamin E found in walnuts might halt the growth of lung and prostate cancer cells. Walnuts have high concentrations of antioxidants, which help the body ward off life-threatening maladies such as cancer, heart disease and diabetes, as well as debilitating ailments such as arthritis, osteoporosis and Alzheimer's disease (CWC, p. 6).

The Almond Board of California (ABC) initiated its nutrition research program in 1995, with funding of \$300,000 for studies on cardiovascular disease, decreased cancer risk, glucose metabolism, and analysis of the nutrient content of almonds. Both funding and the number of studies increased rapidly. Now, with annual health research budgets of over \$1 million, the ABC has ongoing research relationships with more than 20 scientific organizations and universities around the world. In terms of research support, the topic with the largest budget is cardiovascular research (24%), followed by research on the composition of almonds (20%), research on antioxidants (19%), cancer research (14%), and research on weight (3%). The website [www.almondsarein.com](http://www.almondsarein.com) lists 11 ongoing almond nutrition research projects on topics in the above areas. Research topics include food allergy, Vitamin E content, analysis of the chemical composition of almond skins, colon cancer, cholesterol levels and reduction, the effect of almonds on glycemic control and insulin response, and the effects of almond consumption on appetite, energy and weight. The website lists references for 37 publications reporting nutritional characteristics and research results on potential health benefits of consuming almonds.

## Qualified Health Claims

Both almonds and walnuts have secured FDA qualified health claims, the strawberry research program has a stated goal of obtaining a qualified health claim, and the CAC's Nutrition Advisory Committee is researching new and necessary information, timing and feasibility to

submit a qualified health claim about avocados and heart health to the FDA (CAC, Oct. 2006). The CAC writes that they expect the process to take about three to five years (p. 58).

The International Tree Nut Council Nutrition Research and Education Foundation petitioned the FDA for authorize a health claim about the relationship between the consumption of nuts and reduced risk of coronary heart disease (CHD) on the label or in the labeling of whole or chopped nuts and certain nut-containing products.<sup>2</sup> The petition contained two model health claims (FDA, 2003):

1. Diets containing one ounce of nuts per day can reduce your risk of heart disease.
2. Eating a diet that includes one ounce of nuts daily can reduce your risk of heart disease.

The FDA concluded that there is not significant scientific agreement that consumption of nuts may reduce the risk of CHD and declined to authorize a health claim. The FDA did conclude, however, that there is a sufficient basis for a qualified health claim about nuts and reduced risk of CHD, and approved the following qualified health claim and disclosure statement on July 14, 2003 (FDA, 2003):

"Scientific evidence suggests but does not prove that eating 1.5 ounces 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.]"

The CWC submitted a separate petition to the FDA for a model health claim for walnuts stating, "Diets including walnuts can reduce the risk of heart disease." In a letter dated March 9, 2004, the FDA concluded that: "Based on FDA's reassessment of the scientific evidence subsequent to our initial July 14, 2003 qualified health claim enforcement discretion decision, the agency still concludes that there is not significant scientific agreement that the claim "Diets including walnuts can reduce the risk of heart disease" is supported by the totality of publicly available scientific evidence. Thus, FDA will consider exercising enforcement discretion for a qualified claim as presented below (FDA, 2004):

"Supportive but not conclusive research shows that eating 1.5 ounces 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 coronary heart disease. See nutrition information for fat [and calorie] content."

The FDA ended its response to the walnut petition with the statement:

"Please note that scientific information is subject to change, as are consumer consumption patterns. FDA intends to evaluate new information that becomes available to determine whether it necessitates a change in this decision. For example, scientific evidence may become available that will support significant scientific agreement or that will no longer support the use of a qualified claim, or that may raise safety concerns."

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<sup>2</sup> The petition named peanuts and nine tree nuts, including almonds, Brazil nuts, cashew nuts, hazelnuts, macadamia nuts, pecans, pine nuts, pistachio nuts, and walnuts, as appropriate for the claim.

It is interesting to note that nutrition and health research budgets for the ABC and the CWC have increased since approval of qualified health claims for nuts and walnuts. Several factors support continued interest in nutrition and health research. Consumer interest in diet and health is growing and is impacting food choices. Each of the four California commodity groups has discovered that results from nutrition and health research can support a highly productive public relations effort. Media news reports and stories on these research results is low cost and have the additional benefit of being more believable than advertising to many people. Commodity group leadership and membership are confident that their research programs yield high returns through increased demand for their products. Anecdotal evidence lends support to these views. The walnut industry points to the positive impact on demand of McDonald's decision to add fruit and walnut salad as a menu item, a decision that was heavily influenced by results of CWC nutrition and health research. There is also solid evidence of increasing demand for avocados and almonds attributable to advertising and promotion, some of which is based on health and nutrition topics.

## Nutrition and Health Promotion Strategies

While the research thrusts for the four groups are similar, their advertising and promotion strategies differ. The ABC first emphasized public relations for their health message and then shifted almost all advertising and promotion to a health message after the FDA issued the qualified health claim for nuts. The ABC partnered with the American Heart Association and focused on promotion of California almonds as part of a heart-healthy diet. The CSC has focused all consumer communications on a health message for strawberries since initiation of their nutrition and health research program in 2003. The CAC continues to use only public relations for their health message to avocado consumers and targets health and nutritional professionals with promotional materials.

The CWC continues to emphasize public relations activities for the health benefits of walnuts after laboratory testing of advertising themes found that the message on the health benefits of walnuts is best communicated through a third party such as a magazine, newspaper, doctor, nutritionist or other credible source (CWC Summer Report, June 2001, p. 2). While advertising in Germany, Italy, Spain, Japan has included health as one of the messages, the advertising emphasis has been on quality, taste, and uses for walnuts in meal preparation, with public relations used for the health and nutrition message<sup>3</sup>.

Overall, consumer and media interest in diet and health issues appears to assure cost effectiveness for public relations programs. For example, the ABC increased public relations expenditures to \$1 million during 1998-1999, but estimated that the advertising value equivalency of exposures related to the health benefits of consuming almonds increased to \$7 million. The CWC estimates that publicity generated as a result of the FDA ruling on the qualified health claim for walnuts generated over 70 million impressions by the end of the 2003-

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<sup>3</sup> A review of CWC newsletter reports provides information on promotional activities in major export markets, including Canada, Germany, Italy, Spain, Israel, Japan, and Korea, [http://www.walnuts.org/news/new\\_nletters.asp](http://www.walnuts.org/news/new_nletters.asp)

04 crop year from news stories, magazine articles, and associated publicity on diet and health. Media impressions attributed to the CWC public relations program in the U.S. increased from a little over one billion in 2001-02 to over two billion in 2004-05 at a cost per million impressions that decreased from \$0.59 in 2001-02 to \$0.37 in 2004-05 (CWC, 2006).

Partnering by the ABC, the CAC, and the CWC with other organizations, such as the American Heart Association, the Spanish Heart Foundation and the American Diabetes Association, provides product exposure in diets offering particular benefits such as heart healthy diets, healthy food choices for diabetics, or weight control diets. The funds allocated to nutrition research by each organization tend to add to total research rather than substitute for traditional research on production and post-harvest problems.

Published health and nutrition research results have been a positive factor in having almonds, avocados, strawberries and walnuts included in dietary recommendations by various organizations and agencies. As noted by the CWC, for example, a key recommendation of the 2005 Dietary Guidelines for Americans, announced in January 2005 by the USDA and U.S. Department of Health and Human Services is for consumers to consume more polyunsaturated fat (and less saturated and trans fat). Special emphasis was given to increasing intake of essential fatty acids, including omega-3 fatty acids, specifically noting plant sources of omega-3 fatty acids such as walnuts. This recommendation is consistent with recommendations of the American Heart Association, the U.S. Food and Drug Administration, and the National Academy of Sciences. This recommendation is expressed in the “MyPyramid Plan” announced by the USDA in April 2005.

## Policy Questions

The significant expenditures on health and nutrition research by government sponsored commodity organizations and the approval of qualified health claims by the FDA have raised a number of questions. The EU’s new Regulation on Health and Nutrition Claims is also a source of controversy. Following is a brief discussion of some of the issues being discussed.

Some agricultural producers argue that commodity organizations should not spend their mandatory assessments on health and nutrition research while others point to the positive impact of research results on product demand. Producers have a long history of supporting production research but very little experience with health and nutrition research. Government sponsorship of research through the agricultural experiment stations is well accepted and, while producers have developed an appreciation for the need to provide funding to help direct production research, the need or opportunities for health and nutrition research were not appreciated. As one might expect, producer opposition was much stronger before research results were available. Now, several commodity groups are considering health and nutrition research programs as a possible way to expand product demand. Critics also point to the possible problem of a commodity organization not supporting research or suppressing research results that are unfavorable to their interests’, a criticism that could apply to any privately sponsored research. Open and widely circulated requests for proposals (RFP’s) and the execution of contracts with Universities, where faculty expect to publish their research results, helps to minimize the

problem of suppressing results but not the selection of projects. Supporters of commodity organization sponsored health and nutrition research have argued convincingly that the research is in their interest and if they do not provide financial support, it will not get done.

The question of “who benefits from health and nutrition research” is relevant. The producers funding the research obviously believe that the research is yielding positive benefits or they would reduce rather than increase expenditures. Commodity organizations funding health and nutrition research, however, face a potential free rider problem in a global economy. For example, the results of health and nutrition research funded by California almond and walnut producers will apply to almonds and walnuts regardless of where they might be produced. This may not be a serious problem for California almond producers, who account for the majority of world almond production but it may be important for producers of a commodity with a smaller market share that faces competition from other countries in both domestic and export markets. Firms that are able to obtain patent or trademark protection on products of their research programs may be able to capture the majority of benefits. Economic theory argues that improved information will benefit consumers and improve economic efficiency. Consumers can benefit from information that is used to make diet choices that lead to improved health outcomes. These benefits include “feeling better,” reduced medical care, increased life spans, improved labor productivity, and all of the other personal and economy-wide payoffs accruing from a healthier population.

The FDA’s approval of qualified health claims, which is the result of a legal ruling related to First Amendment rights, is controversial. Food manufacturers know that health claims can help product sales, even if the science supporting the claim is not strong. They argue that consumers should have access to emerging science. Critics believe that qualified health claims are confusing and not well understood by consumers. This view tends to be supported by FDA research. Derby and Levy (2005) asked people to look at a hypothetical product and an accompanying health claim that was similar to those carried by real products. Two of the four products included were a fake tuna product with a claim that the omega-3 fatty acids may help fight heart disease and a spaghetti sauce with a claim that lycopene could help fight cancer. An FDA “Questions and Answers” sheet on the findings of the Derby and Levy study summarizes the results as (Sept. 28, 2005):

1. “Qualifying statements that used only words to convey the strength of science underlying a claim were not understood by consumers.”
2. “Qualifying statements that included a “report card grade” were understood by consumers to convey a rank order of the strength of science underlying a claim, but ‘B’ grades were understood to convey greater scientific certainty than unqualified health claims (i.e., claims that meet the significant scientific agreement standard). (In the FDA consumer research study, FDA did not use an “A” letter grade for the experimental conditions representing claims that met the significant scientific agreement standard, but simply stated the substance/disease relationship.)”
3. “Even when qualified health claims were understood as intended, qualifying statements had unexpected effects on consumers’ judgments about the health benefits and overall healthfulness of the product bearing the claim. Sometimes, these qualified health claims led to more positive product perceptions.”

After releasing the results of the Derby and Levy study, the FDA held a meeting on November 17, 2005 to assess consumer perceptions of health claims. A transcript of the meeting is available at <http://www.cfsan.fda.gov/~dms/qhctran.html#qhc>.

The EU Regulation on Health and Nutrition Claims was adopted by the Council of Ministers on December 20, 2006 and is effective July 1, 2007. The stated objectives of the Regulation are to achieve a high level of consumer protection, to improve the free movement of goods within the internal market, to increase legal security for economic operators, and to ensure fair competition in the food sector. The Regulation covers voluntary nutrition and health claims made on foods; labeling, presentation and advertising; trademarks and brand names. Provisions of the regulation will be phased in over time. Presently it appears that all health claims, which must be approved by the European Food Safety Authority (EFSA), will be based on and substantiated by generally accepted scientific evidence. There do not appear to be any provisions that allow for U.S. type “qualified health claims.” An early task for the EFSA is to consult on establishing a Community positive list of permitted health claims. This list will be derived from the various lists of claims based on generally accepted evidence that are being compiled by member states. Companies wishing to use health claims not on the positive list are required to prepare applications that include evidence for a particular health claim.

The development and approval of the EU Regulation on Health and Nutrition Claims was controversial and its implementation is guaranteed to spark controversy. A news account in the Guardian Unlimited about issues involved when the regulation of food health claims was proposed helps to outline some points of contention (2003). The news story reported, “Heavy lobbying is expected from food manufacturers who have argued that new rules would hit consumer choice and hurt business. The European Breakfast Cereal Association described the proposed measures as overly restrictive and not proportionate to the objective pursued.” On the other side, Sue Davies of the Consumers Association said: “There are vast numbers of products on the shelves promising health claims but it has always been impossible for consumers to distinguish between the real and the bogus. This is a great victory for consumers but it is only the first hurdle. We have a long way to go before we see these much-needed changes on the shelves.” The European Food Safety Authority will face political pressure from both sides of the table. Food manufacturers whose long-standing claims are not approved will protest, as will policy makers intent on combating obesity and improving diets. Manufacturers may face significant financial and time commitments to develop the scientific evidence needed for approval of a health claim. There is concern that small firms may be at a competitive disadvantage because of these requirements.

## Concluding Comments

Health and nutrition claims for food products can be a very effective marketing tool. This has encouraged some firms to use misleading, dubious and just plain false claims in their labeling and promotion that has led to government action and regulation in many countries. The U.S. and EU now have rules in place requiring approval for health claims based on sound scientific evidence before such claims are used. In the U.S., the FDA is examining ways to clarify the meaning of qualifications to permitted health claims while in the EU, regulations are just

becoming effective. The objective is to provide reliable information to guide consumers' healthy food choices.

Commodity groups are sponsoring nutrition/health research and promotion with the objective of increasing demand for their products. As part of this process they are adding to the research base on nutritional components of food products, beneficial effects of particular food components, and food component-disease interactions. They are also communicating the results to health and nutrition professionals and consumers in their outreach programs. Their programs appear to have a positive impact on product demand and there is increasing interest in discovering new health and nutrition benefits from consuming many commodities, including apples, blueberries, cranberries, kiwifruit, milk, and table grapes, to mention a few.

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