Regulating Health Claims on Food Products

The Balance between Consumer Choice and Consumer Protection

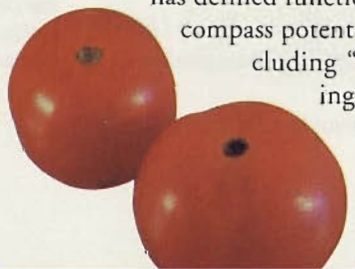
by Laurian Unnevehr, Michael R. Ward, and Clare Hasler

New scientific understanding of the role of diet in preventing disease is rapidly emerging. Scientists are beginning to understand how some components of food could promote health and reduce the risk of illness. Examples include phytochemicals that might prevent cancer or other components of food that might reduce the risk of cardiovascular disease. These so-called "functional" components of food differ from more widely understood "nutritional" components of food, such as calories and protein.

This emerging knowledge potentially increases consumer welfare by broadening the range of health-promoting activities. Consumer demand for this information and the functional food products that it may generate is growing as consumers live longer and become more affluent. Here we discuss the potential health benefits of functional foods, recent policy regulating health claims of functional foods, and how to evaluate policy decisions in this area.

The potential for functional foods to improve consumer well-being

What are functional foods? The Institute of Medicine of the U.S. National Academy of Sciences has defined functional foods as those that "encompass potentially healthful products," including "any modified food or food ingredient that may provide a health benefit beyond the traditional nutrients it contains." In other words, functional foods are those which may prevent disease or otherwise enhance health. Other terms frequently used for these kinds of food components or products include "nutraceuticals" or "designer" foods. Scientists are identifying functional components of foods that could reduce risks from the two leading causes of death in the United States: cancer and cardiovascular disease.



Phytochemicals, for example, have recently been the focus of intense research efforts because of their cancer preventive properties. Phytochemicals are non-nutrient, physiologically active plant components present in relatively small amounts compared to the macronutrients (fats, carbohydrates, and proteins). Epidemiological studies have demonstrated that populations consuming phytochemicals through a plant-based diet high in grains, legumes, fruits, and vegetables have a markedly reduced incidence of cancer. Only recently have biological scientists begun to identify the mechanisms through which phytochemicals reduce cancer risk. Some phytochemicals, like the organosulfur compounds in allium vegetables such as garlic and onions, "detoxify" carcinogens and thus help the body to eliminate them. Others, such as carotenoids in yellow, red, and green vegetables, function as antioxidants by scavenging free radicals that can attack and damage cellular membranes and DNA. Lycopene in tomatoes is an-

other example of a phytochemical that acts as an antioxidant, and has been shown to be especially effective in preventing prostate cancer. Phytoestrogens, such as those found in soybeans (for example, genistein), have a structure similar to the body's natural forms of estrogen. Thus, phytoestrogens may reduce the effect of the more potent, naturally occurring estrogens which can promote estrogen-dependent cancers, such as those of the breast and prostate.

Research has also identified functional foods that reduce the risk of cardiovascular disease. One study widely reported in the popular press has identified a mechanism by which a component in red wine reduces hardening of the arteries (Renaud and DeLorgeril). Many studies have shown that soy protein reduces blood cholesterol (Anderson, Johnstone, and Cook-Newell). Yet another example of a functional food is cranberry juice, which reduces the incidence of urinary tract infections (Avorn et al.).

To improve their health and well-being, consumers need information about the implications of new research results and new products that make it easier to consume the functional components of foods. Public policy plays a role in regulating and providing information to consumers, and public policy can influence the incentives to develop new functional food products.

Dramatic changes in public policy regarding food health claims

Public policy regarding health claims on food has experienced dramatic changes during the past decade. In general, these changes have led to greater use of health-related information in product marketing, but such use is still very strictly regulated. A watershed development in food labeling policy occurred with the passage in 1990 of the Nutrition Labeling and Education Act (NLEA). It directed the Food and Drug Administration (FDA) to change the way that food labels were regulated, in order to make additional nutritional information available to consumers. As a result, most food products now carry a revised label that provides information about saturated fat, cholesterol, and dietary fiber, in a format designed to help consumers choose a more healthful and nutritious diet. One study estimated that the potential health benefits from these new labels could be as much as 1.2 million life years gained during the next twenty years (Zarkin et al.).

The NLEA confirmed the authority of the FDA to regulate health claims on food labels and in food labeling. Congress mandated that the FDA review ten diet-disease relationships and establish whether and how claims could be made on behalf of certain foods. The final FDA

regulations in 1993 established seven allowable health claims:

- calcium and a reduced risk of osteoporosis
- sodium and an increased risk of hypertension
- dietary saturated fat and cholesterol and an increased risk of coronary heart disease
- dietary fat and an increased risk of cancer
- fiber-containing grain products, fruits, and vegetables and a reduced risk of cancer
- fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and a reduced risk of coronary heart disease
- fruits and vegetables and a reduced risk of cancer

Additional health claims were to be allowed only after stringent review of the scientific evidence. In January 1997, the FDA approved the first food-specific health claim under the NLEA, in response to a petition from the Quaker Oats Company. The authorized health claim describes the relationship between consumption of whole oat products and coronary heart disease risk reduction. Products containing a certain minimum level of soluble fiber from oat bran per serving may carry one of the following statements: "Soluble fiber from foods such as oat bran, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease," or "Diets low in saturated fat and cholesterol that include soluble fiber from oatmeal may reduce the risk of heart disease."

The FDA spent two years reviewing studies to establish a scientific consensus that consumption of oat products reduces cholesterol levels. To make this connection and establish a product content standard, the scientists first had to identify a specific functional component in oat bran responsible for this biological effect, in this case beta-glucan. Next they had to identify the minimum quantity that should be consumed to benefit health.

The FDA approval process sets an important precedent for health claim policy. It demonstrates that the standard will be one of scientific consensus and that any health claim must include the appropriate dietary context (low in saturated fat and cholesterol in the oat example). Furthermore, the health claim can be used on any product, not just those produced by the petitioner. Thus, General Mills can use the claim for its oat cereals, even though Quaker Oats incurred the costs of supporting the petition and review.

In addition to the FDA's regulation of labeling on food, the Federal Trade Commission (FTC) regulates advertising to prevent consumer deception. The FTC coordinates its regulation of health claims in food product advertising with FDA's labeling policy, but the FTC allows firms more advertising flexibility. For example, the FTC allowed Quaker Oats to mention the cholesterol-lowering effects of oats in print advertisements, prior to the FDA approval of a specific claim for the product label.

Some of the changes in food labeling regulation since 1990 were spurred by the efforts of public interest groups and the food industry to foster greater health awareness. This began in 1984, when the National Cancer Institute (NCI) endorsed messages about the benefits of dietary fiber for Kellogg's cereal. In 1991, the NCI and the Produce for Better Health Foundation launched the "5 a Day for Better Health" program to encourage Americans to eat five servings a day of fruits and vegetables. In 1992, the American Heart Association (AHA) allowed use of their red "heart check" mark on products that meet FDA's regulatory requirements for making a coronary heart disease health claim. These third-party efforts to extend information provide consumers with more assurance about the validity of health claims.

The recent approval of Quaker Oats's petition shows that health claims policy is still evolving in the United States. The growing international trade in processed food products may also influence industry efforts to support petitions. The United States has regulated health claims more stringently than many European countries, where functional claims on food products are more common. The recent Uruguay Round GATT agreement allows countries to set their own standards, as long as these are clear and science-based. Whether some of the products now marketed in Europe will be introduced into the United States, and how these health claims will be received by FDA, remains to be seen.

In addition to these new developments in food health claims policy, there have been even more recent dramatic changes in the way that dietary supplements are regulated. This is important for functional foods, because they have physiological effects similar to some drugs. Functional health components can be the basis of dietary supplements (beta-carotene, for example). The Dietary Supplement Health and Education Act (DSHEA) of 1994 changed how FDA regulates these products. The DSHEA allows manufacturers to make certain claims and market products without obtaining FDA's preapproval. They must notify FDA thirty days before marketing a product with a claim. The burden of proof to demonstrate harm from these products rests on FDA. Since the passage of the DSHEA, many new supplement products have been introduced on the market, many of which use functional components of food.

Current public policies concern the food industry, the dietary supplement industry, consumer ad-

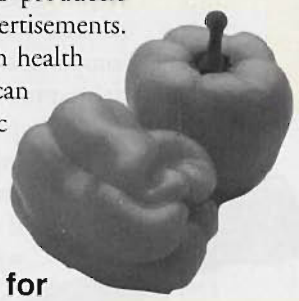
vocacy groups, and public agencies. Some charge, for example, that less stringent regulation of supplements promotes their development instead of food products, and may discourage consumers from eating a more nutritious and balanced diet. Others worry that consumers may be confused by these differences in regulation, and may attach the same credibility to both supplement and food label claims, even though the latter have been subjected to more rigorous scientific review. FDA is concerned about its inability to prevent the potential harmful effects of supplements. At the same time, many food industry firms would like to see more flexibility in FDA's approach to health claims on food products. Consumer advocates are concerned that specific product health claims will detract from public education messages about the importance of a healthy overall diet. These concerns relate to the incentives for generating and providing diet-health information.

Economic incentives for creating and disseminating diet-health information

Who will do the research and provide consumers with information about the health attributes of food? Food producers have an incentive to fund such activities but may also have an incentive to exaggerate the health benefits of their products. Moreover, since health information provided by one producer may also benefit its competitors, producers may be reluctant to bear these costs. Third parties, such as the AHA, have credibility with consumers and are less concerned about producer benefits. However, they rely on voluntary donations that are likely to represent only a fraction of the true consumer interest. News writers and dieticians disseminate information but have no incentive to pay for the research that generates new information.

These shortcomings in the supply of health information are the basis for specific public policies. Verification of the accuracy of health claims by the FDA and enforcement of advertising substantiation laws by the FTC attempt to increase the reliability of producer-supplied information. Publicly funded government agencies, principally the National Institutes of Health, supply the bulk of the health-related research. Finally, government-supplied consumer education and research extension efforts, like those of the Cooperative Extension Service, disseminate recent scientific discoveries to professional organizations and the public.

These third-party sources, news reports and health professionals, most often provide information about the links between overall diet and health outcomes. Consumers obtain information linking health benefits to specific product choices most easily when specific purchase decisions are being made: in the grocery store or restaurant, when coupons are being clipped, or when shopping lists are being written. For the most part, the health information available at these times is supplied by food producers through package labels and product advertisements. Therefore, public policy regarding which health claims producers are permitted to make can have important consequences for public health. So the question for public policy is how to regulate product-specific claims so as to best promote public health.



Using a cost-benefit standard for health claims

What should be required from food producers and the scientific community before a new health claim is justified? With the addition of the new claim linking oat products with coronary heart disease risk reduction, eight specific health claims are now permitted. It is widely expected that new health effects from functional foods will be uncovered. Allowable claims usually require a scientific consensus regarding the consumption of a class of food products and a desirable health effect. We propose that a cost-benefit standard for acceptance of new health claims replace the requirement of a scientific consensus.

The justification for restricting producers from making health claims is that unsubstantiated claims can cause consumers harm. Consumers face a financial loss if a false claim leads them to choose a higher-priced food. Perhaps more important, they could suffer detrimental health effects if the product is bad for them or its consumption causes them to forego a product that would have been better for them. A consensus standard practically eliminates the likelihood that false and potentially harmful claims will be permitted.

However, the degree of substantiation for possible health claims differs. Likewise, the potential harm to consumers of a false claim depends on the specific claim and the products involved. Health claims for products that are no more expensive than likely alternatives will not lead to financial losses. Furthermore, if the product carrying the health claim replaces alternatives with no clear health advantages, the likely detrimental effect on consumers' health will be minimal. In these circumstances, the downside risks to permitting a potentially false claim are relatively small. In such instances, the reduced level of scientific substantiation for the health claim might be warranted in order to balance the potential benefits with the potential costs.

Health claims that have only minimal scientific substantiation are still likely to be rejected under this standard. Likewise, health claims that have achieved scientific consensus will continue to be

accepted. The difference is in how to treat health claims for which consensus has not been achieved despite considerable substantiation. In these circumstances, we propose that policy makers turn to a comparison of the potential benefits should the claim prove true with the potential costs should the claim prove false. In cases where the alternative products are cheaper and are known to have their own health benefits, a cost-benefit standard would likely still lead to rejection. Only when the downside risk is minimal would a cost-benefit standard accept a claim that a consensus standard rejects.

A need for choices and information

The new scientific findings regarding diet and health offer the opportunity to improve health. In order for consumers to use and benefit from this knowledge, choices in the marketplace must expand and methods of conveying this information must be found. Public policy must foster better information and more consumer choice, while still safeguarding consumers from unnecessary risks.

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