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HEALTH CLAIMS AND LABELING REGULATION: HOW WILL CONSUMERS LEARN ABOUT FUNCTIONAL FOODS?

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Consumers find out about functional foods through product specific claims about their benefits. Regulation differs for provision of information in advertising versus food labels and for dietary supplements versus whole foods. There are new controversies about labeling genetically modified organisms. Regulation of information is controversial among consumers and the food industry.

Key words: functional foods; health claims; food labels; food regulation.

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. These so-called "functional" components of food differ from more widely understood "nutritional" components of food, such as calories and protein.

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. For example, lycopene in tomatoes is a phytochemical that acts as an antioxidant, and has been shown to be especially effective in preventing prostate cancer (Giovannucci, 1999). 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 & DeLorgeril, 1992). Many studies have shown that soy protein reduces blood cholesterol (Anderson, Johnstone, & Cook-Newell, 1995). Yet another example of a functional food is cranberry juice, which reduces the incidence of urinary tract infections (Avorn *et al*., 1994).

An understanding of functionality may increase demand for existing food products, such as tomatoes, by providing consumers with new information about health benefits. Alternatively, functional components may be delivered in new products or incorporated into different foods, such as the

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addition of calcium to orange juice. Biotechnology can potentially play a role in developing new functional foods, by allowing the functional components of foods to be modified or produced in consistent quantities per serving. For example, researchers at the University of Illinois have found that the phytochemical content of broccoli varies widely and, thus, new varieties might be genetically engineered to produce consistent quantities of beneficial phytochemicals.

Information On Food Functionality And Regulation

Functional foods can increase consumer welfare by providing new opportunities to promote health through dietary choice. But to exercise these choices, consumers need information about the links between diet and health. Public policy plays a role in regulating the provision of information to consumers. Current policies differ for provision of information in advertising versus food labels and for dietary supplements versus whole foods. New controversies about labeling and testing of genetically modified organisms will complicate the regulatory picture.

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. 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 allowed use of their red "heart check" mark on products that meet the United States (U.S.) Food and Drug Administration's (FDA's) regulatory requirements for making a coronary heart disease health claim.

The Nutrition Labeling and Education Act (NLEA) of 1990 directed the 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. In addition, FDA reviewed several diet disease relationships and established seven allowable health claims, including calcium and a reduced risk of osteoporosis, and sodium and an increased risk of hypertension (Kurtzweil, 1998). 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 approval process for the oat bran petition set several important precedents for health claim policy. It demonstrated that the standard depends upon scientific consensus, and the scientific review first had to identify a specific functional component in oat bran responsible for reducing cholesterol and the minimum quantity that should be consumed to benefit health. The approved health claim must include the appropriate dietary context (e.g., low in saturated fat and cholesterol). 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.

Approval of the oat bran petition opened the door for additional product specific claims. Approval of a health claim linking psyllium seed husk soluble fiber and reduced cholesterol was published in February 1998; approval of a petition to link soy protein with reduced blood cholesterol was published in October 1999. But other claims have been denied. A petition to link calcium with reduced blood pressure, and another to link wheat bran fiber and colon cancer, were both turned down in 1997.

The FDA Modernization and Accountability Act (FDAMA) became law in November 1997. It contains provisions to reduce the bureaucratic hurdles in the health claim approval process. Specifically, it directs the FDA to authorize health claims that are based on the published authoritative statements from U.S. Government agencies with official responsibility in the health area, such as the Centers for Disease Control (CDC), the National Academy of Sciences (NAS), or the National Institutes of Health (NIH). Thus, health claims could be made without going through the lengthy FDA review process, if they have already been published by these agencies. Pre-market notification (120 days) to the FDA is required, and the FDA could take action against such claims if they are proved misleading. In July 1999, General Mills received approval to proceed with a claim linking whole grain foods to reduced risk of heart disease and cancer, based on statements from the National Academy of Sciences.

Regulation Of Supplements And Biotechnology

Apart from the FDA's regulation of food labeling, 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.

Coincident with these developments in food health claims policy, there have been 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 the FDA's pre-approval. They must notify the FDA 30 days before marketing a product with a claim. The burden of proof to demonstrate harm from these products rests on the 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 health labeling policies have raised concerns in the food industry, the dietary supplement industry, and among consumer advocacy groups. 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. The 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 the FDA's approach to health claims on food products, a concern that the FDAMA Act was designed to address. Some consumer advocates are concerned that specific product health claims will detract from public education messages about the importance of a healthy overall diet.

With the advent of controversies about genetically modified organisms (GMOs) in food, there is yet another dimension to food labeling policy. Under current FDA policy, GMOs are reviewed for food safety before they are marketed. Therefore, labeling is viewed as unnecessary, since approved GMOs do not pose risks to human health. But consumer advocates argue that consumers have the right to know if a food contains GMOs, because they may wish to avoid GMOs for ethical reasons or because they are concerned that regulatory review has not been sufficient to prevent negative health and environmental impacts (Consumer's Choice Council, 2000). Legislation has been introduced in the House and the Senate during the last six months to require labeling of foods containing GMOs. If new functional food products are created using GMOs, and this kind of legislation is passed, then mandatory labeling for GMO content could also impact any functional food products that are genetically engineered. This raises a number of interesting hypothetical questions. How would a "contains GMO" label influence consumer perceptions of functional food health claims? How would the safety review for GMOs in the regulatory process interact with review for a product specific health claim?

The issues surrounding regulation of food information grow more complex. As consumers live longer, become more affluent and, hence, more interested in preventing chronic disease, their demand for this information and associated food products should grow. At the same time, information technology will make it easier for consumers to obtain information and to make more varied dietary choices. The current regulatory approach to food labeling is focused on validating and filtering the information provided to consumers. This approach might become more important as a way of summarizing relevant new science for consumers. Or, this approach might become outdated as label information is overtaken by other means of communication. Regulating information to foster consumer choice and well being in a world of rapid scientific advances and changing information delivery systems will remain a significant challenge.

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