The best regulatory policies are grounded in sound science and modified periodically as new knowledge becomes available. The current legal and regulatory structure for food has served our society well in many ways, but, like any patchwork system created over decades, it has areas where the existing requirements are no longer in keeping with today’s needs. Certain current policies limit the scope and accuracy of consumer information about functional foods; other policies hinder the development and marketing of innovative functional foods, denying those health benefits to consumers. In deliberating and reviewing the science related to functional foods, the IFT Expert Panel identified the policy limitations below and formulated science-based recommendations that would enhance the development and marketing of functional foods.

**Wording Claims to Avoid Drug Classification**

To avoid drug classification, some claims may not accurately convey the actual effects of the food and may confuse consumers. Sometimes compliance with the regulations results in misleading (if not outright false) statements of the underlying science.

Currently, the wording of structure/function claims and health claims cannot imply a disease claim. The words used to describe health claims must be carefully phrased so that the claim is true and not misleading and so that it is in compliance with the requirements of current food and drug regulations.

The FDA rule regarding structure/function claims (FDA, 2000a) lists criteria and examples of proper structure/function claims compared to disease (drug) claims. Phrasing structure/function claims to avoid implying that the food prevents a certain disease often results in convoluted claims that contradict the supporting science.

For example, a claim that a food lowers cholesterol would be considered a drug claim because it implies abnormal cholesterol levels. Thus, functional foods that affect cholesterol levels state that the food “maintains normal cholesterol levels,” which is a permissible structure/function claim. However, such a statement is potentially misleading if the food in fact lowers cholesterol levels.

This issue is not merely academic, as products currently on the market demonstrate. Because of the stature given structure/function claims for dietary supplements at the time when spreads containing stanol/sterol esters were to come on the market, a decision was made by the manufacturers to offer the spreads as a dietary supplement with a structure/function claim. FDA would not accept this classification, informing the manufacturers that the spreads containing these ingredients were in fact foods. Generally recognized as safe (GRAS) status was then established for the stanol/sterol esters. This was during a time when the future policies for structure/function claims for food remained unclear. Therefore, a petition for a health claim was filed linking consumption of phytostanol and phytosterol esters to a reduced risk of heart disease. After the time-consuming and costly health claim petition was approved, then the related cholesterol-lowering “disease” claim was allowed on the label.

The IFT Expert Panel recommends that product labeling be allowed to accurately reflect the scientific evidence. As long as claims are scientifically valid, enormous public health benefits would result from having consumers understand and act on the claimed product benefit. The Expert Panel anticipates very few potential problems from structure/function claims that imply reduction of disease risk (e.g., “lowers cholesterol” equals lower risk of heart disease) if the claims have adequate scientific basis. The potential benefit may improve the public health (e.g., lowering serum cholesterol from increased consumption of the food or low fat diet).

**Defining Nutritive Value**

Current FDA policy requires that the health benefit attributed to a food component be derived from its “nutritive value.” FDA states that, “nutritive value means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy” (21 CFR §101.14(a)(3)). There is no consensus on the meaning of this definition, and conflicts exist between legislation, regulations, and other Agency documents. Tying health benefits to nutritive value has proven to be a very restrictive policy from the standpoint of recognizing the advances of nutrition science and communicating beneficial information about foods to consumers.

The IFT Expert Panel recommends that FDA not restrict the health effects of foods to the very limited concept of nutritive value. Rather, the Expert Panel supports basing structure/function and health claims on a broad-based scientific criterion that addresses the extensive links between health and nutrition and other scientific disciplines such as physiology, endocrinology, biochemistry, neurology, and genetics. This interpretation is consistent with the desires of all parties. Consumers, manufacturers, and regulators want the same thing: credibility in the claims on food products. Credibility clearly depends on good science, and, to date, when the
science has been good, FDA has found a way to approve new ingredients and new claims. Therefore, the Expert Panel believes that regulatory oversight will be more consistent and appropriate if FDA replaces “nutritive value” with a more appropriate definition: “that benefits for functional foods should be based on nutritive value or through the provision of a physical or physiological effect that has been scientifically documented or for which a substantial body of evidence exists for plausibility.”

The two case studies presented below demonstrate where confusion pertaining to nutritive value was a major impediment to providing appropriate health information and/or new products to consumers.

**Case Study: Stanol and Sterol Esters and Coronary Heart Disease**

An example of the problems presented by requiring demonstration of “nutritive value” may be further understood by reviewing the case of stanol esters and sterol esters used in BENECOL® and Take Control® spreads, respectively. FDA has stated that a structure/function claim made for a conventional food product (but not for a dietary supplement) must be based on “nutritive value” because foods are legally defined as consumed primarily for “taste, aroma, or nutritive value.”

The first of the two spread products to be marketed was BENECOL. Prior to going to market, the manufacturer shared its planned labels with FDA, and it was apparent that the product would be marketed as a dietary supplement. Under that planned positioning, the “nutritive value” issue would have been irrelevant. However, FDA rejected its sale as a supplement, arguing that it resembled, and would be used as, a conventional food. In repositioning BENECOL as a food, the issue of “nutritive value” became germane, as it did for Take Control, because their stanol and sterol ester ingredients, respectively, were the basis of their cholesterol structure/function claims.

Ultimately, FDA allowed both products to be marketed as conventional foods. The basis for the Agency’s conclusion that the ingredients provided “nutritive value” is that any substance added to foods also must have either taste, aroma, nutritive value, or provide a technical function (21 CFR §§172.5 (a)(1) and 182.1 (b)(1)). Of these three criteria, the stanol and sterol esters could only bear a health claim if they were found to provide nutritive value since they clearly do not contribute any of the other three.

The IFT Expert Panel agrees that stanol/sterol esters are components of food that provide health benefits in the same way that dietary fiber is viewed as providing health benefits. The beneficial effects of fiber are based on their physical and physiological effects in the gastrointestinal tract. From the standpoint of nutrient requirements, humans do not require dietary fiber; nevertheless dietary fiber provides benefits of gut motility and cholesterol binding. The cholesterol-lowering effects of the sterol/stanol esters similarly bind cholesterol in the gut to prevent their reabsorption.

**Case Study: Cranberries and Urinary Tract Health**

In presenting the Agency’s position on permissible claims for cranberries, FDA specified the proper wording for structure/function claims as well as the requirement that a structure/function claim for foods be derived from the “nutritional value” of the food. FDA did not define nutritive value in this example.

In the preamble to the Sept. 23, 1997, final rule on labeling of dietary supplements (FDA, 1997b), FDA used cranberry products’ effect on urinary tract health to illustrate the Agency’s position regarding structure/function claims. FDA noted that the claim that cranberry juice cocktail prevented the recurrence of urinary tract infections was a claim that the product would prevent a disease, and therefore would bring the product under the “drug” definition in §201(g)(1)(B) of the FDC Act. “… However, a claim that cranberry products help to maintain urinary tract health may be permissible on both cranberry products in conventional food form and in a dietary supplement form if it is truthful, not misleading and derives from the nutritional value of cranberries.”

FDA’s example prompted the cranberry industry to propose a structure/function claim regarding the beneficial effect of cranberry on urinary tract health. Although the industry had ample evidence to support such the claim and meet the “truthful and not misleading” standard, the requirement for contributing “nutritional value” remained to be determined. Unfortunately, the cranberry structure/function claim preceded FDA’s determination that the stanol/sterol esters qualified for a structure/function claim. The cranberry industry developed the position that cranberry food products contained “nutritive value” in light of FDA’s broad definition as noted in the preamble to the regulations implementing NLEA (FDA, 1993a), and thus proceeded to make claims regarding cranberry products helping to maintain urinary tract health. FDA did not object to the cranberry claim, implying that the industry’s broad interpretation of nutritive value was acceptable.

**Defining Differences in Qualified Health Claims**

The IFT Expert Panel supports scientifically defensible health and nutrition messages in the marketplace and therefore supports the concept of qualified health claims. However, consumers may be misled if qualified health claims are not adequately differentiated from approved health claims. To promote consumer understanding, the wording of qualified health claims should clearly indicate the degree of scientific support or certainty associated with a biological effect or modification of disease risk. Both FDA and the International Food Information Council are conducting research to better understand effective consumer messages regarding emerging diet and health relationships. The Expert Panel encourages the Agency to consider the information derived from these studies prior to issuing proposed rules for qualified health claims.

FDA’s interim guidelines for qualified health claims
provide limited language options for claims with varying levels of scientific evidence. The Agency is encouraged to allow flexibility in language, when equivalent language can communicate effective messages that adequately qualify the level of science supporting such claims.

As FDA has indicated, a “weight of scientific evidence” standard, tempered by the “credible evidence” test, should be applied to qualified health claims. Although the Expert Panel supports the use of any health and nutrition claims that are truthful, non-misleading, and consistent with available science, qualified health claims may be inappropriate when the supporting data are inadequate. The IFT Expert Panel recommends that FDA prohibit claims relying on “very limited and preliminary studies” and develop guidelines that protect consumers from limited scientific information. This type of claim has a high degree of uncertainty and may do more harm than good.

The following examples demonstrate how such claims might be worded.

A claim like “diets high in X may reduce disease risk Y” would require the current significant scientific agreement (SSA) standard with the totality of the publicly available evidence supporting a substance/disease relationship and SSA among qualified experts that the relationship is valid.

A claim like “most studies suggest diets high in X reduce disease risk Y” would be authorized when scientific data strongly indicate: (1) an effect or a relationship between substance X and disease Y; and (2) a low risk of negative health outcomes if consumers follow this advice. In addition, qualified experts agree that the claim statement is valid.

A claim like “emerging data indicate diets high in X may reduce disease risk Y” would be allowed if there are limited data regarding the association between substance X and disease risk Y. These claims also may be modified to include the type of studies that support the relationship (e.g., “only a few epidemiological reports …”). However, there must be agreement among qualified experts that the claim statement is valid.

In all situations, the claims should not be authorized if following the dietary advice poses a risk of negative health effects.

FDA’s interim system for qualified health claims does not use biological mechanisms. In the past, FDA recognized the value of clinical interventions, epidemiologic and mechanistic research in contributing to the totality of the evidence used to establish a diet and health relationship, both at the Keystone Dialog and in the guidance for claims that meet the SSA standard. FDA is encouraged to incorporate recommendations for mechanistic research in their evaluation system for qualified health claims.