A comprehensive U. S. Dept. of Agriculture study employed new technology to assess the antioxidant content of more than 100 foods, including fruits, vegetables, cereals, breads, nuts and spices. The study found antioxidants in many more sources than had been expected. A rapidly growing body of research continues to show antioxidants are important in maintaining health and reducing the risk of disease. Increasingly, companies want to make claims concerning antioxidants in their products. These claims can fall into any of three claim categories—nutrient content claims, structure/function claims or health claims. Another, more specific category of claim is a dietary guidance claim.

**Nutrient Content Claims**

Nutrient content claims characterize the level of a nutrient in a food. FDA regulations permit use of the term “antioxidant” in nutrient content claims for conventional food and dietary supplements. However, antioxidant nutrient content claims are limited to nutrients that already have an established Reference Daily Intake (RDI) and scientifically recognized antioxidant activity.

The following claims are authorized, if the level of each nutrient is sufficient to qualify for the terms: “high/rich in/excellent source of” (at least 20 percent of the RDI), “good source/contains/provides” (10 to 19 percent of the RDI), and “more/fortified/enriched added/extra/plus” (at least 10 percent more of the RDI per reference amount customarily consumed than an appropriate reference food). Antioxidant nutrient content claims must name the nutrient(s) referenced in the claim itself or through use of a symbol referring to a statement elsewhere on the same panel that lists the specific antioxidant(s).

The list of antioxidants must be printed in type size no smaller than half the size of the largest nutrient content claim, or 1/16 inch, whichever is larger. Beta-carotene may be listed if the level of vitamin A present as betacarotene is sufficient to qualify for the claim. In addition, the term “antioxidant” may be used to describe nutrients without RDIs, so long as the claim is true and does not characterize the level of the nutrient. Thus, it is permissible to declare the quantity of an antioxidant with no established RDI.

**Structure/Function Claims**

Structure/function claims describe the effect of a food or nutrient on the structure or function of the body but may not suggest the food is useful in the diagnosis, cure, treatment, prevention or mitigation of a disease or health-related condition. The degree of substantiation necessary for a structure/function claim is not clarified, but at minimum competent and reliable scientific evidence should support truthfulness of the claim. Antioxidant structure/function claims might include such phrases as “supports immune function,” or “helps maintain cell integrity.”

The Dietary Supplement Health and Education Act requires a disclaimer applicable to dietary supplement structure/function claims: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat,
cure, or prevent any disease.” But this is not required for conventional/functional food. The FDA takes the position that structure/function claims for a food must be based on the nutritive value of that food, which is not a requirement for dietary supplement structure/function claims. Although the FDA has not provided a definition of nutritive value in the context of structure/function claims, the agency defines nutritive value in the context of health claims as having a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients or providing energy.

**Health Claims**

Health claims characterize the relationship between a substance and a disease or health-related condition. Such a claim must be authorized by the FDA or be based on authoritative statements of a scientific body of the U.S. government submitted to the FDA. Generally, a food is not permitted to bear a health claim if it contains a “disqualifying level” of fat, saturated fat, cholesterol or sodium (levels vary depending upon the product). The FDA makes exceptions to the disqualifying nutrient levels when there is a public health benefit, such as the health claim for plant sterol/stanol esters in salad dressings and spreads and a reduced risk of coronary heart disease.

Food bearing a health claim must generally contain, prior to fortification, at least 10 percent of the Daily Value of one of the following: vitamin A, vitamin C, iron, calcium, protein or fiber. In 1993, the FDA denied a petition to authorize a health claim linking the antioxidant vitamins A, C and E with a reduced risk of cancer in conventional food. Last year, the FDA authorized a qualified health claim for the consumption of antioxidant vitamins and reduced risk of certain kinds of cancer. The claim must include one of three disclaimers, indicating that “some scientific evidence” suggests the effect, but that “this evidence is limited and not conclusive.” The FDA is currently reviewing qualified health claim petitions for antioxidants, including lycopene, tomatoes and reduced risk of cancer, and lutein and zeaxanthin and reduced risk of eye diseases (age-related macular degeneration and cataract formation).

**Dietary Guidance Statements**

Dietary guidance statements refer to general dietary patterns, practices, and recommendations that promote health, such as “diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases.” Dietary guidance statements may mention a disease/health-related condition or a substance, but not both. The FDA has no authority to approve dietary guidance statements, but such statements must be truthful and not misleading.

Leslie T. Krasny is a partner at the law firm of Keller and Heckman LLP, San Francisco office. She specializes in food and drug law, with emphasis on food safety, food labeling, ingredient evaluation, organics, biotechnology and advertising. She is a member of the California Bar and holds a master’s degree in cell and molecular biology. For more information about Keller and Heckman, visit the firm’s Web site at www.khlaw.com.