



# Health Connections

LINKING NUTRITION RESEARCH TO PRACTICE

## A FOOD LABELING UPDATE:

# Putting the “E” in the NLEA

Government efforts to confront the growing obesity epidemic – including the newly released Dietary Guidelines for Americans 2005<sup>1</sup> – coupled with a desire to provide consumers with information about the health consequences of their food choices, have resulted in major changes to the food label. Some changes allow health claims with less scientific rigor. Others include the mandatory listing of *trans* fatty acids and known allergens (see Sidebars). Future changes could place greater emphasis on the calorie content of foods and define carbohydrate content claims. This issue of *Health Connections* summarizes these new and upcoming changes and provides health professionals with information to assist clients in using food labels to improve their food choices – and their health.

### THE NLEA – CORNERSTONE TO NUTRITION LABELING

The Food and Drug Administration (FDA) regulates the label on packaged foods. The food label provides a variety of information ranging from regulated ingredient listing and manufacturer information to consumer-focused cooking instructions, serving suggestions and recipes. However, the Nutrition Facts panel – and any accompanying voluntary claims and descriptors – comprise the major elements of nutrition information authorized by the 1990 Nutrition Labeling and Education Act (NLEA).

The Nutrition Facts panel lists total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars and protein. These values are shown both as a quantitative amount per serving and, except for sugars and protein, as a percent of a dietary reference value, the Daily Value (DV). The NLEA also established regulations for health and nutrient content claims and standardized serving

sizes so consumers could compare similar food products.<sup>2</sup>

### CARBOHYDRATE CLAIMS AND DEFINITIONS

FDA initially excluded carbohydrate from being eligible for nutrient content claims, citing possible consumer confusion as dietary fiber and sugars were already included in the value for total carbohydrate. In addition, a decade ago consumer interest in carbohydrates was relatively low and claims were rarely made. The current interest in low carbohydrate diets and desire to monitor carbohydrate intake, however, have made providing carbohydrate information on labels imperative. With no standards in place, manufacturers have created a proliferation of confusing claims for newly created, reformulated or merely newly marketed food products to promote products based on their carbohydrate content. In response to consumer interest and food industry petitions, FDA plans to issue regulations on carbohydrate content claims such as “low carb,” “reduced carb” and “carb-free,” as well as guidance on the use of “net carb” by October 2005.

### LENDING PROMINENCE TO CALORIES – A RESPONSE TO THE OBESITY CRISIS

In 2004, FDA’s Obesity Working Group’s (OWG) comprehensive report “Calories Count” ([www.fda.gov/oc/initiatives/obesity](http://www.fda.gov/oc/initiatives/obesity)) outlined key

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Mary Jo Feeney, MS, RD, FADA

### HEALTH CONNECTIONS EDITOR

Mary Jo Feeney specializes in nutrition communications and marketing. With over 30 years experience in public health nutrition and education, she currently is a leading consultant to the food, agriculture and health care industries. A charter Fellow of the American Dietetic Association, Mary Jo served on the Board of Directors of both the American Dietetic Association (ADA) and its Foundation (ADAF) and received the association’s Medallion Award in 1996.

recommendations to better communicate the calorie content of foods through the food label. These changes, which still need to go through the rule-making process, include:

- Increasing the type size for calories in the Nutrition Facts panel.
- Adding a % DV column for calories to show how much a serving contributes to total daily calorie intake, based on a 2000 calorie/day diet.
- Eliminating the “Calories from fat” line, placing the emphasis on total calories rather than on fat content.
- Evaluating if commonly consumed serving sizes used in the Nutrition Facts panel need updating.
- Considering dual-column nutrition labeling for multiple-serving packages that could reasonably be consumed as a single serving, or requiring such packages to be labeled as single servings.
- Allowing comparative claims across different product categories to help consumers make healthy substitutions (see answer to second interview question on next page).

## SETTLED SCIENCE EMERGES AS NEW STANDARD FOR HEALTH CLAIMS

Health claims initially authorized by the NLEA required significant scientific agreement (SSA) among experts qualified to evaluate such claims based on the totality of publicly available scientific evidence. These claims were “unqualified.” Through the 2003 Consumer Health Information for Better Nutrition initiative, FDA acknowledged that consumers can benefit from more information on food labels. As a result FDA now permits claims based on “somewhat settled science” rather than SSA. Food products may carry these health claims provided that FDA has determined that the claims are scientifically supportable, are presented in a non-misleading way and describe the scientific uncertainty about the claim. These claims are “qualified” by a disclaimer. A listing of qualified health claims can be found on the FDA website: [www.cfsan.fda.gov](http://www.cfsan.fda.gov). Table 1 provides a brief summary of different types of label claims.

### SIDEBAR 1: MANDATORY ALLERGEN DECLARATION

The passage of the Allergen Labeling and Consumer Protection Act of 2004 requires all food labels by January 1, 2006 to declare the common name of any of the eight identified food allergens (egg, wheat, peanuts, milk, tree nuts, soy, fish, crustaceans) in a “contains” statement next to the ingredient statement. Alternatively, a parenthetical description of the allergen can be included in the ingredient list, such as “albumen (egg).” Ingredients such as spices, flavorings, colorings or incidental additives that contain a major food allergen also must be labeled.

### SIDEBAR 2: TRANS FATTY ACIDS LABELING

By January 1, 2006, all labels must list *trans* fatty acids on a separate line immediately under saturated fat if the *trans* fat is more than 0.5 g per serving or if claims are made about fat, fatty acids or cholesterol. If *trans* fat is not listed, there must be a footnote stating that the food is “not a significant source of *trans* fat.” *Trans* fat will be listed only as a gram amount. While studies have established the relationship between *trans* fatty acids and increased risk of coronary heart disease, FDA has not established a Daily Value.

**TABLE 1: TYPES OF FOOD LABEL CLAIMS**

Type	Definition	Level of Regulatory Review	Example
Nutrient Content Claim	Describes level of a nutrient in a food such as “free,” “high,” and “low” or compares levels of nutrients in different foods such as “more,” “reduced,” and “lite.”	FDA authorized.	Good (>10% DV) or Excellent (>20% DV) source of calcium.
Unqualified Health Claim	Characterizes relationship between a specific food or food component and a disease or health-related condition.	FDA authorized with Significant Scientific Agreement (SSA).	Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
Qualified Health Claim (introduced in 2003)	Describes a relationship between a food or nutrient and disease.	FDA approved with disclaimer or qualifying language indicating the level of supporting evidence. Does not meet SSA standard.	Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease.
Structure/function Claim	Describes effect a substance has on the structure or function of the body without reference to a disease.	Truthful, substantiated and not misleading but not pre-reviewed or authorized by FDA.	Calcium builds strong bones.
Dietary Guidance	Refers to a category of foods or role of dietary patterns, practices and recommendations that promote health.	Truthful and non-misleading. Not pre-reviewed by FDA.	Diets rich in fruits and vegetables may reduce the risk of some types of cancer.

In an interview with Cary Frye, Vice President of Regulatory Affairs with the International Dairy Foods Association, we explore what these label changes mean for consumers, health professionals and the food industry. Ms. Frye manages regulatory issues, including product safety and nutrition, quality control, standards of identity, labeling, and weights and measures for the dairy industry.

**Q. What is your perspective on the potential impact label changes will have – particularly those developed to address obesity – in helping consumers make healthier choices?**

A. We should consider the impact any label change has on consumers' total food choice behavior – whether changes stigmatize favorite foods, provide information so complex that it is ignored, or result in the use of supplements rather than “whole foods.” The goal of food labeling is to provide meaningful – not merely more – information.

The proposed anti-obesity changes – and potential impact – could be years away because of the rule-making process. Nevertheless, consumers can manage their weight using the current label information on serving size and calorie content per serving. Health professionals can educate clients on appropriate serving size and on how to calculate total calories if more than one serving is eaten.

**Q. How might a food label communicate to consumers that “calories count”?**

A. FDA has proposed a new health claim for “reduced” or “low” calorie foods that might say: “Diets low in calories may reduce the risk of obesity, which is associated with diabetes, heart disease and certain cancers.” In addition, FDA is encouraging manufacturers to use appropriate comparative labeling statements to make it easier for consumers to make lower calorie substitutions. An example is: “Instead of cherry pie, try our delicious low fat cherry yogurt – 29 percent fewer calories and 86 percent less fat.”

In the dairy industry, there are a variety of products lower in fat, sugar, or calories. The food label reflects these nutrient attributes in the name of the product, such as “reduced sugar, low-fat yogurt.” Scientific research suggests that dairy foods can be part of the solution to the obesity crisis. The dairy industry, therefore, has developed claims to communicate dairy's weight loss benefits such as the structure/function claim: “Adequate dairy consumption is associated with lower body weight and reduced body fat.” More information on the use of healthy weight with dairy claims can be found at [www.idfa.org](http://www.idfa.org).

**Q. Why is the provision of nutrition information on the food label a “win-win” for both the food industry and the consumer?**

A. The regulatory framework for qualified health claims offers the food industry more flexibility in providing consumers with science-based information. Products with nutrient attributes that support a substantiated claim enable manufacturers to compete voluntarily in the marketplace with products that improve the quality and variety of the food supply. The consumer, in turn, can benefit from food labels by having the information readily at hand to make informed choices to meet their health needs and goals.

**Q. What is your advice to health professionals to help clients benefit from the information on the food label?**

A. The food label offers health professionals the opportunity to implement the educational intent of the NLEA. Health professionals help make new – as well as existing – information on food labels more credible. They provide the context and science behind the numbers and claims. The food label cannot be a stand-alone source of calorie, weight management or health information. Consumers need guidance to improve their health through nutritious choices, rather than selective avoidance.



Cary Frye, Vice President of Regulatory Affairs with the International Dairy Foods Association

**REFERENCES**

<sup>1</sup>Dietary Guidelines for Americans 2005. [www.healthierus.gov/dietaryguidelines/index.html](http://www.healthierus.gov/dietaryguidelines/index.html)

<sup>2</sup>Food and Drug Administration. [www.cfsan.fda.gov/~dms/hclclaims.html](http://www.cfsan.fda.gov/~dms/hclclaims.html)

**PRACTICE POINTS FOR THE HEALTH PROFESSIONAL**

- Help clients establish health goals and individualize their diets using food label information. Consumers who know how to use the Nutrition Facts panel to compare foods will be better equipped to make appropriate choices to meet their specific health needs (e.g. low in fat and saturated fat if heart disease is a concern; high in calcium for bone health).
- Develop an educational framework for making dietary choices using the Nutrition Facts panel as a base. Other sources of information that clients can use for more specific information on food products include the company website, phone number, and pamphlets distributed at retail stores.
- Ensure that clients are making food choices in the context of a healthy diet where all foods, in moderation, can be options. Consumers may make choices based on isolated nutrient information on the Nutrition Facts panel at the expense of choosing an overall healthy diet. Other factors to consider in selecting diets include taste, cost and dietary needs and preferences of other family members.
- Educate clients on common food sources and health implications of consuming *trans* fats, in preparation for mandatory labeling in 2006. Some labels already provide this information to assist the consumer in making appropriate choices.
- Stay current with new food labeling regulations, the rule-making process and comment period through the FDA website so that you can continue to be a valuable resource to clients.