Proposed Federal Food Labeling Regulations

Implication for Diabetes Education and Care

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On 8 November 1990, President Bush signed into law the Nutrition Labeling and Education Act of 1990 (NLEA, P.L. 101–535). Sections of this act amend the federal Food, Drug, and Cosmetic Act of 1938 and include the most comprehensive changes in food labeling proposed in >50 yr.

Although still in tentative form, the proposed changes to the code of federal regulations is a significant development for dietitians, nurse educators, physicians, and other professionals providing nutrition education to people with diabetes. When implemented, the labeling will have a far-reaching impact on food choices, nutrition knowledge, and healthful nutrition practices. The regulations should clarify many of the common misunderstandings people with diabetes have about nutrient content claims.

The proposals require that nutrition information on both food labels and restaurant menus be readily understandable by the public. They also extend the coverage of nutrition labeling to nearly all food products, change the priorities of the nutrition label, produce more ingredient labeling, standardize serving sizes and nutrient content claims, and regulate health claims.

Although the Food and Drug Administration (FDA) regulates almost all food products and the ingredients that are added to foods, meat and poultry are regulated by the U.S. Department of Agriculture's Food Safety and Inspection Services (FSIS). Meat and poultry were exempted from the NLEA, but the FSIS is also issuing labeling proposals for meat and poultry. FSIS and FDA are working together to harmonize their proposals as much as possible.

The NLEA set a specific timetable for implementation of food labeling changes. FDA was required to issue proposed regulations to implement the act within 12 mo (November 1991) and to issue final regulations within 24 mo (November 1992). Final rules based on these proposals and feedback will become effective 6 mo after their final publication (approximately May 1993).

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Before NLEA's passage, the American Diabetes Association (ADA) felt it important to clarify its position on food labeling. ADA was concerned about certain misleading, though perhaps legal, food labeling. The association's view was that people with diabetes require food labels containing specific items:

1. An ingredient listing that allows consumers to know the composition of a food, i.e., whether it is mainly fat, mainly sugar.

2. Nutrition information labeling providing readily available information concerning calories (to assist in weight control and/or loss); total fat, saturated fat, cholesterol (for those with lipid abnormalities or cardiovascular disease); total carbohydrate content (to assist in regulating glycemic response); protein control (for those with renal disease); and sodium (for those with hypertension).

3. Nutrient content claims on the food label that allow people with diabetes to quickly determine whether a product is worth buying from a cost or nutritional view.

Recommendations in the ADA Position Statement on Food Labeling speak to these concerns (1). The ADA position has been shared with the FDA and, through a volunteer task force, has guided ADA's responses to FDA requests for comments to labeling proposals from 1990 to 1992. It also guides ADA's Advertising Review Panel in determining what food ads are acceptable for association journals or magazines and what food products are appropriate for ADA corporate partnerships.

FDA FOOD LABELING PROPOSED REGULATIONS— People with diabetes use information from food labels to decide what foods to purchase and con-

Table 1—*Mandatory nutrient labeling information to be included on the food label under proposed 21 code of federal regulations 101.9(c)*

NUTRITION INFORMATION PER SERVING
SERVING SIZE
SERVINGS PER CONTAINER
CALORIES PER SERVING
CALORIES FROM TOTAL FAT
TOTAL FAT PER SERVING (G)
SATURATED FAT (G)
CHOLESTEROL (MG)
TOTAL CARBOHYDRATE PER SERVING (G)
COMPLEX CARBOHYDRATE (G)
SUGARS (G)
DIETARY FIBER (G)
PROTEIN (G)
SODIUM (MG)
% REFERENCE DAILY INTAKE FOR VITAMIN A, VITAMIN C, CALCIUM, AND IRON
NUTRITION PROFILE (% OF THE DAILY REFERENCE VALUE; SEE TABLE 4)

Carbohydrate content would be calculated by subtracting the sum of the crude protein, total fat, dietary fiber, moisture, and ash from the total weight of the food. Previously, dietary fiber was not subtracted.

sume. The proposed mandatory nutrient labeling information and ingredient listing is generally considered helpful for making food choices. However, consumers often misunderstand nutrient content claims and health claims. Changes proposed by FDA, if finalized, will have far-reaching implications. The following summarizes the food labeling proposals pertinent to diabetes mellitus, indicates how they compare with ADA's position, then describes some implications for health professionals.

Nutrition information label

Table 1 lists the proposed *mandatory* nutrient labeling information to be included on the food label, and Table 2 provides an example of simplified nutrient information format that could be used in special cases. Of particular interest are the proposed regulations for serving size, total carbohydrates per serving, and the new terms *reference daily intake* (RDI) and *daily reference value* (DRV).

Serving sizes. The FDA proposes to define serving and portion sizes on the basis of the amount of food customarily consumed in a snack or meal. It would also establish reference amounts customarily in a snack or meal for 131 food product categories. Serving sizes are to be identified by common household measures and, parenthetically, by metric amounts (e.g., one cup [240 ml]). Individual serving containers that contain less than two servings (i.e., <200% of the reference amount) will be required to base the nutrition information on the contents of the entire container.

The ADA position statement also indicates that servings should be of the size typically used, in a common household measure, and in standardized form. Many people with diabetes use meal planning methods such as the American Dietetic Association's and ADA's *Exchange Lists for Meal Planning* and *Healthy Food Choices*, in which the food amount is geared to an average amount of carbohydrate, protein, fat, and calories. Because the FDA chose not to use serving sizes as defined in the exchange system, some serving sizes will not correspond (Table 3).

Carbohydrate per serving. The NLEA has proposed that both sugars and complex carbohydrates be listed on the nutrition information part of the label. To facilitate this, the FDA is proposing chemical definitions for these two words:

- Sugars are the sum of all free mono- and oligosaccharides through four saccharide units (such as glucose, fructose, lactose, sucrose, and glucose polymers up to four saccharide units) and their derivatives. . .that have similar sweetening, nutritional, and metabolic effects (such as sugar alcohols) (proposed 21 Code of Federal Regulations [CFR] 101.9(c)(6)(ii)(A)).
- Complex carbohydrates are defined as the sum of dextrins (saccharide units of ≥10) and starches (proposed 21 CFR 101.9(c)(6)(i)).

When sugar alcohols are present in the food, sugar alcohol content must be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of mannitol, sorbitol, xylitol, and any other sugar alcohols that meet the above definition of sugars (proposed 21 CFR 101.9(c)(6)(ii)(B)).

The ADA position statement indicated that sugars and complex carbohydrate should be optional in the nutrient labeling information. ADA chose optional rather than mandatory declaration for these terms because there was no official commonly accepted terminology. Internally, the diabetes community itself has not used consistent terminology for components of carbohydrate. For example, the ADA Position Statement on Food Labeling uses *simple sugars* and *starches*, whereas the glossary to the *Exchange Lists for Meal Planning* uses *sugar* and *starch*. Adding to the confusion, the FDA has traditionally held (and still does) that sugar in an *ingredient list* means sucrose and does not include any

Table 2—*Example of simplified nutrient information format permitted under proposed 21 code of federal regulations 101.9(c)*

NUTRITION INFORMATION PER SERVING	
SERVING SIZE	12 FL. OZ. (360 ML)
SERVINGS PER CONTAINER	1
CALORIES	145
TOTAL FAT	0 g
TOTAL CARBOHYDRATE	36 g
SUGARS	36 g
PROTEIN	0 g
SODIUM	20 mg

The Food and Drug Administration proposes a simplified nutrient information format for labels in which core nutrient requirements (total calories, total fat, total carbohydrate, protein, and sodium) are included but other nutrients do not need to be declared if they are present in insignificant serving amounts. The table above shows a simplified format for a soft drink. From the *Federal Register*, 27 November 1991, p. 60375.

Table 3—*Comparison of proposed Food and Drug Administration (FDA) serving sizes for some reference foods and serving sizes in Exchange Lists for Meal Planning*

Reference foods	Reference amount, FDA	Exchange Lists amount
Butter, margarine, oil shortening	1 Tbsp	1 tsp
Crackers	15 g	Varies, usually more
Cereals (hot)	1 cup	1/2 cup
Rice (prepared)	140 g	Approx 70 g (1/3 cup)
Juices	1 cup	Varies (usually 1/3–1/2 cup)
Nuts and seeds	40 g	Varies (usually 7–10 g)

Data from Data Base for Exchange Lists for Meal Planning, Appendix p. 51–77, from the American Diabetes Association, and The American Dietetic Association: *Nutrition Guide for Professionals, Diabetes Education and Meal Planning*. Alexandria, VA, 1988.

other sugars. Thus, in the past, foods containing sweeteners other than sucrose could be labeled sugar free. Common terminology/definitions make mandatory declaration of sugars and complex carbohydrate more useful.

The new FDA definitions adequately address many of ADA's concerns about misleading information on food labels related to carbohydrate. Clearly, fructose and sugar alcohols are included in the proposed definition of sugars, and thus would need to be labeled appropriately.

RDI and DRV. FDA proposes to replace the current U.S. recommended dietary allowances (U.S. RDAs), established by 1974, with the RDI and DRV. The change is meant to give consumers a firmer basis for comparing the nutrition content of foods.

The RDI is a population-adjusted mean of the National Academy of Science/National Research Council's RDAs (2). FDA considers the RDI a more meaningful benchmark for the intake of certain nutrients than the U.S. RDAs. It represents intake levels of a nutrient that should be achieved. FDA must set these levels to regulate food fortification and the nutritional equivalency of imitation foods.

Currently, labels are required to carry the percentage of the U.S. RDA for many nutrients. This standard was developed when there was substantial concern with helping consumers avoid frank nutritional deficiencies. Today, however, when deficiencies are less common than in the past, the main emphasis of nutrition information is achieving the optimum diet to promote and maintain health (3,4). Reflecting this trend, the FDA proposes to put less emphasis on daily allowance by requiring the percentage of RDIs only for vitamin A, vitamin C, calcium, and iron (Table 1). Other vitamin and mineral RDIs will be optional.

The NLEA requires that the nutrient labeling part of the food label enable consumers to understand how a food product would fit into a total daily recommended diet. As a result, the FDA has proposed a new term, the DRV, to represent food components for which the leading consensus reports have provided quantitative recommended intakes (3,4). The FDA has proposed DRVs for eight food components (total fat, saturated fat, unsaturated fat, cholesterol, carbohydrate, fiber, sodium, and potassium). Intakes are usually described as a percentage of calorie intake for measurement (e.g., ≤30% of calories from fat), though sodium, potassium, and cholesterol DRVs are independent of calories. The FDA is *not* proposing a DRV specifically for sugars or complex carbohydrate because the consensus reports did not provide a quantitative recommendation for their intakes.

The DRVs are based on a reference diet of 2350 kcal, which is the population-adjusted mean of the recommended energy allowance for people ≥4 yr of age. As shown in Table 4, some DRVs, such as that for fat, give consumers maximum recommended intakes. Others, such as that for potassium, represent minimum intakes. The DRV is a contrived number that may have little relationship to the total food energy requirements for any given person. For example, many people with diabetes are on weight-reduction diets of perhaps 1200–1500 kcal. If the reference value of 2350 kcal/day is used, health educators will need to educate their patients about information derived from the DRVs. The DRVs on the food label may be too high for a person on a weight-loss diet.

Ingredient listing

Ingredient listings will continue in their current format, with ingredients listed in descending order by weight. Previously, foods with standards of identity defined by the CFR were not required to list ingredients (e.g., peanut butter). Proposed 21 CFR 101.4(a)(1) now requires even these foods to declare ingredients on the label.

FDA proposed that when more

Table 4—*Daily reference values (DRVs)*

Food Component	Unit of measurement	DRV
Total fat	Grams	75
Saturated fat	Grams	25
Unsaturated fat	Grams	50
Cholesterol	Milligrams	300
Total carbohydrate	Grams	325
Dietary fiber	Grams	25
Sodium	Milligrams	2400
Potassium	Milligrams	3500

The above DRVs are established for food components based on a reference caloric intake of 2350 kcal. Note that the caloric contribution from protein is assumed to be ~15%.

than one sweetener is used in a product, the common or usual name of each will be in a parenthetical list in descending order by weight following the term *sweeteners* in the ingredient statement. *Sugar* in the ingredient listing only refers to sucrose (proposed 21 CFR 101.4(a)(21)).

Nutrient content claims

People with diabetes may benefit from foods in which the content of certain nutrients has been reduced (as with sugar or fat) or increased (as with fiber). Unfortunately, consumers with diabetes often misunderstand nutrient content claims.

Section 3 of the NLEA addresses this issue by adding a section to the Food, Drug, and Cosmetic Act stating that a food is misbranded if it bears a claim in its label or labeling that expressly characterizes the level of a nutrient, unless such claim has been specifically defined (or otherwise exempted) by regulation.

One of the major focuses of the ADA Position Statement on Food Labeling was misunderstanding by consumers and even educators about undefined nutrient content claims. ADA was particularly concerned about claims such as "light" or "low sugar" that imply a product is reduced in calories when in fact it is not. It was also concerned with products labeled "no sugar" or "low sugar" that contain concentrated fruit juice, sugar alcohols, or other caloric sweeteners.

The FDA has proposed comparative claims definitions for nine core terms, called *descriptors* or *nutrient content claims*, that can be used to describe a food. These are: *free*, *low*, *reduced*, *less* (or *fewer*), *light* (or *lite*), *high*, *source of*, *more*, and *fresh*.

Free, *low*, *reduced*, and *less* are defined for calories, sodium, total fat, saturated fat, and cholesterol. *Free* and *less* are defined for sugars.

Light is defined as 33.3% fewer calories; if more than half of the calories are from fat, fat must be reduced by at least 50%. *More*, when used to describe protein, vitamins, minerals, dietary fiber, or potassium, is ≥10% of the DRV or RDI. For carbohydrates and unsaturated fat, more means ≥4% of the DRV.

Source is 10–19% and *high* is ≥20% of the RDI or DRV. *Fresh* is a raw food that has not been frozen, heat processed, or otherwise preserved.

Relative claims such as *reduced*, *light*, and *low* must be accompanied by a statement that compares the food for which the claim is made to a specified reference food.

Absolute claims proposed by the FDA include *sugar free* or *calorie free*.

Sugars free. The term *sugars free* (proposed 21 CFR 101.60(c) indicates the absence (<0.5 g sugars/serving) of total sugars, not just sucrose. This means that products containing, e.g., maltodextrin or polydextrose (at least 10% of polydextrose by weight qualifies as sugar) cannot be labeled sugar free. In addition, any food bearing a statement about the absence of sugars must bear a statement indicating that the food is not low calorie or calorie reduced unless the food meets the requirements for a low or reduced calorie food.

FDA proposes five terms as synonyms for sugars free: *no sugars*, *zero sugars*, *no added sugars*, *without added sugars*, and *no sugars added*. Under the FDA's proposed definition of sugars, a product with added ingredients such as jam, jelly, concentrated fruit juice, or sugar alcohols (polyols) could not be labeled with any of the above terms. The ADA position statement is equivalent with the above interpretation.

Calorie free. Calorie free (proposed 21 CFR 101.60(b)(1)) means <5 kcal/serving.

Cholesterol free. The FDA proposes that, if a food is inherently free of or low in cholesterol the food must be labeled to refer to all foods of that type and not to a particular food. For example, canola oil, *a cholesterol-free food*, contains 14 g fat/serving. In addition, the food must contain ≤2 g saturated fat/serving. The ADA position statement specifically addressed this term and expressed concern that cholesterol free had sometimes been used to imply that cholesterol had been removed from the food when, in actuality, the food never contained cholesterol.

Low (and synonyms little or few, small amounts of, low source of). FDA is proposing to define *low* for total fat, saturated fat, cholesterol, and sodium but not for sugars.

- Low sodium is proposed to be ≤140 mg/serving and per 100 g and very-low-sodium will be ≤35 mg/serving and per 100 g.
- Low fat foods are proposed to be those containing ≤3 g fat/serving and per 100 g. Percent fat free claims are proposed only for use on foods or meals that meet the proposed definition of low fat.
- Low saturated fat claims are proposed to be for foods containing ≤1 g saturated fatty acids/serving and not >15% of calories from saturated fatty acids.
- Low cholesterol is proposed to mean ≤20 mg/serving and containing ≤0.2 mg cholesterol/g food.
- The low calorie definition will stay the same. It has been defined previously in the CFR as a food containing ≤40 kcal/serving. In addition, low-calorie foods (except for sugar substitutes) must contain no more than 40 kcal/100 g food. Note that many sugar substitutes contain >40 kcal/100 g; however, they have considerably less weight per percentage of total weight than other foods and so are excluded from the second part of the definition.

Reduced. FDA proposes to define *reduced* for all specified nutrients (total fat, saturated fat, cholesterol, and sodium) as 50% of amounts in an unmodified reference food. In the case of calories, reduced would mean a reduction of at least 33.3% and a minimum reduction of 40 kcal/serving (present 21 CFR 105.66(d)) recodified as 101.60(b)(4). The term *reduced sugars* is not being defined and thus cannot be used on labels.

Light or lite (proposed 21 CFR 101.56). Most consumers believe that the calorie level has been reduced if light or its synonym lite is used. Therefore, FDA proposes to prohibit either term from being used to describe a food that is not reduced in calories by 33.3% and, if applicable, in fat by 50%, unless it describes a physical attribute of the food and descriptive qualifying information (light in color, light in texture) is used. The qualifying information must be in the same size, type, style, color, and prominence as the word light and must be in the immediate proximity of it. The claim must also cite a reference food. Note that for a food in which fat contributes ≥50% of the calories, a food may only be labeled light if it contains 33.3% fewer calories and 50% less fat.

Some long-standing uses of the term light (or lite) to characterize the particular nature of a few products will be allowed. Thus, corn syrup and molasses may still be labeled as light and dark.

Diet. Current law allows use of the term *diet* only when a food is represented as being useful for reducing caloric intake or reducing or maintaining body weight. Thus, *diet* can be used only if the food is labeled low calorie or reduced calorie. This is in agreement with the ADA Position Statement.

Health professionals and people with diabetes will be interested to note that diet soft drinks are a specific exception (at least if the word diet was in the brand name of the soft drink before 25 October 1989). Diet Coke and Diet Pepsi are safe from labeling changes.

Less or fewer. Some foods are significantly reduced in level of certain nutrients, but not as much as the reduced definition requires. A decrease in the level of the nutrient that is ≥25% compared with the reference food can be labeled less or fewer. Less sugars will be an allowed nutrient content claim, provided it meets the above criteria (proposed 21 CFR 101.60(c)(4)).

Although the above proposed definitions for nutrient content claims are for individual foods, the FDA is also proposing rules for nutrient content claims for meals, such as frozen meals. Restaurants that use content descriptors such as light or low on a menu must comply with FDA regulations as well.

The FDA has limited proposed definitions to nutrients for which there are proposed DRVs, the exception being the term *sugars free* and terms relating to caloric levels in foods. This approach should have the advantage of linking nutrient content claims to established reference values, thereby providing a consistent definition. Consistency of definition can help health professionals clear up consumers' confusion about many of the terms.

Health claims

In general, FDA proposes that health claims must address a particular diet-related disease or condition for which the U.S. population or an identified subgroup is at risk. If health claims do not address a diet-related disease, they must explain the prevalence of the disease or health-related condition in the U.S. and the relevance of the claim to total daily diet.

Claims will be considered in the areas of calcium, fiber, sodium, and fat. Specific messages written by the U.S. Public Health Service will be the only health messages allowed on the label. Furthermore, the proposed regulations require that health claims and nutrient content claims made for restaurant foods must meet requirements for such claims, with the exception that nutrition labeling is not required to accompany the claims.

IMPLICATIONS — The above interpretation of the FDA proposed food labeling regulations is a brief summary. For in-depth information, as well as for background information and exemptions, refer to the *Federal Register* of 27 November 1991 (p. 60366–60878) and 21 June 1991 (p. 28592–28636). The latter involves the ingredients listing; the former, everything else discussed.

All of the above FDA proposals (except those now in the CFR) are still tentative. Final rules will take into consideration comments received from consumers, industry, voluntary and professional organizations, and others. The full set of FDA labeling proposal changes have the potential to have wide-reaching impact on food choices, nutrition knowledge, and healthful nutrition practices. The costs to implement these sweeping changes are significant.

The FDA proposed regulations address most, if not all, of ADA's concerns about food labeling, as identified in its Position Statement on Food Labeling. With the proposed definitions of sugars and complex carbohydrates and with the proposed absolute, relative, and comparative claims definitions, labels should be much less misleading. Specifically, the proposed FDA rules address many of the common misunderstandings and confusion people with diabetes have about nutrient content claims. For example:

- Sugars free would have a quantitative definition.
- Fructose and sugar alcohols would be tied to the sugars definition and so foods containing them could not be mislabeled as sugar free.
- Words such as *no added sugars*, *without added sugars*, or *no sugars added* could not be used on labels if the product contains added ingredients such as concentrated fruit juice.
- Light and lite have proposed definitions that are tied to reduced calorie definitions.

More complete labeling can result in the classification of many more foods in terms of exchanges. People with diabetes can also use the information to select for use of a wider variety of foods in their meal plans.

A goal of FDA in revamping food labels is to encourage product innovation. Health professionals must be continually alert to new products being de-

veloped, particularly those with a focus toward people with diabetes.

Consistency of definitions for nutrient content claims will facilitate education efforts and may reduce confusion concerning the overall use of the terms. However, the need for basic diabetes and nutrition education is still paramount. As stated in the ADA Position Statement: "To properly use the information imparted by food labels, consumers must be educated about and must understand basic principles of good nutrition and how to use food-label information. Food labels cannot compensate for inadequate nutritional knowledge. This is particularly true for people with diabetes who must be knowledgeable about foods in relation to diabetes management."

Health professionals working with patients who have diabetes must educate themselves about the new labeling regulations so they can assist their patients or clients to be knowledgeable consumers. Products interpreting this new information for health professionals and for education of consumers are being developed and should be available as soon as the regulations are final. One example is the National Food Processor Association's Food Label Education Project. This project will produce an educational kit for consumer educators including an educator's resource guide, reproducible information sheets, reproducible slicks of a consumer brochure, and a diskette containing text and graphics so that educators can customize information. More than 40 organizations, including ADA and its Council on Nutritional Sciences and Metabolism and Council on Education, have reviewed materials. The product should be ready in early 1993 as the new labeling goes on the supermarket shelves. (Contact ADA's Division of Medical and Scientific Affairs for further information.)

A food labeling revolution is in process. Although we know the FDA proposals, we are not yet sure of the specific final outcomes. ADA has a food labeling position and has input into the FDA regulatory process. Whatever happens, consumers with or without diabetes mellitus will benefit.

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