

## Implications for Nutrient Databases

Janet McDonald, PhD, RD  
US Food and Drug Administration  
Millbrae, California

### BACKGROUND

On March 7, 1989, Louis W. Sullivan, Secretary of the U.S. Department of Health and Human Services, calling the current food label a "Tower of Babel," announced plans for a comprehensive food labeling initiative to be undertaken by the Food and Drug Administration. In the *Federal Register* of August 8, 1989 (54 FR 32610), FDA published an advance notice of proposed rulemaking (ANPRM) that solicited public comment on a wide range of food labeling issues to help the agency determine what, if any, changes in food labeling requirements were needed to make the food label more useful and understandable to consumers. During October to December, 1989, FDA held four public hearings in Chicago, IL, San Antonio, TX, Seattle, WA, and Atlanta, GA, respectively, each focusing on a different aspect of food labeling. In the fall of 1989, in conjunction with the U.S. Department of Agriculture (USDA), FDA contracted with the National Academy of Sciences' Institute of Medicine to review current food labeling policies and recommend options for improvement. This latter effort resulted in the publication of the report entitled "Nutrition Labeling: Issues and Directions for the 1990s" (NAS-IOM, National Academy Press, Washington, D.C., 1990).

In the February 13, 1990 *Federal Register* (55 FR 5176), FDA published a reproposal of its health messages regulation, withdrawing its August 4, 1987 proposal. On July 19, 1990, FDA published in the *Federal Register* (55 FR 29476) proposed regulations on (1) Reference Daily Intakes and Daily Reference Values, (2) the mandatory status of nutrition labeling and nutrient content revision, and (3) serving sizes. These proposed rules comprised Phase 1 of FDA's food labeling initiative and incorporated comments from both the ANPRM and the four hearings. Written

comments to the three proposals were solicited by the deadline of November 16, 1990. (In the same issue of the *Federal Register*, a tentative final rule on cholesterol labeling was published with a 30-day comment period.) On November 8, 1990, however, President Bush signed into law the Nutrition Labeling and Education Act of 1990 (Public Law 101-535), hereafter referred to as the NLEA or the Act, which amends the Federal Food, Drug, and Cosmetic Act "to prescribe nutrition labeling for foods, and for other purposes." The law supercedes the labeling regulations proposed by FDA. Thus, while there are many similarities between the NLEA and FDA's proposed rules, there are sufficient differences that reproposals or supplemental proposals must be made for legal and other reasons. This will necessitate the publication of more than 25 documents before the November 8, 1992 deadline for all final regulations that Congress imposed on FDA. If final regulations are not published by that date, then the proposed regulations will serve as final rules.

### NUTRITION LABELING AND EDUCATION ACT OF 1990

The major provisions of the NLEA are summarized in the appendix. Of particular note, although there are some exemptions, nutrition labeling will be required on most FDA-regulated packaged foods. Moreover, the Act calls for retailers to provide labeling information voluntarily for the 20 most frequently consumed varieties of raw fruit, vegetables, and finfish/shellfish.

In addition to the total number of calories per serving, the calories derived from total fat per serving must be declared for foods subject to mandatory labeling. The amount of the following nutrients must also be disclosed: total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates,

sugars, dietary fiber, total protein, and such vitamins, minerals, or other nutrients determined by the Secretary to be important in assisting consumers to maintain healthy dietary practices. Except for the mandatory declaration of complex carbohydrates and sugars, the NLEA contains the same nutrient labeling requirements as described in FDA's July 19, 1990 proposed regulation. The Act, however, is flexible in that it states that the Secretary may by regulation add or delete nutrients from the required list, if it is determined that such information may/may not assist consumers. Thus, it is likely that comments will be solicited regarding the declaration of complex carbohydrates and sugars. Definitions for the two terms must be established, and appropriate methods must be developed for monitoring compliance should label declaration of these components be required by the final regulation.

With regard to the mandatory declaration of saturated fat, this term also must be defined. Evidence that stearic acid does not appear to have the same cholesterol-raising propensity as other saturated fatty acids raises the question whether it should be considered a saturated fatty acid. Moreover, how should trans fatty acids be handled for labeling purposes?

Other uncertainties must be resolved with respect to dietary fiber declarations, particularly if a manufacturer wishes to highlight the content of soluble/insoluble fiber in a product. The analytical problems associated with dietary fiber measurements are discussed in the previously mentioned NAS-IOM report on nutrition labeling.

Although, heretofore, declaration of nutrients on labels has been based on analytical testing of products, in a 1979 ANPRM, FDA and USDA set forth a policy encouraging the use of properly evaluated databases for all appropriate segments of industry. Nutrient databases will constitute the means by which retailers will be expected to provide nutrition labeling information for the 20 most frequently consumed raw agricultural commodities and fish. FDA is prepared to review and evaluate analytical data generated by trade associations, or other groups, for possible approval. Presently, nutrient data are lacking for many of the several hundred species of fish and shellfish, and the extent of "natural" variation of nutrients in raw fruit, vegetables, and fish based on such factors as variety, season, source, size, and age is largely unknown.

One of the major issues with respect to the NLEA is harmonization. Not only is it important for FDA to work with USDA, which has recently announced its own labeling initiative for meat and poultry products, but we must also strive to harmonize our labeling

requirements with those of Canada (with whom the United States has a free trade agreement), the European Community (which will represent a powerful economic block in 1992), and possibly Mexico (should a free trade agreement be established with that country).

#### IMPLICATIONS FOR NUTRIENT DATABASES

Regarding the effect of the NLEA on databases, there is some potentially bad news, but mostly good news. The nutrients required to be declared by the NLEA will likely affect the analyses performed by or for the food industry and, ultimately, determine what goes into databases. Laboratory analyses are costly. With the proposed withdrawal of mandatory listing of thiamin, riboflavin, and niacin, for example, product analyses for these nutrients may not be performed. This could hamper dietary intake calculations not only for patients/clients but also for various research purposes, including epidemiological studies and food consumption surveys. In addition, modification of industry nutrient database systems will be necessary. Computer programs will need to reflect the new requirements for serving sizes and nutrition label content as well as for ingredient listing.

From a positive standpoint, however, because nutrition labeling will be mandatory for most foods, more analytical data will be generated, and eventually, there will be far more brand name product information available for inclusion in databases. Moreover, the new requirement for listing of such components as saturated fat, cholesterol, and dietary fiber will result in the narrowing of some data gaps. Thus, the completeness and accuracy of nutrient databases should improve because the problem of missing data or having to impute values from similar foods will be resolved to a large extent.

By November 8, 1992, FDA plans to have available a revised version of its "Compliance Procedures for Nutrition Labeling." There will be a new publication entitled "FDA Nutrition Labeling Manual: A Guide for Using Databases", which will give alternatives to current procedures.

## APPENDIX

Summary of H.R. 3562, as amended  
Nutrition Labeling and Education Act of 1990

PUBLIC LAW 101-535 NOVEMBER 8, 1990

----Requires disclosure of:

- serving size in a common household measure
- # of servings per container
- # of calories per serving
- # of calories derived from total fat per serving
- Total amount of fat, saturated fat, cholesterol, sodium, sugars, dietary fiber, protein, total carbohydrates and complex carbohydrates
- Total amount of important vitamins and minerals
- *Percentage of fruit or vegetable juice contained in beverages (information panel)*
- *Mandatory ingredients in standardized foods (Effective Date 11/8/91)*
- Certified colors in ingredients list

----The Secretary may add to or delete from the above mandatory list of nutrients.

----The above labeling information would be required to be provided by retailers for the 20 most frequently consumed types of raw agricultural commodities, raw fish and shellfish if retailers fail to provide such information voluntarily. Retailers may provide this information in a single location in their store.  
Effective date for voluntary labeling: 11-8-91.

----Food exempted from the labeling requirement:

- Food sold in restaurants
- Food sold at prepared food counters in grocery stores
- Infant formula
- Medical foods
- Food sold in bulk between wholesalers
- Food sold in small packages have a partial exemption
- Food with insignificant amounts of nutrients
- Food sold by merchants with total sales of not more than \$500,000/year or food sales not more than \$50,000/year

----Except as noted above, regulations to implement these nutrition labeling requirements must be promul-

gated within 24 months and must, among other things,

- permit the voluntary addition of nutrition information of the same type that is required by law.
- permit nutrition information and labeling to remain the same on similar foods or foods packed as an assortment, even though there are minor nutritional variations among such foods.
- require the nutrition information to be presented in a manner which enables consumers to understand the relative significance of the information in the context of a total daily diet.

----Removes food standards (except those for dairy products and maple syrup) from formal rulemaking requirements.

----Nutrient Content Claims

- A claim which characterizes the level of one or more of the required nutrients (such as high fiber, low sodium, or no cholesterol) is allowed only if the characterization of the level uses terms which are defined by the Secretary.
- No claim with respect to cholesterol may be made if the food contains an amount of fat or saturated fat that increases the risk of a health-related condition or disease, except under certain limited circumstances.
- No claim with respect to saturated fat may be made if the food contains cholesterol, unless the amount of cholesterol is disclosed with the claim.
- No claim with respect to dietary fiber may be made, unless the food is low in total fat or the level of total fat is disclosed in the claim.
- For all nutrient content claims, a statement directing the consumer to the nutrition information panel must appear in appropriate proximity to such claim, and if the product contains any other nutrients in amounts that increase the risk of a health-related condition or disease, the statement must identify the nutrient.
- The Secretary must define "free", "low", "light/lite", "reduced", "less", and "high".
- Regulations must be promulgated in 24 months.

----Health Claims

- A claim which characterizes the relationship of one or more of the required nutrients to disease (such as fiber preventing cancer, or low cholesterol preventing heart disease) may only be allowed if such claim is authorized by the Secretary as scientifically valid, and if the other

required nutrients are present in amounts which do not increase the risk of a health-related condition or disease (unless the Secretary finds that the claim would assist consumers).

- Claims involving voluntarily labeled nutrients must be made in the same manner as with claims for nutrients required to be on the label.
- The Secretary will determine the appropriate standard and procedure for claims made regarding vitamins, minerals and other dietary supplements.
- Regulations must be promulgated in 24 months.

----State Enforcement

- States are authorized to enforce these new labeling requirements on behalf of the Federal Government (30 days advance notice required).

----National Uniformity

- The bill provides for national uniformity in nutrition labeling and claims and in certain other labeling matters.

----Implementation Date

- Except as noted, labeling regulations must be implemented by May 8, 1993.