UPDATE ON FOOD LABELING

Donna A. Dennis

Office of Nutrition and Food Sciences
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington, D.C.

Abstract

The publication of the 1988 "Surgeon General's Report on Nutrition and Health" and the 1989 National Academy of Sciences report, "Diet and Health: Implications for Reducing Chronic Disease Risk," together with increasing public interest in food label reform, has led to activities by government organizations to change the way food is labeled. In 1989, the Food and Drug Administration undertook a comprehensive initiative to revise the food label. This initiative addressed issues of nutrition labeling content and format, ingredient labeling, food descriptors and food standards, and health messages. The agency held four public hearings across the country in 1989, and in response to testimony at these meetings and written comments to the agency, has developed a three-phase approach to respond to these issues. Congress is also developing food labeling bills. The Waxman bill (H.R. 3562 Nutrition Labeling and Education Act of 1990) provides for mandatory nutrition labeling of food and specifies conditions and a petition procedure for using nutritional content claims and health claims on food labels.

Introduction

The area of food labeling has been extremely active, particularly during 1989, and some results from this activity may be visible soon. These include publication of proposed new regulations related to nutrition labeling and passage of a Nutrition Labeling Bill by Congress. Because of the volume and diversity of activity in the area of food labeling, I will summarize some of the food labeling activities of this past year and some of the expected outcomes of these activities. I will discuss in somewhat greater detail the Nutrition Labeling and Education Act of 1990 and the agency's current regulations and proposed regulations that would be affected by this act.

Since the last major revision of the food label, which took place in 1973, scientific knowledge about the relationship between diet and health has grown dramatically. In particular, the 1985 Dietary Guidelines, "Nutrition and Your Health: Dietary Guidelines for Americans" (USDHHS-USDA, 1985), the 1988 "The Surgeon General's Report on Nutrition and Health" (USDHHS, 1988), and the 1989 National Academy of Sciences (NAS) report, "Diet and Health: Implications for Reducing Chronic Disease Risk" (NRC, 1989), all emphasize the importance of diet in the risk for certain chronic disease. These publications include recommendations for diet modification and in some cases for information on the food label as well. Public interest in food label reform has increased steadily throughout the 1980s and has led to activities supporting changes in food labeling.

FDA Labeling Initiative

In July 1989, the Secretary of the Department of Health and Human Services (DHHS), Dr. Louis W. Sullivan, asked the Food and Drug Administration (FDA) to consider "sweeping changes" in the way foods are labeled, and directed the agency to undertake a comprehensive initiative to revise the food label.

On August 8, 1989, FDA announced its labeling initiative and requested public comment in five subject areas. The agency specifically requested comments on the following:

1. Whether to revise the requirements for nutrition labeling;
2. Whether to change the nutrition label format on food packages;
3. Whether to revise the requirements for ingredient labeling;
4. Whether to formally define commonly used food descriptions and/or reconsider the use of food standards of identity; and
5. How to reasonably permit the use of messages on food labels that link food components to the prevention of disease.

The agency requested public comment on specific issues in these areas.
As part of its labeling initiative, FDA held four public hearings in late 1989 to receive additional public comments on these topics. The hearings were held in Chicago, San Antonio, Seattle, and Atlanta. FDA also held approximately 50 Consumer Exchange meetings across the country to receive additional responses on these food labeling issues.

The agency received over 2600 comments on its labeling initiative, including testimony from 197 presenters at the four public hearings and summaries of responses from over 1600 participants in the Consumer Exchange meetings. In addition FDA received over 5500 responses to a questionnaire developed by the Center for Science in the Public Interest.

FDA has evaluated these comments and responses. I will touch on some of the major trends from the comments. However, a more complete breakdown of the response on different issues is available from this office.

The public comments indicated strong support for FDA to require nutrition labeling on most foods. They also supported increased labeling of certain food components (fatty acids, cholesterol, and fiber), as well as a more readable label format, uniform nationwide nutrition labeling, formal definitions of descriptors such as "low fat" and "high fiber," and consumer education to explain changes in the food label. Other requested changes included addressing the "and/or" labeling of fats and oils, deleting the required listing of certain vitamins and minerals on the nutrition label, and requiring more complete ingredient labeling.

One area of significant disagreement was how to resolve the issue of health messages. Although commentors expressed widespread agreement on the need to resolve the health message issue, there was a divergence of opinions about whether to permit health messages of any kind on food packages. Nutritionists, health educators, state officials, and many consumers expressed concern about the accuracy of health messages and claimed that health messages are misleading and unbalanced. Industry and trade associations favored health messages and stressed their value as an educational tool for consumers. They focused on the need for a uniform national policy and their opposition to preclearance of health messages or predetermined limitations on the subjects for health messages. They also expressed opposition to the standard of scientific community consensus on the ability of scientific data to support health messages. Industry criteria for acceptable documentation of health messages ranged from "weight of evidence" to "good reason to believe."

FDA Response

FDA has developed a three-phase approach for responding to the issues addressed in the hearings. In the first phase (completed by mid-1990), the agency published several proposals in the Federal Register of July 19, 1990, relating to revisions of nutrition labeling, the update of the U.S. Recommended Daily Allowances (U.S. RDAs), and the establishment of standard serving sizes. The agency also initiated development of alternative formats that consumers might find more useful or understandable. In nutrition labeling, the agency has required nutrition labeling on most foods, with exemptions for some food categories; revised the list of nutrients required on the nutrition label (e.g., added saturated fatty acids, cholesterol, and calories from fat); and made optional some

currently required nutrients (e.g., thiamine, riboflavin, and niacin).

In the second phase (to be completed in late 1990), FDA intends to publish proposed regulations defining descriptors, including fat and fiber descriptors. It also intends to address ingredient labeling issues, such as whether percentage listing of ingredients should be required; whether specific flavors, colors, and spices should be declared; and whether all sugars in a product should be labeled together. The agency also intends to initiate consumer testing of alternative nutrition label formats to determine which format best communicates nutrition information to consumers.

In the third phase (to be completed in 1991), FDA intends to propose revisions to the nutrition label format that have been identified through previous consumer market research and to evaluate public concerns about food standards.

In addition to these activities, FDA is also completing rulemaking on cholesterol descriptors and health messages.

Activities of Other Groups

FDA is not the only organization involved in the current activities in food labeling. The Institute of Medicine of the NAS is completing a scientific investigation of food labeling under contract to the U.S. Department of Agriculture (USDA) and DHHS. Its final report is expected in the fall.

In addition there is considerable activity in the area of label harmonization: between FDA and USDA, between the United States and Canada (under the U.S.-Canada Free Trade Agreement), and between the U.S. and the European Community. The results from the NAS investigation of food labeling are expected to facilitate these negotiations.

Another area of activity involves the states, both legislatively (e.g., Proposition 65) and in state regulatory actions against product labels, especially in the area of health messages.

State activity in food labeling is of considerable concern to industry, which wants Federal preemption for food labeling. Industry has expressed concern about the prospect of preparing a different food label for a product for each of the 50 states.

Finally, one very important area of activity in food labeling is that of Congress. Currently, Congress is considering two nutrition labeling bills: the Metzenbaum bill, S. 1425; and the Waxman bill, H.R. 3562. These bills have been reported out of Committee in their respective arms of Congress. Their differences may be resolved in the near future and the resulting bill sent forward for presidential signature. These bills cover not only quantitative nutrition labeling, but also conditions for use of descriptors and health messages on food labels. If such a nutrition labeling bill is enacted, FDA must initiate new proposed regulations to implement the new Act. Therefore, I will describe some of the salient features of one of these bills (the Waxman bill as it appeared after Committee markup) and compare existing and proposed FDA regulations to the provisions of this bill.

The Waxman Bill

The Waxman bill (H.R. 3562, Nutrition Labeling and Education Act of 1990) provides for mandatory nutrition labeling of food and specifies conditions and procedures for using nutrient content claims and health claims on food labels.

Nutrition Labeling. Current requirements for nutrition labeling are found in the Code of Federal Regulations

(CFR), Title 21, section 101.9. This regulation provides for voluntary nutrition labeling of food products, unless the product is fortified or unless a nutritional claim is made for the product, in which case nutrition labeling is mandatory. The regulation also specifies the format and content of the nutrition label. The regulation currently requires the following to be declared on the nutrition label:

Serving size
Number of servings/container
Calories
Protein
Carbohydrate
Fat
Sodium
Percentage of the U.S. RDA for
- Protein
- Vitamin A
- Vitamin C
- Thiamine
- Riboflavin
- Niacin
- Calcium
- Iron

The regulation also provides for the voluntary declaration of potassium, other vitamins and minerals, and in conjunction with 21 CFR 101.25, cholesterol and fatty acids. The declaration of these nutrients is voluntary unless a nutritional claim is made or unless they are added to the food. In those instances, their declaration is mandatory.

The Waxman bill provides for mandatory nutrition labeling and the listing of the following on the nutrition label:

* Serving size (household units)
Number of servings/container
* Calories
Calories from fat
Calories from saturated fat
* Fat
Saturated Fat
* Cholesterol
* Sodium
Carbohydrates
Complex carbohydrates
Sugars
* Fiber
* Protein

The bill specifies that the starred nutrients must be highlighted on the label either with larger type, bold type, or contrasting color.

The list of nutrients is not an absolute list, however, and the bill provides that the Secretary of DHHS can, by regulation, add to or delete from the list.

The list of nutrients specified in the bill differs from the current requirement for declared nutrients by adding:

Calories from fat
Calories from saturated fat
Saturated fat
Cholesterol
Complex carbohydrates
Sugars
Fiber

and by deleting % U.S. RDA of:

Protein
Vitamin A
Vitamin C
Thiamine
Riboflavin
Niacin
Calcium
Iron

21 CFR 101.9 specifically provides for a number of exemptions from nutrition labeling, including infant formulas, most dietary supplements, medical foods, bulk food for manufacturing, certain institutional food, and fresh fruits and vegetables. In contrast, the Waxman bill provides for the following exemptions:

- Restaurant food
- Deli counter food
- Infant formulas
- Medical foods
- Bulk food for manufacture
- Small packages, if provided for by regulation
- Foods that are insignificant sources of nutrients, if provided for by regulation
- Foods produced by small business (< $500,000 annual sales) unless nutrition information is provided or a nutrition claim is made
- Dietary supplements, as provided for by regulation

The Waxman bill does, however, specifically provide for nutrition labeling of bulk containers at a retail establishment and for labeling of fresh produce and fish. It specifies nutrition labeling of the 20 most frequently consumed fruits, the 20 most frequently consumed vegetables, and the 20 most frequently consumed fish, and indicates that these may be determined regionally. The details for labeling of the fresh produce and fish are to be provided by regulation.

The bill requires that regulations to implement these nutrition labeling provisions be proposed within 12 months of the enactment of the bill and final regulations issued within 18 months. If the proposed rule is not final within 18 months, the proposal becomes final. The bill further specifies that these implementing regulations must address:

- Format, to allow the public to understand the significance of the information in the context of the daily diet
- Standards to define serving size
- Permission to include other voluntary information

- Permission to use a constant label or ranges even
  - if minor variations occur during normal processing or production
  - for assortments of similar foods

Consumer Education. The Waxman bill provides for activities to educate consumers about the availability of nutrition information on labels and the importance of this information to health.

Nutrient Content Claims. Examples of nutritional content claims are low sodium and low cholesterol. The Waxman bill addresses the issues of both nutrient content claims and health claims on food labels. I will discuss the nutrient content claims first.

Currently FDA, on its own initiative, has promulgated or is promulgating regulations to define specific content claims on food labels. (The content claims are also called descriptors.) FDA has promulgated regulations that define low and reduced calories (21 CFR 105.66) and sodium-free, very low sodium, low sodium, and reduced sodium (21 CFR 101.13). It has also proposed (in the Federal Register of November 25, 1986) a regulation that defines cholesterol-free, low cholesterol, and reduced cholesterol.

Food products whose labels contain these descriptors must comply with the conditions specified in the regulation; otherwise the product is deemed misbranded. However, the use of descriptors on food labels that are not the subject of regulations (e.g., low fat) are not prohibited unless they are false or misleading.

The Waxman bill provides conditions for the use of content claims for nutrients that are listed on the nutrition label. Such claims can be used in food labeling only if the claims are defined by regulation. The bill provides for a petition process for establishing such regulations, which I will discuss in connection with health messages.

The bill also provides that if a claim is made, the food label must contain, next to the claim, the statement "See _____ for information about calories, fat, cholesterol, sodium, and other nutrients." The blank refers to the panel on which the information may be found.

The bill provides some specific requirements for certain content claims. Claims for "free" can be made only if the component is usually present in the food. Cholesterol claims can be made only if the level of saturated fat is shown next to the claim (or as the bill states "in close proximity and equal prominence"). Saturated fat claims can be made only if the level of cholesterol is shown next to the claim. High fiber claims can be made only if either the product is low in fat (as defined by regulation) or the fat level is shown next to the claim. Finally the bill specifies that the Secretary of DHHS may, be regulation, prohibit specific claims on specific foods because the claim is misleading in light of the level of another nutrient in the food.

The bill also contains a "grandfather" exemption for brand names (e.g., Light and Lively) that were in use before October 25, 1989, and an exemption for standardized foods (e.g., low-fat milk). Finally, the bill provides exemptions for infant formulas and medical foods.

Health Messages. Health messages are label claims about the value of ingestion (or reduced ingestion) of a dietary component, as part of a total dietary pattern, in either lowering the risk or forestalling the premature onset of a particular chronic disease condition.

Until a few years ago, FDA considered such claims to be drug claims. The inclusion of such a claim on a food label, in the absence of a New Drug approval, rendered the product an unapproved new drug. However, more recent scientific knowledge about the relationship between diet and health has caused the agency to revise its policy on such claims. Its initial new policy, described in the proposal of August 4, 1987, established some

general guidelines for permitting well-supported health messages on food labels. The agency received considerable adverse comment on this proposal, however. Furthermore, some manufacturers took advantage of uncertainties created by the proposal and made drug claims on health fraud products, which, they asserted, were consistent with the proposal.

Therefore in the Federal Register of February 13, 1990, FDA proposed a new regulation to establish procedures for permitting valid health messages on food labels. The agency also withdrew its previous proposal on health messages. The proposed regulation would establish the following requirements for health messages:

1. The claim is truthful and not misleading;
2. The claim is limited to describing the value that ingestion (or reduced ingestion) of a dietary component, as part of a total dietary pattern, may have in lowering the risk, or forestalling the premature onset, of a particular disease condition;
3. The claim is consistent with generally recognized medical and nutritional principles for a sound total dietary pattern;
4. The claim is based on and consistent with the conclusions set forth in an applicable scientific summary and consumer health message summary accepted by FDA;
5. The claim includes a reference to the applicable consumer health message summary; and
6. The food is nutrition-labeled in accordance with 21 CFR 101.9.

The proposal would require the development of the following three items as a means of regulating the content of health messages:

1. Scientific summaries - These would summarize the most relevant scientific information on the role of the food component in preventing or retarding the onset of a chronic disease condition.
2. Consumer health message summaries - These would describe, in lay language, the supporting scientific information on the diet/chronic disease relationship for the food component. These summaries are intended for distribution to the general public.
3. Model label statements - These are intended for use on food labels to convey appropriate information regarding diet/chronic disease interactions; however, valid health messages are not limited to these statements.

In addition, the agency is proposing to develop a consumer guide to food labeling. This guide would discuss in general terms how to use various types of consumer-oriented information found on the food label.

The proposal also would establish a procedure under which a Public Health Service (PHS) Committee would determine the adequacy of scientific data to support health message claims on food labels. This committee would include members from PHS and from the Food Safety and Inspection Service of USDA. For each diet and chronic disease topic, the Committee would evaluate the scientific summary, the consumer health message summary, and the model label statements to determine the adequacy of the data to support health messages. The Committee could also recommend additional topics for the development of scientific summaries, consumer health message summaries, and model label statements.

The proposal tentatively identified six topic areas as appropriate subjects for initial consideration:

1. Calcium and osteoporosis
2. Sodium and hypertension
3. Lipids and cardiovascular disease
4. Lipids and cancer
5. Dietary fiber and cancer

6. Dietary fiber and cardiovascular disease

The proposal also noted that, under the proposed process, FDA and the PHS committee would consider any valid and reliable publicly available scientific evidence, regardless of the source. The proposal requested comments on the process, however, as well as on the proposed scientific standard to be applied in determining the sufficiency of evidence to support a health message.

Finally, the proposal discussed FDA's interim enforcement policy for regulatory action against food products containing health messages. The proposal stated that manufacturers may continue to include health messages on their products. However, FDA would evaluate these messages on a case-by-case basis and would exercise its enforcement discretion in bringing regulatory action against label claims in appropriate circumstances. The agency provided guidance on how it is likely to exercise its enforcement discretion, based on:

1. Whether the claim fell within the six topics noted above;
2. Whether the claim is adequately supported by the scientific evidence;
3. Whether the claim is exaggerated;
4. Whether the food component is present in sufficient quantities (or reduced sufficiently) to justify the claim;
5. Whether the benefits from the component (or reduction of the component) are outweighed by the negative attributes of another component of the food with respect to the same disease condition.

The Waxman bill establishes conditions for the use of health-related claims for nutrients that are required on the nutrition label. It provides that such health messages can be used in food labeling only if:

1. They meet the requirements of a regulation;
2. They are made for foods that do not contain any nutrients in an amount which increases the risk of disease to persons in the general population (as determined by the regulation).

The bill requires that a regulation must be based on significant agreement among scientific experts that the totality of publicly available evidence supports the claim.

The bill requires that the regulation must:

1. Describe the relationship between a nutrient required in nutrition labeling and a disease or health-related condition;
2. Describe the significance of each nutrient;
3. Require the claim to be stated so that it is accurate and comprehensible to consumers; and
4. Not require prior approval of specific health claims if the claims are in accordance with the regulation.

The bill provides for a petition process in which acceptance or rejection of a petition must be determined within 90 days of receipt. If accepted, a proposed regulation must issue within another 90 days. It also provides exemptions for medical foods, infant formulas, and restaurant foods.

Regulations to implement both nutritional content and health claims provisions of the bill must be proposed within 12 months and be final in 18 months. (If the regulations are not final within 18 months, the proposal becomes final.) The regulations must identify permitted content and health claims and must make determinations in six areas (calcium and osteoporosis; sodium and hypertension; fat and cancer; fat and cardiovascular disease; fiber and cancer; and fiber and cardiovascular disease) within 12 months. (These six areas

are the six tentative topic areas listed in FDA's proposal for health messages.)

An additional provision of the bill is the modification of the definition of "drug" to exclude classification as a drug solely because of a permitted health claim. Moreover, it provides for uniformity of nutrition labeling and claims and also provides that states may petition for exemptions from uniformity.

Conclusion

There is currently a tremendous amount of activity in the areas of nutrition labeling, including quantitative labeling, descriptive labeling, and health-related label claims. The FDA is progressing in its effort to codify the changes in nutrition labeling that are desired by consumers and justified by the scientific information. Congress is also progressing in its effort to accomplish the same goal. Although the exact nature of the final results is not yet known, it is clear that in the near future there will be some changes in nutrition labeling.

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