Food Labeling Regulations Changing

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On November 27, 1991, USDA's Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's (HHS) Food and Drug Administration (FDA) published proposed parallel regulations for mandatory nutrition labeling on food. FDA also published a final regulation on voluntary nutrition labeling, while FSIS published a proposed regulation on voluntary nutrition labeling. The two agencies estimate the costs of changing nutrition labels to be $2.8 billion. But the health benefits—estimated at $5.6 billion over a period of 20 years—greatly exceed these costs.

These efforts represent both agencies' responses to over a decade of consumer demand for better nutrition information on food. After a 90-day period for public comments, final rules are expected to be published by November 1992. New labels will be required on most packaged food products beginning May 1993.

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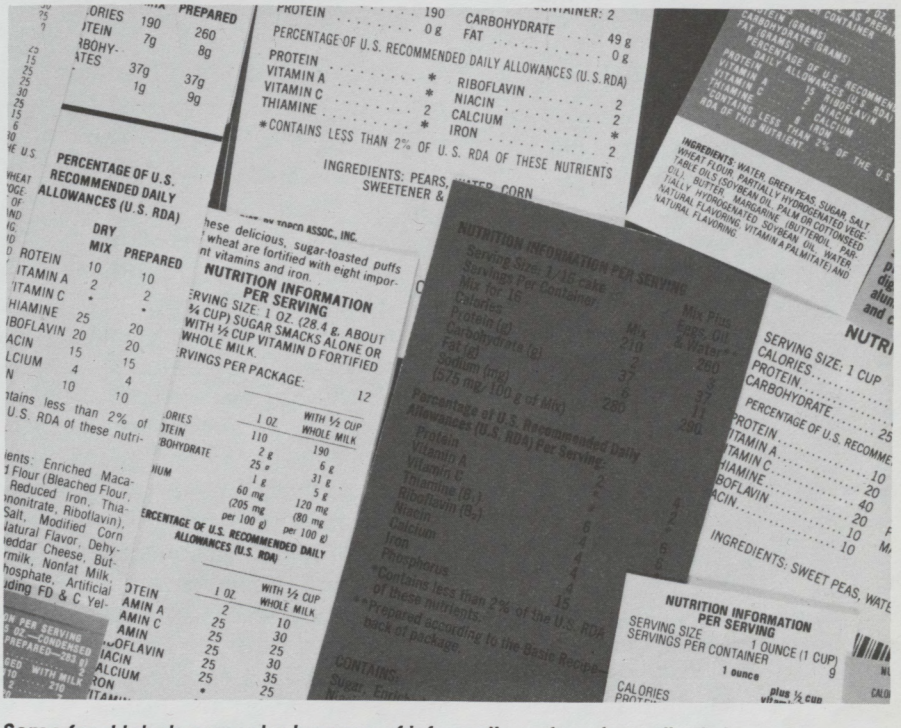
Present Labels a Source of Confusion

As awareness of the link between diet and health increases, consumers have expressed more concern about food choices. Industry has responded by developing "healthier" foods and by labeling the nutrition content, on a largely voluntary basis, for approximately half the processed food products sold.

However, consumers have complained that the ingredient and nutrition information available on food labels is not always useful. For example, many products do not list cholesterol and fiber contents, nutrients of interest to many



Some food labels present a barrage of information—from ingredients to nutrition information—but most people are left confused.

consumers today. And, differences in serving sizes make it difficult to compare the nutrition content of different products. Consumers also perceive health claims and product descriptors as confusing, such as when a product high in saturated fat is labeled as "low in cholesterol," or when a product light in color or texture is labeled as "light."

The absence of nutrition labeling on nearly half of all packaged foods, or labeling that is confusing, may partially explain the results of a recent study by USDA's Economic Research Service (ERS). The study found that groups of women with higher diet/health awareness changed their food selections but did not reduce total fat intake much more than other women. The study suggests that the women had difficulties making comparisons across food categories, and basically traded one source of fat for another (see "Diet/Health Concerns About Fat Intake" in the January/March 1991 issue of *FoodReview*). Thus, they were not successful in following USDA/HHS Dietary Guidelines to reduce consumption of fat.

If most food products contain clear and consistent nutrition labels, motivated consumers should find it easier to make changes in their food choices. For example, most consumers probably do not know how much fat a serving of 2-percent milk contains. But many have been able to translate the message to reduce fat intake by shifting consumption from whole milk to lowfat or skim milk.

Current Regulations

FSIS regulates the labeling of meat and poultry products, and FDA regulates the labels on all other food products. Both agencies have allowed manufacturers to include nutrition information, if it follows a prescribed format. However, nutrition labeling is required only if a nutrition claim is made, or, for FDA products, if a nutrient has been added to a food.

New regulations governing food labeling will provide consumers with uniform, comparable information about nutrients and product descriptors.

It is estimated that some 60 percent of FDA-regulated foods and 35-50 percent of processed, packaged meat and poultry products bear nutrition labels. Such labeling is not usually available on eggs, fresh produce, fresh or frozen meats, poultry, and seafood, or on foods sold in restaurants, fast food places, institutions, vending machines, and grocery store carryout bars. In addition, labels now provide information on some nutrients which are no longer of public health importance (such as the B vitamins), but are not required to provide information on nutrients of current interest to consumers, such as saturated fat, cholesterol, and fiber.

Background for New Labeling Regulations

In 1989, FSIS and the Department of Health and Human Services commissioned the Institute of Medicine (IOM) of the National Academy of Sciences to make recommendations on nutrition labeling (see box for details). On July 19, 1990, FDA published a proposal for new regulations in the *Federal Register*. Before FDA finalized these regulations, however, Congress passed the Nutrition Labeling and Education Act of 1990 (NLEA), which amends the Federal Food, Drug and Cosmetic Act, to make nutrition labeling mandatory for most FDA-regulated foods. FDA proposed regulations to implement this law on November 27, 1991. These regulations should become effective by spring 1993. They represent the first major change in FDA nutrition labeling regulations since their origin in 1973.

Although the NLEA does not cover meat and poultry products, FSIS has been working with FDA to develop parallel regulations for these products. FSIS published tentative positions for nutrition labeling as an advance notice of proposed rulemaking in the April 2, 1991, *Federal Register*. Keeping pace with FDA, FSIS also published proposed regulations for nutrition labeling in the November 27, 1991, *Federal Register*. FSIS proposes to establish mandatory nutrition labeling for processed meat and poultry products and to issue voluntary guidelines for nutrition information for single-ingredient, raw meat and poultry products.

Throughout the process of preparing these regulations, FDA has held public meetings around the country, often in conjunction with FSIS, to obtain input from both the public and the food industry.

Both sets of proposed regulations have a 90-day period for public comment, after which the final regulations will be prepared. (See box for a comparison of current regulations, the National Academy of Sciences' IOM recommendations, and FDA and FSIS proposals for nutrition labeling.)

The two agencies have emphasized their commitment to work together and provide consumers with the most uniform label possible. Thus, FSIS proposes to adopt the list of nutrients adopted by FDA, to define serving sizes consistent with those defined by FDA, and to follow the same definitions for product descriptors, such as "lowfat," "free," "light," and "reduced."

USDA proposes two additional descriptors unique to meat and poultry: "lean" and "extra lean." FSIS believes consumers need additional descriptors unique to meat and poultry, since these products tend to be higher in fat and cholesterol than many nonmeat products (thus few would be able to meet FDA's definition for lowfat and low-cholesterol). Since the amount of fat and cholesterol may vary greatly in meat and poultry products, unique descriptors would help characterize the fat level of these products and would help consumers make better informed selections.

The Controversy Over "Trans-Fatty" Acids

The new nutrition labels aim to inform consumers without confusing them. But as new information becomes available on the complexities of the diet/health links, a number of scientists question whether the new labels will be too simplistic to be useful.

For example, some recent studies indicate that dietary trans-fatty acids, like saturated fats, may be associated with increased serum cholesterol levels. Trans-fatty acids occur when a vegetable oil (a polyunsaturated fat) is hydrogenated or solidified into shortening, margarine, or commercial fats for deep frying.

Under the proposed regulations, the amount of trans-fatty acids will not be included in the information on saturated fats on food labels since the oil is not completely saturated during hydrogenation. Canada's labeling standards recognize trans-fatty acids as separate components, and require the amounts to be listed on food labels. Should FDA and FSIS change the regulations to do the same?

Are the Costs Worth It?

Costs of changing nutrition labeling are difficult to quantify, as are the health benefits associated with such changes. For FDA-regulated products, about 17,000 firms and 257,000 labels will be affected, with total costs to packaged-food producers running approximately $1.3 billion. Voluntary labeling in supermarkets and restaurants is estimated to cost $155 million and $116 million, respectively. For USDA-regulated products, nearly 9,000 federally- and State-inspected plants would be affected, at a cost of approximately $1.3 billion. Therefore, total cost for all affected businesses is estimated to be approximately $2.8 billion.

Analysts estimate that the new labeling regulations would save up to a staggering $5.6 billion over 20 years in death and health care costs related to cancer and coronary heart disease alone (the two largest public health problems in the United States). Decreased rates of cancer, coronary heart disease, osteoporosis, obesity, and hypertension are just a few of the benefits we would expect to see with mandatory labeling regulations. These benefits—measured as the monetary value of years of life saved from premature death—are estimated to greatly exceed the costs. The benefits were calculated using a study of how consumer behavior changes in response to additional nutrition information and were based on only the two largest public health problems, cancer and coronary heart disease. ■

A Comparison of Nutrition Labeling Regulations and Positions

	Current Regulations	National Academy of Sciences' IOM Recommendations (IOM)
Background	USDA's Food Safety and Inspection Service (FSIS) regulates labels for meat and poultry products through regulations and policy memoranda, which set out current requirements for nutrition labeling as required by the Federal Meat Inspection Act and the Poultry Products Inspection Act. The Department of Health and Human Service's Food and Drug Administration (FDA) regulates all other food products under legislation enacted in 1938. Nutrition labeling rules on packaged food labels were introduced during the last major revision of FDA labeling regulations in 1973.	In 1989, FSIS and FDA sponsored a study by the Institute of Medicine (IOM) at the National Academy of Sciences to provide options to improve food labeling. The study made a number of recommendations, described below.
Nutrition Labeling on Processed and Fresh Foods	Nutrition labels are voluntary for FDA products unless a nutrient has been added or the product label makes a nutritional claim. FSIS labels are also voluntary, unless a nutrition claim is made. FSIS does not permit fortification or the adding of nutrients to products. An estimated 60 percent of FDA-regulated products and 30-50 percent of FSIS-regulated products contain the voluntary nutrition labels. When a nutrition label is provided, it must follow a prescribed format.	IOM recommended mandatory nutrition labeling for all packaged foods, with some exemptions. The mandate would include institutional-size packages and commodities distributed through USDA food programs. It also recommended point-of-purchase nutrition label information for produce and for fresh and frozen meat, poultry, and seafood. IOM proposed exempting small packages and foods that have no nutritional significance (like chewing gum).
Label Approval and Compliance	FSIS requires that all labels used on, or in conjunction with, meat and poultry products be approved for their content and design before the product is marketed. Manufacturers must provide FSIS nutrition data to substantiate any nutrition claims. FDA, on the other hand, relies on manufacturers to comply with prescribed labeling regulations. Manufacturers of FDA-regulated products can use a new label and risk that FDA will challenge the product as being mislabeled (such as the recent challenge over the term "fresh" on some food labels). FDA has approved databases for use in generic labeling of certain products.	IOM questioned the adequacy of analytical methods for nutrient analyses. Current methods of food analysis do not permit precise measurement of nutrient values for many food components. IOM recommended flexibility in selection of analytical methods for label verification. It found FDA's system less costly than USDA's system of label verification. It favored FDA and USDA certifying databases containing representative values for use when labeling fresh food products.

Food and Drug Administration (FDA) Proposals

In 1990, FDA published in the *Federal Register* several proposed rules related to nutrition labeling. These have been superseded by passage on November 8, 1990 of the Nutrition Labeling and Education Act of 1990 (P.L. 101-535), which amends the Federal Food, Drug, and Cosmetic Act. On January 11, 1991, FDA published a notice recognizing the impact of NLEA. In the summer, FDA published proposals on the listing of ingredients in "standardized foods," the declaration of the percentage of fruit and vegetable juices in beverages, and voluntary nutrition labeling for the 20 most commonly consumed raw vegetables, fruit, and fish. On November 27, 1991, FDA published in the *Federal Register*, 22 more proposed rules, one final rule, and two notices. These defined the requirements for nutrition labeling, listed "reference amounts" for broadly defined food categories, and established procedures for determining serving sizes. These also defined descriptors such as "low-fat," approved certain health claims, and described the technical provisions that tie the program together. Regulations are proposed to become effective May 8, 1993.

Nutrition labeling will be mandatory for most FDA-regulated packaged food products and voluntary for 20 of each of the most frequently consumed varieties of raw vegetables, fruit, and raw fish. If retailers fail to comply substantially with the guidelines for voluntary nutrition labeling, they could become mandatory after the spring of 1995. Exemptions are provided for foods of minimal nutritional value, small packages (less than 12 square inches available for labeling), restaurant food, and food produced by small businesses (annual total gross sales below $500,000 or annual gross sales of food below $50,000).

FDA set forth procedures for determining labeling compliance. FDA is updating its compliance manual, which contains information on database development and nutrition label computations. FDA proposed to exempt products from certain procedures for determining label compliance when: nutrition information is founded on an FDA-approved database, the label was computed following FDA guidelines, and the food was handled according to current good manufacturing practices to prevent nutrition loss.

Food Safety and Inspection Service (FSIS) Proposals

On April 2, 1991, FSIS published an advance notice of proposed rulemaking in the *Federal Register*, and requested comments, information, data, and recommendations from consumers, industry, public health officials, and other interested parties. In response to the comments received, and parallel to FDA's proposed regulations, FSIS published in the November 27, 1991, *Federal Register* a proposal to amend the Federal meat and poultry inspection regulations to permit voluntary nutrition labeling on retail cuts of single-ingredient, raw meat and poultry products (such as ground beef and chicken breasts); and establish mandatory nutrition labeling for most processed meat and poultry products.

FSIS proposes to establish mandatory nutrition labeling for most processed meat and poultry products, but will allow nutrition labeling to be voluntary for single-ingredient, raw meat and poultry products (paralleling FDA's approach). For example, ground turkey with one natural flavoring would fall under the mandatory program. FSIS proposes to exempt from package nutrition labeling small packages (less than 1/2-ounce net weight) and other than consumer-size packages if nutrition information for these foods is made available through alternative means, such as posters or pamphlets. Wholesale foods that are not sold directly to the consumers and are intended for further processing--such as bulk cooked sausage crumbles--would also be exempt. In lieu of a small business exemption, FSIS is considering various ways to minimize compliance costs for all companies.

FSIS will require manufacturers to maintain records to support the information on nutrition labels, and to make this information available for review upon request. FSIS anticipates that approved databases will be the source for the voluntary nutrition labeling of single-ingredient, raw meat and poultry products.

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A Comparison of Nutrition Labeling Regulations and Positions—*Continued*

	Current Regulations	National Academy of Sciences' IOM Recommendations (IOM)
List of Nutrients	In 1973, FDA adopted a regulation recodified in 1977 for a specific label format when nutrition information is listed per serving size. Required components include calories, protein, carbohydrates, fat, sodium, calcium, iron, vitamin A, vitamin C, thiamin, riboflavin, and niacin. Information on other nutrients may also be provided, but disclosure of fiber, cholesterol, and fatty acid composition is not required. FSIS allows nutrition information to be presented in this same format and style. FSIS also permits an abbreviated labeling format that includes calories, protein, carbohydrates, and fat.	IOM recommended required disclosure of calories, carbohydrates, fiber, total fat, saturated and unsaturated fat, cholesterol, and sodium. Required information on calcium and iron would use descriptors (like "very good source of"). IOM recommended optional disclosure of complex carbohydrates and sugars. Foods high in complex carbohydrates are desirable for being low in fat and calories and high in fiber. Concerns about sugar derive from dental effects, nutrient dilution, and excess calories rather than contribution to disease conditions.
List of Ingredients	FSIS regulations require ingredients that are fabricated from two or more ingredients be listed on the product's label by their common or usual names in descending order of predominance. FSIS requires full ingredient labeling on all meat and poultry products. FDA exempts products subject to standards of identity (official recipes used to define the composition of standard products, such as peanut butter, mayonnaise, and orange juice) from having to provide full ingredient labeling. Both agencies allow disjunctive labeling of fats and oils and use of the general term "vegetable oil" when "and/or" labeling is used. This allows processors to adjust ingredient content based on current costs and prices.	IOM recommended that even foods under a standard of identity should be required to provide full ingredient listings. IOM favored grouping all sugars together and listing components parenthetically. It also recommended use of "and/or" labeling for sugars and for fats and oils in the ingredient statement to increase producer flexibility and reduce costs. Full nutrition labeling would list the saturated fat content at the highest possible level that would be achieved with any mixture of the listed fats and oils.
Serving Size	Nutrition information is provided as the amount per serving. Manufacturers determine the serving size, which need not be uniform within or between product categories, making comparisons among products difficult. In addition, serving sizes are sometimes expressed in units that consumers do not understand.	IOM determined that serving sizes should be standardized, so that nutrition information would be comparable within and across product categories. IOM recommended that FDA and FSIS jointly establish serving sizes for limited, broad categories of foods to help consumers make product comparisons. IOM suggested basing the standard serving sizes on dietary guidance recommendations rather than on amounts consumed. These suggestions are to make their use in educational programs less difficult and to permit consistency among serving sizes shown in dietary guidance material and on the food label.
Descriptors	FSIS permits nutrition information, such as claims that a product is "95% fat-free." Several policy memoranda outline FSIS criteria for expressions such as "low calorie," "low sodium," "low fat," and "lean." FSIS has no regulatory definitions. FSIS does not now permit health claims linking food attributes to disease or health-related conditions. FDA has regulatory definitions for descriptors about calories and sodium. FDA has developed informal policy for trial shelf-labeling programs covering descriptors for fat, fiber, and calcium, and for defining expressions such as "good source of."	IOM recommended that FDA and USDA define and standardize the terms "light," "lite," and "diet." It also suggested using quantitative descriptors of nutrient content, limited to two categories--low and very low, or high and very high--with specific levels of nutrients established for each descriptor. IOM recommended against allowing descriptors to claim the absence of an undesirable component (such as "cholesterol-free") in foods that do not normally contain that component. IOM emphasized the importance of consistent, established definitions for both USDA and FDA.

Food and Drug Administration (FDA) Proposals

FDA's proposed regulation focuses on nutrients currently accepted as significantly affecting consumer health. The amount per serving of the following nutrients is proposed to be included on labels: calories, calories from total fat, total fat, saturated fat, cholesterol, total carbohydrates, complex carbohydrates, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. Listing thiamin, riboflavin, and niacin, among other nutrients, is optional. Nutrition information must be presented as quantitative amounts or as percentages of a daily reference value. A simplified nutrition label format is allowed for foods containing insignificant amounts of more than half the required nutrients.

FDA's proposal, published June 21, 1991, requires full ingredient labeling even if the food is covered by a standard of identity. Food labels must explain that ingredients are listed in descending order of predominance by weight. Beverages containing vegetable or fruit juice must state on the label the percentage of vegetable or fruit juice in the drink. All FDA-certified color additives must be listed by name. All sweeteners must be listed together in the ingredient list. Labels must declare protein hydrolysates and specify the source of that additive (such as from hydrolyzed milk protein). To assist people with allergies to milk protein and sulfites, labels must identify caseinate as a milk derivative when used in nondairy foods, such as coffee whiteners, and declare use of sulfiting agents. Final rules are expected in spring 1992.

On November 27, 1991, FDA proposed a regulation on serving sizes that would require nutrition content to be based on amounts customarily consumed (as required by the NLEA) and to be expressed in common household and metric measures, such as "1 cup (240 ml)." The proposal includes "reference amounts" for 131 broadly defined food categories, based on food-consumption survey data on amounts of food commonly consumed per eating occasion by persons 4 years of age and older. Manufacturers must follow the proposed procedures to convert the reference amounts to serving sizes appropriate for their specific products. Any package containing less than two servings would be considered a single-serving container.

On November 27, 1991, FDA proposed definitions for nine terms that could be used to describe a food. These are "free," "low," "high," "source of," "reduced," "light" or "lite," "less" (or, for calories, "fewer"), "more," and "fresh." Claims for cholesterol are tied to levels of saturated fat in the food. Meal-type products may not use the term "reduced." The current proposal allows health claims on food labels for only four nutrient/disease relationships: calcium and osteoporosis, sodium and hypertension, fat and cardiovascular disease, and fat and cancer. It also sets nutrient levels beyond which a health claim cannot be made.

Food Safety and Inspection Service (FSIS) Proposals

FSIS proposes to adopt FDA's proposed list of nutrients. As with FDA, additional nutrients would be required to be listed if the label makes any claims about them. Certain optional nutrients would also be permitted. FSIS would allow a simplified format when more than half of the 15 required nutrients are present in insignificant amounts. At a minimum, the abbreviated label would include total calories, total fat, total carbohydrates, protein, and sodium.

FSIS will continue requiring full ingredient labeling on all meat and poultry products, whether or not the food is covered by a standard of identity.

FSIS has worked closely with FDA to establish broad product categories, appropriate reference amounts, and procedures for determining serving sizes. This consistency between agencies will provide consumers with a uniform labeling system and facilitate comparisons between USDA-regulated and FDA-regulated foods (such as between beef vegetable soup and vegetarian vegetable soup). Of the 131 food categories above, there are 23 meat and 22 poultry product categories, with corresponding reference amounts in grams, to be declared in common household and metric measures. If household measures (such as "1 cup") are not applicable, units of the whole piece or package should be used. Serving sizes for meal-type products would refer to the product in its entirety. For products packaged in individual units or pieces (such as hot dogs), FSIS proposes that serving sizes refer to the number of whole units closest to the reference amount.

FSIS proposes to adopt FDA's definitions for descriptors. In addition, FSIS believes that it is in the best interest of the consumer to establish descriptors unique to meat and poultry products that will differentiate between products with lower levels of fat and cholesterol. FSIS proposes to define two--"lean" and "extra lean"--that would be used only for meat and poultry products. FSIS will publish at a later date a separate proposed regulation on health claims in line with FDA's proposal.